CERUS CORP
Form 10-Q
August 10, 2009
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 June 30, 2009

or

¨ TRANSITION REPORT PURSUANT TO SECTION 13 OR 15 (d) OF THE SECURITIES EXCHANGE ACT OF 1934
For the transition period from: to

Commission File Number 0-21937

CERUS CORPORATION

(Exact name of registrant as specified in its charter)

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

2411 Stanwell Drive

Concord, California 94520

(Address of principal executive offices, including Zip Code)

(925) 288-6000

(Registrant s telephone number, including area code)

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

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

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

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

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

As of July 22, 2009, there were 32.6 million shares of the registrant s common stock outstanding.

Table of Contents

CERUS CORPORATION

QUARTERLY REPORT ON FORM 10-Q

THREE AND SIX MONTHS ENDED JUNE 30, 2009

TABLE OF CONTENTS

Table of Contents

PART I: FINANCIAL INFORMATION

ITEM 1. FINANCIAL STATEMENTS

CERUS CORPORATION

CONDENSED CONSOLIDATED BALANCE SHEETS

UNAUDITED

(in thousands)

	June 30, 2009 (Unaudited)	December 31, 2008 (see Note 1)
Assets		
Current assets:		
Cash and cash equivalents	$ 7,790	$ 10,303
Short-term investments	5,072	12,275
Accounts receivable, net of allowance of $60 and $180 at June 30, 2009 and December 31, 2008, respectively	6,133	7,152
Inventories	9,755	11,109
Prepaid expenses and other current assets	1,108	1,204
Total current assets	29,858	42,043
Non-current assets:		
Property and equipment, net	1,465	1,844
Long-term investment in related party	2,203	2,329
Restricted cash	315	315
Other assets	720	808
Total assets	$ 34,561	$ 47,339
Liabilities and stockholders equity		
Current liabilities:		
Accounts payable	$ 6,946	$ 7,963
Accrued liabilities	4,864	4,490
Accrued restructuring	361	
Deferred revenue	659	445
Total current liabilities	12,830	12,898
Non-current liabilities		
Other non-current liabilities	138	163
Total liabilities	12,968	13,061
Commitments and contingencies (Note 7)		
Stockholders equity		
Preferred stock	9,496	9,496
Common stock	33	33
Additional paid-in capital	411,533	410,444
Accumulated other comprehensive income	47	212
Accumulated deficit	(399,516)	(385,907)

Total stockholders equity	$ 21,593	$ 34,278
Total liabilities and stockholders equity	$ 34,561	$ 47,339

See notes to condensed consolidated financial statements.

Table of Contents

CERUS CORPORATION

CONDENSED CONSOLIDATED STATEMENTS OF OPERATIONS

UNAUDITED

(in thousands, except per share data)

	Three Months Ended June 30,		Six Months Ended June 30,	
	2009	2008	2009	2008
Revenue:				
Product revenue	$ 3,871	$ 4,030	$ 6,956	$ 8,882
Government grants and cooperative agreement	335		738	117
Total revenue	4,206	4,030	7,694	8,999
Cost of product revenue	2,520	3,077	4,614	4,791
Gross profit	1,686	953	3,080	4,208
Operating expenses:				
Research and development	1,625	2,670	3,637	5,454
Selling, general and administrative	5,409	7,439	11,510	14,540
Restructuring	129		841	
Total operating expenses	7,163	10,109	15,988	19,994
Loss from operations	(5,477)	(9,156)	(12,908)	(15,786)
Other income (expense), net	(735)	209	(701)	899
Net loss	$ (6,212)	$ (8,947)	$ (13,609)	$ (14,887)
Per share information:				
Net loss per share basic and diluted	$ (0.19)	$ (0.28)	$ (0.42)	$ (0.46)
Weighted average common shares outstanding used for basic and diluted per share information:				
Basic and diluted	32,650	32,450	32,620	32,330

See notes to condensed consolidated financial statements.

Table of Contents

CERUS CORPORATION

CONDENSED CONSOLIDATED STATEMENTS OF CASH FLOWS

UNAUDITED

(in thousands)

	Six Months Ended June 30,	
	2009	**2008**
Operating activities:		
Net loss	$ (13,609)	$ (14,887)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation and amortization	370	258
Gain on sales of fixed assets	109	
Stock-based compensation	1,046	1,029
Changes in operating assets and liabilities:		
Accounts receivable	1,019	435
Inventories	1,354	(4,427)
Other assets	310	1,051
Accounts payable and accrued expenses	(668)	(576)
Accrued restructuring	361	
Deferred revenue	214	(1,444)
Net cash used in operating activities	(9,494)	(18,561)
Investing activities:		
Purchases of furniture, equipment and leasehold improvements	(100)	(686)
Purchases of short-term investments		(2,285)
Sales of short-term investments		9,021
Maturities of short-term investments	7,038	13,990
Net cash provided by investing activities	6,938	20,040
Financing activities:		
Net proceeds from issuance of common stock, ESPP, and stock options	43	1,216
Payments on capital lease obligations		(15)
Issuance cost for credit facility		(25)
Proceeds from note payable		125
Net cash provided by financing activities	43	1,301
Net increase (decrease) in cash and cash equivalents	(2,513)	2,780
Cash and cash equivalents, beginning of period	10,303	19,625
Cash and cash equivalents, end of period	$ 7,790	$ 22,405

See notes to condensed consolidated financial statements.

Table of Contents

CERUS CORPORATION

NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS

UNAUDITED

Note 1. Summary of Significant Accounting Policies

Principles of Consolidation

The accompanying unaudited condensed consolidated financial statements include those of Cerus Corporation and its subsidiary, Cerus Europe B.V., which are collectively referred to hereinafter as Cerus or the Company, after elimination of all intercompany accounts and transactions. These condensed consolidated financial statements have been prepared in accordance with accounting principles generally accepted in the United States for interim financial information and pursuant to the instructions to Form 10-Q and Article 10 of Regulation S-X. Accordingly, they do not include all of the information and footnotes required by generally accepted accounting principles for complete financial statements. In the opinion of management, all adjustments, considered necessary for a fair presentation have been included, including normal recurring accrual adjustments and reclassifications. In connection with filing its Annual Report on Form 10-K, the Company adjusted the quarterly amounts originally reported in its Form 10-Q for the quarter ended June 30, 2008 for inventory and other income (expense) and net loss per share basic and diluted as of and for the three and six month periods ended June 30, 2008. The adjustment resulted from the translation of inventory into U.S. dollars. Operating results for the three and six-month periods ended June 30, 2009 are not necessarily indicative of the results that may be expected for the year ending December 31, 2009, or for any future period.

These condensed consolidated financial statements and notes should be read in conjunction with the Company s audited financial statements and notes thereto for the year ended December 31, 2008, included in its 2008 Annual Report on Form 10-K. The accompanying balance sheet as of December 31, 2008 has been derived from the Company s audited financial statements as of that date.

Use of Estimates

The preparation of financial statements requires management to make estimates, assumptions and judgments that affect the reported amounts of assets, liabilities, revenue and expenses, and related disclosures of contingent assets and liabilities. On an ongoing basis, management evaluates its estimates, which are based on historical experience and on various other assumptions that are believed to be reasonable under the circumstances. Actual results may differ from those estimates under different assumptions or conditions.

Revenue

The Company recognizes revenue in accordance with the SEC s published Staff Accounting Bulletin, or SAB, No. 104, Revenue Recognition, published by the Securities and Exchange Commission, or SEC, and Emerging Issues Task Force, or EITF No. 00-21, Accounting for Revenue Arrangements with Multiple Deliverables, as applicable. Revenue is recognized when (i) persuasive evidence of an agreement with the funding party exists; (ii) services have been rendered or product has been delivered; (iii) pricing is fixed or determinable; and (iv) collection is probable.

The Company s main sources of revenues through June 30, 2009 were product revenue from sales of the INTERCEPT Blood System and United States government grants and awards.

Revenue related to product sales is generally recognized when the Company fulfills its obligations for each element of an agreement. For all INTERCEPT Blood System sales, the Company uses a binding purchase order and signed sales contract as evidence of written agreement. The Company sells the INTERCEPT Blood System directly to blood banks, hospitals, universities and 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 non-conforming product. Deliverables and the units of accounting vary according to the provisions of the purchase order or sales contract. For revenue arrangements with multiple elements, the Company evaluates whether the delivered elements have standalone value to the customer, whether the fair value of the undelivered elements is reliably determinable, and whether the delivery of the remaining elements is probable and within the Company s control. When all of these conditions are met, the Company recognizes the revenue on the delivered elements. If these conditions are not met, the Company defers revenue until such time as all of the conditions have been met or all of the elements have been delivered. Consideration received is allocated to elements that are identified as discrete units of accounting based on the relative fair value method. At June 30, 2009 and December 31, 2008, the Company had $0.7 million and $0.4 million of short-term deferred revenue on its condensed consolidated balance sheets, respectively. Freight costs charged to customers are recorded as a component of revenue under EITF 00-10, Accounting for Shipping and Handling Fees and Costs. Value-added-taxes, or VAT,

that the Company invoices to its customers and remits to governments, are recorded on a net basis, and are excluded from product revenue.

Table of Contents

Research and Development Expenses

The Company receives certain United States government grants that support the Company s efforts in defined research projects. These grants generally provide for reimbursement of approved costs incurred as defined in the various grants. Revenue associated with these grants is recognized as costs under each grant are incurred. In accordance with Financial Accounting Standards Board, or FASB, Statement of Financial Accounting Standards, or FAS, No. 2, Accounting for Research and Development Expenses, research and development expenses are charged to expense when incurred. Research and development expenses include salaries and related expenses for scientific personnel, payments to consultants, supplies and chemicals used in in-house laboratories, costs of research and development facilities, depreciation of equipment and external contract research expenses, including clinical trials, preclinical safety studies, other laboratory studies, process development and product manufacturing for research use.

The Company s use of estimates in recording accrued liabilities for research and development activities (described previously in this Note under the heading Use of Estimates) affects the amounts of research and development expenses recorded and revenue recorded from development funding and government grants and collaborative agreements. Actual results may differ from those estimates under different assumptions or conditions.

Cash, Cash Equivalents and Short-Term Investments

The Company considers all highly liquid investments with an original maturity of 90 days or less from the date of purchase to be cash equivalents. Cash equivalents consist principally of short-term money market instruments.

In accordance with Statement of Financial Accounting Standards, or FAS, No. 115, Accounting for Certain Investments in Debt and Equity Securities, the Company has classified all debt securities as available-for-sale at the time of purchase and reevaluates such designation as of each balance sheet date. Available-for-sale securities are carried at estimated fair value based on quoted market prices. The Company reports the amortization of any premium and accretion of any discount resulting from the purchase of debt securities as a component of interest income and other, net. The Company s available-for-sale securities consist primarily of United States government agency securities and corporate debt securities.

Unrealized gains at June 30, 2009 and December 31, 2008, are reported in accumulated other comprehensive income on the Company s condensed consolidated balance sheets. The Company reviews all of its marketable securities on a regular basis to evaluate whether any security has experienced an other-than-temporary decline in fair value. During the three and six months ended June 30, 2009, the Company did not recognize any other-than-temporary impairments on investments held in its portfolio. However, during the three and six months ended June 30, 2008, the Company recognized losses totaling $0.2 million and $0.3 million, respectively, associated with investments that had experienced an other-than-temporary decline in fair value. These investments primarily related to fixed income securities. The cost of securities sold is based on the specific identification method.

As of June 30, 2009, the Company also maintained a certificate of deposit for approximately $0.2 million with a domestic bank. The Company holds this certificate of deposit for any potential decommissioning resulting from the Company s possession of radioactive material. The certificate of deposit is held to satisfy the financial surety requirements of the California Department of Health Services and is recorded within other long-term assets on its condensed consolidated balance sheets at June 30, 2009 and December 31, 2008. In addition, the Company has certain other bank guarantees for its international operations, totaling $0.1 million at both June 30, 2009 and December 31, 2008.

Concentration of Credit Risk

Financial instruments that potentially subject the Company to concentrations of credit risk consist primarily of cash equivalents, short-term investments and accounts receivable.

Substantially all of the Company s cash, cash equivalents and short-term investments are maintained pursuant to the Company s investment policy at a major financial institution of high credit standing. The Company monitors the financial credit worthiness of the issuers of its investments and limits the concentration in individual securities and type of investments that exist within its investment portfolio. All of the Company s investments carry high credit quality ratings, in accordance with its investment policy. At June 30, 2009, the Company does not believe there is significant financial risk from non-performance by the issuers of the Company s cash equivalents and short-term investments.

Concentrations of credit risk with respect to trade receivables exist to the full extent of amounts presented in the condensed consolidated financial statements. On a regular basis, including the point of sale, the Company performs credit evaluations of its customers. Generally, the Company does not require collateral from its customers to secure accounts receivable. To the extent that the Company determines specific

invoices or customer accounts may be uncollectible, the Company reserves against the accounts receivable on its balance sheet and records a charge on its statement of operations. At June 30, 2009 and December 31, 2008, the Company recorded allowances for potentially uncollectible accounts receivable of approximately $60,000 and $180,000, respectively. Actual collection losses may differ from management s estimate, and such differences could be material to the Company s financial position and results of operations.

Table of Contents

The Company had three customers each accounting for more than 10% of the Company s outstanding trade receivables and aggregating approximately 49% of outstanding trade receivables at June 30, 2009. To date, the Company has not experienced collection difficulties from these customers.

Inventories

At June 30, 2009 and December 31, 2008, inventory consisted of finished goods of INTERCEPT disposable kits, components thereof, UVA illumination devices, and certain replacement parts for the illumination devices. The Company s supply chain for certain of these components, held as work-in-process on its condensed consolidated balance sheet, can take in excess of one year for production to be complete before the work-in-process is utilized in finished disposable kits. Inventory is recorded at the lower of cost, determined on a first in, first-out basis, or market value. Platelet and plasma system disposable kits generally have two-year lives from date of manufacture. The Company frequently reviews the composition of inventory in order to identify obsolete, slow-moving or otherwise unsalable items. To the extent unsalable items are observed and there is no alternative use, the Company will record a write-down to net realizable value in the period that the impairment is first recognized. At June 30, 2009 and December 31, 2008, the Company had written down approximately $0.4 million and $0.1 million, respectively, associated with potentially obsolete or expiring product.

Property and Equipment, net

Property and equipment is comprised of furniture, equipment, information technology hardware and software and is recorded at cost. At the time the property and equipment is ready for its intended use, it is depreciated on a straight-line basis over the estimated useful lives of the assets (generally three to five years). Leasehold improvements are amortized on a straight-line basis over the shorter of the lease term or the estimated useful lives of the improvements.

The Company evaluates its long-lived assets for impairment in accordance with SFAS No. 144, Accounting for the Impairment or Disposal of Long-Lived Assets. The Company continually monitors events and changes in circumstances that could indicate carrying amounts of its long-lived assets may not be recoverable. When such events or changes in circumstances occur, the Company assesses recoverability by determining whether the carrying value of such assets will be recovered through the undiscounted expected future cash flows. If the future undiscounted cash flows are less than the carrying amount of these assets, the Company recognizes an impairment loss based on the excess of the carrying amount over the fair value of the assets. The Company did not recognize impairment charges related to its long-lived assets during the three and six months ended June 30, 2009 or 2008.

Long-Term Investment in Related Party

At June 30, 2009 and December 31, 2008, the Company held an approximate 13% interest in the voting securities of BioOne Corporation, or BioOne, and accounted for its investment in BioOne under the cost method. The Company regularly evaluates several criteria in determining whether or not it has the ability to exercise significant influence over the operating and financial policies of BioOne. These criteria include but are not limited to: the availability and frequency of access to financial information of BioOne, majority shareholder mix in BioOne, and representation on BioOne s board of directors. As a result of its evaluations, at June 30, 2009 and December 31, 2008, the Company accounted for its investment under the cost method, as it has concluded that predominant evidence exists to support this conclusion.

The Company s investment in BioOne is included in long-term investments in related party on its condensed consolidated balance sheets. The Company has been advised by BioOne that BioOne will need to raise additional capital to support its operations beyond the near term and that there may be third-party investor support for the financing. At June 30, 2009, and on an ongoing basis, the Company evaluates several criteria to determine whether or not facts and circumstances support the carrying value of its investment in BioOne. These criteria include, but are not limited to: third-party investor interest and participation in recent equity offerings at current pricing, business outlook of BioOne and available financial information. The Company periodically re-evaluates the carrying value of its investment in BioOne s equity, and to the extent that the criteria used to support the carrying value change, the Company will need to reassess the recorded basis of its investment in BioOne.

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 in effect 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 as a component of interest income and other, net.

8

Table of Contents

Stock-Based Compensation

The Company maintains an equity incentive plan to provide long-term incentives for employees, contractors, members of the Board of Directors and Scientific Advisory Board. The plan allows for the issuance of non-statutory and incentive stock options, restricted stock, restricted stock units, stock appreciation rights, other stock-related awards, and performance awards that may be settled in cash, stock, or other property. The Company also maintains an employee stock purchase plan within the meaning of Section 423(b) of the Internal Revenue Code.

The Company accounts for stock-based compensation in accordance with FAS No. 123R, Share Based Payment, or FAS 123R. Under the fair value recognition provisions of FAS 123R, stock-based compensation cost is measured at the grant date based on the fair value of the award and is recognized as an expense on a straight-line basis over the requisite service period, which is the vesting period. To the extent that stock options contain performance criteria for vesting, stock-based compensation is recognized once the performance criteria are probable of being met.

The Company continues to apply the provisions of EITF 96-18, Accounting for Equity Instruments that are Issued to Other than Employees for Acquiring, or in Conjunction with Selling, Goods or Services, or EITF 96-18 for its non-employee stock-based awards. Under EITF 96-18, the measurement date at which the fair value of the stock-based award is measured is equal to the earlier of 1) the date at which a commitment for performance by the counter party to earn the equity instrument is reached or 2) the date at which the counter party s performance is complete. The Company recognizes stock-based compensation expense for the fair value of the vested portion of the non-employee awards in its condensed consolidated statements of operations.

Total stock-based compensation recognized on the Company s condensed consolidated statement of operations impacted net loss per common share for the three months ended June 30, 2009, and 2008, by $0.01 per common share and for the six months ended June 30, 2009, and 2008, by $0.03 per common share.

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

Other Comprehensive Income (Loss)

FAS No. 130, Reporting Comprehensive Income, or FAS 130, establishes the standards of reporting and displaying comprehensive income (loss) and its components in the condensed consolidated financial statements. The components of comprehensive income (loss) include net income (loss) and other comprehensive income (loss). The Company s only component of other comprehensive income (loss) for the three and six months ended June 30, 2009, and 2008 was unrealized gains or losses from the Company s available-for-sale short-term investments. Other comprehensive income (loss) is reported as a separate component of stockholders equity.

Income Taxes

The Company accounts for income taxes based upon FAS No. 109, Accounting for Income Taxes, or FAS 109 and FASB Interpretation No. 48, Accounting for Uncertainty in Income Taxes, or FIN 48. Under FAS 109, 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. The Company did not have any recorded liabilities for unrecognized tax benefits at June 30, 2009, or December 31, 2008. The Company recognizes interest accrued and penalties related to unrecognized tax benefits in its income tax expense. To date, the Company has not recognized any interest and penalties in its condensed consolidated statements of operations, nor has it accrued for or made payments for interest and penalties. The Company continues to carry a full valuation allowance on all of its deferred tax assets. The tax years 2004 through 2008 remain subject to examination by the taxing jurisdictions to which the Company is subject.

Net Income (Loss) Per Share Basic and Diluted

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

Table of Contents

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

	Three months ended June 30,		Six months ended June 30,	
	2009	2008	2009	2008
Numerator:				
Net loss	$ (6,212)	$ (8,947)	$ (13,609)	$ (14,887)
Denominator:				
Basic and diluted weighted average number of common shares outstanding	32,650	32,450	32,620	32,330
Net loss per common share basic and diluted	$ (0.19)	$ (0.28)	$ (0.42)	$ (0.46)

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

	2009	2008
Antidilutive securities weighted average shares	6,894	5,260

Guarantee and Indemnification Arrangements

The Company recognizes the fair value for guarantee and indemnification arrangements issued or modified by the Company after December 31, 2002, if these arrangements are within the scope of FASB Interpretation No. 45, Guarantor s Accounting and Disclosure Requirements for Guarantees, Including Indirect Guarantees of Indebtedness of Others, or FIN 45. In addition, the Company monitors the conditions that are subject to the guarantees and indemnifications, as required under previously existing generally accepted accounting principles, in order to identify if a loss has occurred. If the Company determines it is probable that a loss has occurred, then any such estimable loss would be recognized under those guarantees and indemnifications. Some of the agreements of the Company contain provisions that provide for the indemnification of the counter-party to those agreements from damages and costs resulting from claims that the Company s technology infringes the intellectual property rights of a third party or claims that the sale or use of the Company s products have caused personal injury or other damage or loss. The Company has not received any such requests for indemnification under these provisions and has not been required to make material payments pursuant to these provisions.

The Company generally provides for a one-year warranty on certain of its INTERCEPT blood-safety products covering defects in materials and workmanship. The Company accrues costs associated with warranty obligations when claims become probable and estimable. There have been no warranty costs incurred through June 30, 2009. Accordingly, at June 30, 2009, the Company has not accrued for any potential future warranty costs.

Fair Value of Financial Instruments

The Company adopted the provisions of FAS No. 157, Fair Value Measurements, or FAS 157, on January 1, 2008, 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. The carrying amounts and fair value of the Company s short term investments and long term investments in related parties are described in Note 2. Financial Instruments to these condensed consolidated financial statements.

New Accounting Pronouncements

In December 2007, the FASB issued SFAS No. 141 (revised 2007), Business Combinations, or FAS 141(R). FAS 141(R) retains the fundamental requirements of Statement No. 141 to account for all business combinations using the acquisition method (formerly the purchase method) and for an acquiring entity to be identified in all business combinations. However, the new standard requires the acquiring entity in a business combination to recognize all (and only) the assets acquired and liabilities assumed in the transaction; establishes the acquisition-date fair value as the measurement objective for all assets acquired and liabilities assumed; and requires the acquirer to disclose to investors and other users all of the information they need to evaluate and understand the nature and financial effect of the business combination. The adoption of FAS 141(R) on January 1, 2009 did not have an effect on the Company s condensed consolidated financial statements but may have an impact on the Company s condensed consolidated financial statements if and when the Company enters into a business combination.

In April 2008, the FASB issued FASB Staff Position, or FSP, No. 142-3, Determination of the Useful Life of Intangible Assets, or FSP 142-3. FSP 142-3 amends the factors an entity should consider in developing renewal or extension assumptions used in determining the useful life of recognized intangible assets under FAS No. 142, Goodwill and Other Intangible Assets . This new

Table of Contents

guidance applies prospectively to intangible assets that are acquired individually or with a group of other assets in business combinations and asset acquisitions. The Company adopted FSP 142-3 on January 1, 2009, however, adoption did not have an effect on its condensed consolidated financial statements.

In November 2007, the EITF ratified a consensus on EITF Issue No. 07-1, Accounting for Collaborative Arrangements, or EITF 07-1, which requires participants in a collaboration to make separate disclosures regarding the nature and purpose of an arrangement, their rights and obligations under the arrangement, the accounting policy for the arrangement and the income statement classification and amounts arising from the arrangement between participants for each period an income statement is presented. EITF 07-1 became effective for the Company beginning January 1, 2009. Adoption of EITF 07-1 did not have a material impact on the Company s condensed consolidated financial statements.

In April 2009, the FASB issued three amendments to the fair value measurement, disclosure and other-than-temporary impairment standards:

FAS 157-4, *Determining Fair Value When the Volume and Level of Activity for the Asset or Liability Have Significantly Decreased and Identifying Transactions that are Not Orderly.*

FAS 115-2 and FAS 124-2, *Recognition and Presentation of Other-Than-Temporary Impairments.*

FAS 107 and APB 28-1, *Interim Disclosures about Fair Value of Financial Instruments.*

FAS 157, *Fair value Measurements* , defines fair value as the price that would be received to sell the asset or transfer the liability in an orderly transaction (that is, not a forced liquidation or distressed sale) between market participants at the measurement date under current market conditions. FAS 157-4 provided additional guidance on identifying circumstances when a transaction may not be considered orderly.

FAS 157-4 provides a list of factors that a reporting entity should evaluate to determine whether there has been a significant decrease in the volume and level of activity for the asset or liability in relation to normal market activity for the asset or liability. When the reporting entity concludes there has been a significant decrease in the volume and level of activity for the asset or liability, further analysis of the information from that market is needed and significant adjustments to the related prices may be necessary to estimate fair value in accordance with FAS 157.

FAS 157-4 clarifies that when there has been a significant decrease in the volume and level of activity for the asset or liability, some transactions may not be orderly. In those situations, the entity must evaluate the weight of evidence to determine whether the transaction is orderly. It also provides a list of circumstances that may indicate that a transaction is not orderly. A transaction price that is not associated with an orderly transaction is given little, if any, weight when estimating fair value.

FAS 115-2 and FAS 124-2 clarifies the interaction of the factors that should be considered when determining whether a debt security is other than-temporarily impaired. For debt securities, management must assess whether (a) it has the intent to sell the security and (b) it is more likely than not that it will be required to sell the security prior to its anticipated recovery. These steps are done before assessing whether the entity will recover the cost basis of the investment. Previously, this assessment required management to assert it has both the intent and the ability to hold a security for a period of time sufficient to allow for anticipated recovery in fair value to avoid recognizing an other-than-temporary impairment. This change does not affect the need to forecast recovery of the value of the security through either cash flows or market price.

In instances when a determination is made that an other-than-temporary impairment exists but the investor does not intend to sell the debt security and it is not more likely than not that it will be required to sell the debt security prior to its anticipated recovery, FAS 115-2 and FAS 124-2 change the presentation and amount of the other-than-temporary impairment recognized in the income statement. The other-than-temporary impairment is separated into (a) the amount of the total other-than-temporary impairment related to a decrease in cash flows expected to be collected from the debt security (the credit loss) and (b) the amount of the total other-than-temporary impairment related to all other factors. The amount of the total other-than-temporary impairment related to the credit loss is recognized in earnings. The amount of the total other-than-temporary impairment related to all other factors is recognized in other comprehensive income.

FAS 107-1 and APB 28-1 amends FAS 107, *Disclosures about Fair Value of Financial Instruments,* to require disclosures about fair value of financial instruments for interim reporting periods of publicly traded companies as well as in annual financial statements. FAS 107-1 also amends APB Opinion No. 28, *Interim Financial Reporting* , to require those disclosures in summarized financial information at interim

reporting periods.

All three FASB Staff Positions discussed herein include substantial additional disclosure requirements. The effective date for these new standards is the same: interim and annual reporting periods ending after June 15, 2009. The Company adopted these standards at June 30, 2009 and the adoption did not have a material impact on its condensed consolidated financial statements.

Table of Contents

On May 28, 2009, the FASB issued SFAS No. 165, *Subsequent Events* (FAS 165). Under FAS 165, companies are required to evaluate events and transactions that occur after the balance sheet date but before the date the financial statements are issued, or available to be issued in the case of non-public entities. FAS 165 requires entities to recognize in the financial statements the effect of all events or transactions that provide additional evidence of conditions that existed at the balance sheet date, including the estimates inherent in the financial preparation process. Entities shall not recognize the impact of events or transactions that provide evidence about conditions that did not exist at the balance sheet date but arose after that date. FAS 165 also requires entities to disclose the date through which subsequent events have been evaluated. FAS 165 was effective for interim and annual reporting periods ending after June 15, 2009. The Company adopted the provisions of FAS 165 for the quarter ended June 30, 2009, as required, and adoption did not have a material impact on the Company s condensed consolidated financial statements. See Note 14, Subsequent Events, to the Notes to Condensed Consolidated Financial Statements for more detailed discussion.

On June 29, 2009, the FASB issued FAS 168 Accounting Standards Codification™ *and the Hierarchy of Generally Accepted Accounting Principles a replacement of FASB Statement No. 162*. FAS 168 establishes the *FASB Accounting Standards Codification*™ as the source of authoritative accounting principles recognized by the FASB to be applied by nongovernmental entities in the preparation of financial statements in conformity with United States generally accepted accounting principles. FAS 168 will be effective for financial statements issued for interim and annual periods ending after September 15, 2009, for most entities. On the effective date, all non-SEC accounting and reporting standards will be superceded. The Company will adopt FAS 168 for the quarterly period ended September 30, 2009, as required, and adoption is not expected to have a material impact on the Company s condensed consolidated financial statements.

Note 2. Financial Instruments

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

At June 30, 2009, the fair values of certain of the Company s financial assets were determined using the following inputs (in thousands):

Assets	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]	$ 4,528	$ 4,528	$	$
Corporate bonds[2]	2,459		2,459	
United States government agency securities[2]	2,613		2,613	
	$ 9,600	$ 4,528	$ 5,072	$

(1) Included in cash and cash equivalents on our condensed consolidated balance sheet.
(2) Included in short-term investments on our condensed consolidated balance sheet.

The Company classifies investments within Level 1 if quote prices are available in active markets. The Company classifies items in Level 2 if the investments are valued using observable inputs to quoted market prices, benchmark yields, reported trades, broker/dealer quotes or alternative pricing sources with reasonable levels of price transparency. These investments include: United States government agencies and corporate bonds. Investments are held by a custodian who obtains investment prices from a third party pricing provider that uses standard inputs to models which vary by asset class. The Company did not hold financial assets and liabilities which were recorded at fair value in the Level 3 category, which defines that one or more significant inputs or significant value drivers are unobservable, as of June 30, 2009.

12

Table of Contents

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

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

	Carrying Value	June 30, 2009 Unrealized Gain (Loss)	Fair Value
Cash and cash equivalents:			
Cash	$ 3,262	$	$ 3,262
Money Market funds	4,528		4,528
Total cash and cash equivalents	$ 7,790	$	$ 7,790
Short-term investments			
Corporate debt securities	$ 2,441	$ 18	$ 2,459
United States government agency securities	2,584	29	2,613
Total short-term investments	$ 5,025	$ 47	$ 5,072
	$ 12,815	$ 47	$ 12,862

	Carrying Value	December 31, 2008 Unrealized Gain (Loss)	Fair Value
Cash and cash equivalents:			
Cash	$ 3,120	$	$ 3,120
Money Market funds	7,183		7,183
Total cash and cash equivalents	$ 10,303	$	$ 10,303
Short-term investments			
Corporate debt securities	$ 8,741	$ 72	$ 8,813
United States government agency securities	3,322	140	3,462
Total short-term investments	$ 12,063	$ 212	$ 12,275
	$ 22,366	$ 212	$ 22,578

	2009	2008
Due in one year or less	$ 4,528	$ 7,183
Due greater than one year and less than three years	5,072	12,275
Total	$ 9,600	$ 19,458

Realized gains and losses from the sale of available-for-sale investments and from other-than-temporary declines in market value are recorded in Interest income (expense) and other, net. Gross proceeds and the realized losses from the sale of available-for sale investments consisted of the following (in thousands):

	Three Months Ended June 30,		Six Months Ended June 30,	
	2009	2008	2009	2008
Gross Proceeds	$	$ 3,835	$	$ 4,585
Realized Loss Upon Sale	$	$ 188	$	$ 277

Note 4. Inventories

Inventories consisted of the following (in thousands):

	June 30, 2009	December 31, 2008
Work in progress	$ 2,716	$ 3,750
Finished goods	7,039	7,359
	$ 9,755	$ 11,109

Table of Contents

The Company s inventories at June 30, 2009 and December 31, 2008 consisted of finished goods of INTERCEPT disposable kits, components thereof, UVA illumination devices, and certain replacement parts for the illumination devices. The Company is responsible for supplying Fenwal, Inc. with certain components for assembly into finished INTERCEPT disposable kits. The Company accounts for these components as work-in-process until such time as the components are used in the production of finished INTERCEPT disposable sets. The Company s work-in-process components are manufactured over a protracted length of time before being incorporated into the finished disposable kits. As a result, work-in-process costs accumulate for a period of time which can exceed one year.

Note 5. Accrued Liabilities

Accrued liabilities consisted of the following (in thousands):

	June 30, 2009	December 31, 2008
Accrued compensation and related	$ 1,074	$ 636
Accrued inventory	2,391	2,121
Accrued contract and other accrued expenses	1,399	1,733
	$ 4,864	$ 4,490

Note 6. Restructuring

In March 2009, pursuant to the Board of Directors approval, the Company began implementing a plan to focus resources on commercializing the INTERCEPT Blood System in Europe, to consolidate facilities, and to reduce its cost structure. During the six months ended June 30, 2009, the Company incurred costs for one-time termination benefits for employee positions that were eliminated under the restructuring plan, consolidation of facility and related moving costs. Effected employees received severance consideration and continuation of benefits, as well as transition assistance. The Company anticipates continuing to implement its restructuring plan and incurring associated costs through the year ended December 31, 2009.

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

	Balance at December 31, 2008	Restructuring Charge	Cash Payments	Balance at June 30, 2009
One-time termination benefits	$	$ 712	$ 351	$ 361
Other		129	129	
Total	$	$ 841	$ 480	$ 361

Note 7. Commitments and Contingencies

Operating Leases

The Company leases its office facilities and certain equipment under non-cancelable operating leases with initial terms in excess of one year that require the Company to pay operating costs, property taxes, insurance and maintenance. These facility leases generally contain renewal options and provisions adjusting the lease payments if those renewal options are exercised. The Company s facility leases qualify as operating leases under FAS No. 13, Accounting for Leases and as such, are not included on its condensed consolidated balance sheets.

Royalties

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

cell system, and 6.5% for illuminators. These royalties are recorded as part of cost of product revenue.

Table of Contents

Purchase Commitments

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

Note 8. Credit Agreement

In June 2008, the Company entered into a senior secured revolving credit facility with Wells Fargo Bank, N.A., or the Facility, which allowed the Company to borrow up to $10.0 million for working capital and general operating needs. In December 2008, the Company amended the terms of the Facility. The initial term of the Facility was one year. In June 2009, the Facility expired with no amount outstanding under the Facility.

Note 9. Stockholders Equity

Series B Preferred Stock

Fenwal holds 3,327 shares of the Company s Series B preferred stock. The Series B preferred stock has no voting rights, except with respect to the authorization of any class or series of stock having preference or priority over the Series B preferred stock as to voting, liquidation or conversion or with respect to the determination of fair market value of non-publicly traded shares received by the holder of Series B stock in the event of a liquidation, or except as required by Delaware law. Fenwal may convert each share of Series B preferred stock into 100 shares of the Company s common stock at any time. If all shares of Series B preferred stock were converted to common stock, 332,700 shares of common stock would be issued, which represents approximately 1% of the outstanding common stock of the Company at June 30, 2009. The Company has the right to redeem the Series B preferred stock prior to conversion for a payment of $9.5 million.

Note 10. Stock-Based Compensation

2008 Equity Incentive Plan

The Company maintains an equity compensation plan to provide long-term incentives for employees, contractors, and members of its Board of Directors and Scientific Advisory Board. The Company currently grants awards from its 2008 Equity Incentive Plan, or the 2008 Plan. The 2008 Plan allows for the granting of 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 2008 Plan has 3.6 million shares available for grant. Awards under the 2008 Plan generally have a maximum term of 10 years from the date the award is granted. Employee options granted under the 2008 Plan generally vest over four years. The 2008 Plan generally requires options to be granted at 100% of the fair market value of the Company s common stock subject to the option on the date of grant. Performance-based stock options granted under the 2008 Plan are limited to either 500,000 shares or $1.0 million, in the case of performance-based cash awards, per calendar year. As of June 30, 2009, the Company had granted a performance based stock option totaling 50,000 shares.

Employee Stock Purchase Plan

The Company also maintains an Employee Stock Purchase Plan, or the Purchase Plan. The Purchase Plan is intended to qualify as an employee stock purchase plan within the meaning of Section 423(b) of the Internal Revenue Code. Under the Purchase Plan, the Company s Board of Directors may authorize participation by eligible employees, including officers, in periodic offerings. The offering period for any offering can be no more than 27 months.

Restricted Stock Units

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

Restricted stock unit grants made in connection with the Bonus Plan for Senior Management of Cerus Corporation are presented in the following table:

Six Months Ended June 30,	Units granted	Grant date fair value per unit	Units vested at June 30, 2009
2009			
2008	43,086	$ 6.99	
2007	60,620	5.54	20,207
2006	37,098	10.32	24,732
Total	140,804		44,939

Table of Contents

Stock-based Compensation

The Company currently uses the Black-Scholes option pricing model to determine the fair value of stock options and employee stock purchase plan shares. The determination of the fair value of stock-based payment awards on the date of grant using an option-pricing model is affected by the Company s stock price, as well as assumptions regarding a number of complex and subjective variables. The variables used to calculate the fair value of stock-based payment awards using the Black-Scholes option pricing model include the expected term of the grants, the Company s expected stock price volatility, actual and projected employee stock option exercise behaviors, including forfeitures, the risk-free interest rate and expected dividends.

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

Expected Term

The Company estimates the expected term of options granted using a variety of factors. Where possible, the Company estimates the expected term of options granted by analyzing employee exercise and post-vesting termination behavior. To make this estimation, the Company analyzes the population of options granted by discreet, homogeneous groups. If the Company is unable to obtain sufficient information to estimate the expected term for a particular group, it estimates the expected term of the options granted by taking the average of the vesting term and the contractual term of the option, as illustrated in SAB 107 and SAB 110. The expected term of employee stock purchase plan shares is the term of each purchase period.

Estimated Volatility

The Company estimates the volatility of its common stock by using historical volatility of its common stock. The Company has used significant judgment in making these estimates and will continue to monitor the availability of actively traded options on its common stock. If the Company determines that sufficient actively traded options on its common stock exist, it may consider a combination of historical and implied volatility, or solely implied volatility.

Estimated Forfeiture Rate

The Company estimates the forfeiture rate of options at the time of grant and revises those estimates in subsequent periods if actual forfeiture rates differ from those estimates. The Company uses historical data to estimate pre-vesting option forfeitures and records stock-based compensation expense only for those awards that are expected to vest. The Company estimates the historic pre-vesting forfeiture rates by groups that possess a degree of homogeneity regarding average time to vest and expected term. All stock-based payment awards are amortized on a straight-line basis over the requisite service periods of the awards, which are generally the vesting periods.

Risk-Free Interest Rate

The Company bases the risk-free interest rate that it uses in the option valuation model on United States Treasury zero-coupon issues with remaining terms similar to the expected term on the options.

Expected Dividend

The Company does not anticipate paying any cash dividends in the foreseeable future and therefore uses an expected dividend yield of zero in the option valuation model.

The assumptions used to value option grants for three and six months ended June 30:

	2009	2008
Expected term (in years)	5.25-6.50	4.16-6.73
Volatility	59.1%-84.1%	59.1%
Risk free interest rate	2.80%-4.03%	4.03%

16

Table of Contents

The assumptions used to value employee stock purchase rights for the three and six months ended June 30:

	2009	2008
Expected term (in years)	0.50	0.50
Volatility	54.6%-78.8%	54.6%
Risk free interest rate	2.0%-4.4%	4.4%

Total stock-based compensation recognized on the Company s condensed consolidated statement of income for the three and six months ended June 30, 2009 and 2008 was as follows (in thousands):

	Option Grants and Stock Purchase Rights			
	Three Months Ended June 30,		Six Months Ended June 30,	
	2009	2008	2009	2008
Research and development	$ 105	$ 97	$ 274	$ 297
Selling, general and administrative	366	309	772	732
	$ 471	$ 406	$ 1,046	$ 1,029

Activity under the Company s stock option plans is set forth below (in thousands except per share amounts):

	Number of Options Outstanding	Weighted Average Exercise Price per Share ($)
Balances at December 31, 2008	5,063	$ 10.27
Granted	2,064	1.28
Cancelled	(650)	6.60
Exercised		
Balances at June 30, 2009	6,477	$ 7.77

Note 11. Comprehensive Loss

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

	Three Months Ended June 30,		Six Months Ended June 30,	
	2009	2008	2009	2008
Net loss:				
As reported	$ (6,212)	$ (8,947)	$ (13,609)	$ (14,887)
Other comprehensive loss:				
Net unrealized gain/(loss) on available-for-sale securities	(28)	(7)	(165)	65
Comprehensive loss	$ (6,240)	$ (8,954)	$ (13,774)	$ (14,822)

Note 12. Development and License Agreements

Agreements with BioOne

In April 2004, the Company made an investment in the common stock of BioOne, a privately held Japanese corporation. BioOne was formed in 2004 to develop technologies to improve the safety of blood products in Asia, and is funded by equity investments from Japanese venture capital firms, other corporations and individual investors.

Platelet Agreement

In June 2004, Baxter and the Company entered into an agreement with BioOne for commercialization of the INTERCEPT Blood System for platelets in parts of Asia. Under the terms of the agreement, BioOne is responsible, at its expense, for seeking regulatory approvals and will have exclusive rights to market and distribute the INTERCEPT Blood System for platelets in Japan, China, Taiwan,

Table of Contents

South Korea, Thailand, Vietnam and Singapore, following their receipt of regulatory approval in each of those countries. In July 2004 and October 2004, Baxter and the Company each received up-front payments of $10.0 million from BioOne. The Company s portion of the up-front payments was being deferred and recognized ratably as development funding over the development period. The agreement also provides for contingent milestone payments and royalties on future product sales, which would be shared equally by Fenwal (Baxter s assignee) and the Company. The Company did not recognize any revenue under this agreement during the three and six months ended June 30, 2009 or 2008.

Plasma Agreement

In December 2004, Baxter and the Company signed a letter of intent with BioOne to enter into a definitive agreement for commercialization of the INTERCEPT Blood System for plasma in parts of Asia. Under the letter of intent, the Company received a payment of $3.0 million from BioOne, which was recorded as deferred revenue as of December 31, 2004. A definitive agreement with BioOne for the plasma system was signed by Baxter and the Company in June 2005, and in December 2005 the Company received additional up-front payments of $2.0 million in cash and $5.0 million in BioOne s equity, both of which were recorded upon receipt as deferred revenue and recognized over the remaining development period. In December 2006, the Company received a milestone payment from BioOne of $4.5 million in cash and $5.0 million in BioOne s equity, both of which were in recognition of the Company s receipt of a CE mark for the plasma system. The Company evaluates several criteria to determine the fair value of the equity received and to conclude whether or not the facts and circumstances support a fair value for revenue recognition and investment balance. These criteria include, but are not limited to: third-party investor interest and participation in recent equity offerings at current pricing, business outlook of BioOne, and available financial information. Based on this evaluation, the Company recognized the entire $5.0 million of equity received as revenue in December 2006. Since BioOne is a privately-held Japanese company, it is only obligated to provide the Company with annual financial information at the end of its fiscal year which ends in May. Therefore, although the Company used the best available information at the time, there was and can be no absolute assurance that facts and circumstances will not change in the future. The Company did not recognize any revenue under this agreement during the three and six months ended June 30, 2009 or 2008.

Cooperative Agreements with the United States Armed Forces

Since February 2001, the Company has received awards under cooperative agreements with the Army Medical Research Acquisition Activity division of the Department of Defense. The Company received these awards in order to develop its pathogen inactivation technologies for the improved safety and availability of blood that may be used by the United States Armed Forces for medical transfusions. Under the conditions of the agreements, the Company is conducting research on the inactivation of infectious pathogens in blood, including unusual viruses, bacteria and parasites that are of concern to the United States Armed Forces. This funding also supports advanced development of the Company s blood safety technologies. The Company recognized $0.3 million and $0.7 million of revenue under these agreements during the three and six months ended June 30, 2009, respectively, and $0.0 and $0.1 million during the three and six months ended June 30, 2008, respectively. As of June 30, 2009, the Company has received a cumulative $31.7 million of cash payments from awards with the Department of Defense.

Note 13. Segment Information and Geographic Information

At June 30, 2009 and 2008, the Company operated only one segment, blood safety. The Company s chief executive officer is the chief operating decision maker who evaluates performance based on the net revenues and operating income (loss) of the blood safety segment.

During the six months ended June 30, 2009 and 2008, the Company had the following significant customers, listed as a percentage of product revenue:

Customer	2009	2008
Movaco, S.A.	28%	28%
Establishment Francais du Sang	19%	11%
Grifols Italia S.P.A.	10%	
Delrus Inc	8%	14%
Fenwal		15%

During the six months ended June 30, 2009 and 2008, the Company also recognized government grants and cooperative agreement revenue which represented 10% and 1% of total revenue, respectively.

Note 14. Subsequent Events

Subsequent events have been evaluated through August 10, 2009, which is the date the financial statements were issued.

Table of Contents

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

This discussion and analysis should be read in conjunction with our condensed consolidated financial statements and the accompanying notes included in this report and the audited consolidated financial statements and accompanying notes included in our Annual Report on Form 10-K for the year ended December 31, 2008. Operating results for the three and six months ended June 30, 2009 are not necessarily indicative of results that may occur in future periods.

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

Overview

Since our inception in 1991, we have devoted substantially all of our efforts and resources to the research, development, clinical testing and commercialization of blood safety systems and, from 2001 until late 2007, immunotherapies for cancer and infectious disease. With the exception of the financial reporting effects of a non-recurring gain recognized in 2005, we have been generally unprofitable since inception and, as of June 30, 2009, had an accumulated deficit of approximately $399.5 million. Our INTERCEPT platelet system, or the platelet system, and our INTERCEPT plasma system, or the plasma system, have received CE marks and are being marketed in Europe, Russia, the Middle East and selected countries in other regions around the world. We have not yet received regulatory approvals for the platelet and plasma systems in the United States and other countries. The INTERCEPT red blood cell system, or the red blood cell system, is in early stage clinical development.

Our near-term capital requirements are dependent on various factors, including operating costs and working capital investments associated with commercializing the INTERCEPT Blood System, costs associated with planning and conducting studies and clinical trials of our platelet and red blood cell systems, timing and magnitude of payments under grants from the United States government, and costs related to creating, maintaining and defending our intellectual property. Our long-term capital requirements will also be dependent on competitive developments and regulatory factors. Until we can generate a sufficient amount of product revenue and generate positive net cash flows from operations, meeting our long-term capital requirements is in large part subject to access to public and private equity and debt capital markets, as well as to additional collaborative arrangements with partners or government grants, augmented by cash generated from operations and interest income earned on the investment of our cash balances and short-term investments. We believe that our available cash balances will be sufficient to meet our capital requirements into 2010. We expect to prioritize continued commercialization of the platelet and plasma systems in Europe, Russia, the Middle East and in selected countries in other regions around the world over pursuit of regulatory approval of the platelet system in the United States and development and commercialization of the red blood cell system. We expect to continue efforts to establish an acceptable pathway for U.S. regulatory approval of the platelet system. We also expect to complete a Phase I clinical trial of the INTERCEPT red blood cell system in 2009. Further efforts to gain U.S. regulatory approval of the platelet system and significant development of the red blood cell system are dependent upon securing adequate additional funding to support such activities. We have begun implementing a restructuring plan to focus our resources, consolidate facilities and reduce our cost structure. We anticipate activities under the restructuring plan will continue throughout 2009.

We may borrow additional capital from institutional and commercial sources to fund future growth on terms that may include restrictive covenants, including covenants that restrict the operation of our business, liens on assets, high effective interest rates and repayment provisions that reduce cash resources and limit future access to capital markets. To the extent we raise additional capital by issuing equity securities, our stockholders may experience substantial dilution. To the extent that we raise additional funds through

19

Table of Contents

collaboration or partnering arrangements, we may be required to relinquish some of our rights to our technologies or rights to market and sell our products in certain geographies, or grant licenses on terms that are not favorable to us. Recently, the credit markets and the financial services industry have been experiencing a period of unprecedented turmoil and upheaval characterized by the bankruptcy, failure, collapse or sale of various financial institutions and an unprecedented level of intervention from the United States federal government. These events have generally made equity and debt financing more difficult to obtain. In addition, our independent registered public accountants have indicated that our recurring operating losses raise substantial doubt as to our ability to continue as a going concern. This opinion may make it more difficult for us to raise funds when needed. As a result of these and other factors, we do not know whether additional capital will be available when needed, or that, if available, we will be able to obtain additional capital on reasonable terms. If we are unable to raise additional capital due to the recent disruptions to the credit and financial markets in the United States and worldwide or other factors, we will need to curtail planned development and commercialization activities.

Since February 2006, we have begun to recognize modest product revenue from the sale of our platelet and plasma systems in Europe, Russia, the Middle East, and certain other countries around the world. Prior to initiating such commercial operations, our primary sources of revenue were milestone payments, development contracts and collaborative agreements and grants from United States government agencies, including the United States Armed Forces and the National Institutes of Health, or NIH. We must conduct significant research, development, preclinical and clinical evaluation, commercialization and regulatory compliance activities for our products that, together with anticipated general and administrative expenses, are expected to result in substantial losses at least until after our platelet and plasma systems gain widespread commercial acceptance in Europe, Russia, the Middle East, and selected countries in other regions around the world. Our ability to achieve a profitable level of operations in the future will depend on our ability to successfully commercialize and achieve market acceptance of our blood safety products. We may never achieve a profitable level of operations.

Under the agreements with BioOne, we have received milestone payments in the past and may receive additional contingent milestone payments and royalties on future product sales.

We pay royalties to Fenwal on product sales, at rates of 10% of net sales for the platelet system, 3% for the plasma system, 5% for the red blood cell system, and 6.5% on sales of UVA illuminators. In December 2008, we amended and extended our manufacturing and supply agreement with Fenwal to include Fenwal s manufacture of finished disposable kits for the platelet and plasma systems through December 31, 2013. Under the amended manufacturing and supply agreement, we pay Fenwal a set price per kit, which is established annually plus a fixed surcharge per kit. In addition, at the end of each year, volume driven manufacturing overhead will be paid or refunded if actual manufacturing volumes are lower or higher, respectively, than the annually estimated production volumes.

We are responsible for the commercialization and ongoing development of the platelet and plasma systems, except in parts of Asia, where BioOne is responsible for such commercialization. Subject to the availability of adequate funding from partners, government grants, and/or capital markets, we also anticipate continuing our expenditures in support of preclinical and clinical trials and device development of our red blood cell system over the next several years if we can attract financing from partners, government grants, and/or the capital markets.

In November 2007, we spun-off our immunotherapy business to Anza Therapeutics, Inc., or Anza. In exchange for contributed tangible and intangible assets, we received Preferred Stock representing an equity interest of approximately 20% of Anza s preferred equity. Anza ceased its operations on March 31, 2009. The terms of sale provided Anza a right to redeem up to 1,000,000 of such shares for a nominal amount upon the failure to occur of certain circumstances relating to possible research grant funding from the DoD. We have been advised that, based upon such provision, Anza may seek to redeem 1,000,000 shares held by us. If such shares are redeemed by Anza, we would own fewer shares of Anza s Preferred Stock, reducing our preferred equity interest to approximately 16.0% of Anza s outstanding preferred equity. There is no assurance that the equity will have monetary value at such time we are allowed to sell it or that we will receive any proceeds upon liquidation or sale of Anza. We are evaluating whether Anza may redeem such shares in the present circumstances.

Because of the risks and uncertainties underlying Anza s business we have not assigned a value to our ownership interest in Anza on our condensed consolidated balance sheets. Prior to Anza ceasing operations in March 2009, we had provided certain transition services to Anza under terms of a transition services agreement under which Anza reimbursed us for our direct costs associated with providing such services. The transition services we were providing to Anza were generally ancillary in nature and did not involve Anza s core business or any scientific research or development. We also sublet 14,800 square feet to Anza under a month-to-month sublease that expired on March 31, 2009.

Through June 30, 2009, in addition to the product revenues from sales of our platelet and plasma systems, we have recognized revenue from grants and cooperative agreements with the Armed Forces.

Critical Accounting Policies and Management Estimates

The preparation of financial statements requires us to make estimates, assumptions and judgments that affect the reported amounts of assets, liabilities, revenues and expenses, and related disclosures of contingent assets and liabilities. On an ongoing basis, we evaluate our estimates, including those related to revenue recognition, inventory valuation, accrued liabilities, non-cash stock compensation

Table of Contents

assumptions, and income taxes. We base our estimates on historical experience and on various other assumptions that we believe to be reasonable under the circumstances, the results of which form our basis for making judgments about the carrying value of assets and liabilities that are not readily apparent from other sources. Actual results may differ from those estimates under different assumptions or conditions.

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

Revenue Revenue is recognized when (i) persuasive evidence of an agreement with the funding party exists; (ii) services have been rendered or product has been delivered; (iii) pricing is fixed or determinable; and (iv) collection is probable.

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

Revenue related to the cost reimbursement provisions under development contracts is recognized as the costs on the projects are incurred. We receive certain United States government grants and contracts that support research in defined research projects. These grants generally provide for reimbursement of approved costs incurred as defined in the various grants. Revenue associated with these grants is recognized as costs under each grant are incurred.

Revenue related to substantive at-risk milestones specified under development contracts is recognized as the milestones are achieved. To date, we have not received license fees or milestone payments that are refundable. To the extent that license fees or milestone payments that we have received are subject to future performance criteria, we recognize revenue ratably over the estimated term of the license or the development period. We have received up-front payments from collaboration agreements which are deferred and recognized over the period during which we estimate we are likely to have involvement. We have also received equity in two privately held companies in addition to cash as consideration for licensed rights or technologies. We evaluate several criteria to determine the fair value of the equity received and to conclude whether the facts and circumstances support a fair value for revenue recognition and the investment balance. These criteria include, but are not limited to, third-party investor interest and participation in recent equity offerings at current pricing, business outlook of the privately held company, and available financial information of the privately held company. The financial information we receive is generally only available on an infrequent basis. Although management uses the best available information at the time, there can be no absolute assurance that facts and circumstances will not change in the future. Should these facts and circumstances change, they may negatively impact our condensed consolidated financial statements.

Inventory We own work-in-process inventory for certain components of INTERCEPT disposable kits, finished INTERCEPT disposable kits, illuminators, and certain replacement parts for our illuminators. Our supply chain for certain of these components, held as work-in-process on our condensed consolidated balance sheet, can take over one year to complete production before being utilized in finished disposable kits. Under our manufacturing agreement with Fenwal, our carrying value of INTERCEPT disposable kits is dependent on an annually set price. In addition, at the end of each year, volume driven manufacturing overhead is either paid or refunded by or to us if manufacturing volumes are higher or lower than the anticipated manufacturing volumes at the time the price is established. As a result, at each interim period, manufacturing overhead can fluctuate and requires us to use judgment in accruing the manufacturing overhead. In addition, we use judgment in determining whether the manufacturing overhead is a cost of our inventory and recoverable when product is sold. Inventory is recorded at the lower of cost, determined on a first in, first-out basis, or market value. Our platelet and plasma system disposable kits generally have a two-year shelf life from the date of manufacture. Illuminators and replacement parts do not have regulated expiration dates. We use significant judgment to analyze and determine if the composition of our inventory is obsolete, slow-moving, or unsalable and frequently review such determinations. Our limited history selling the INTERCEPT Blood System limits the amount of historical data we have to perform this analysis. Generally, we write-down specifically identified obsolete, slow-moving, or known unsalable inventory that has no alternative use, using a number of factors including product expiration dates, open and unfulfilled orders, and sales forecasts.

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

Table of Contents

Stock-based compensation We issue stock-based awards to our employees, members of our Board of Directors, our Scientific Advisory Board and certain contractors as strategic, long-term incentives. We recorded stock-based compensation expense for employee awards in accordance with Statement of Financial Accounting Standards, or FAS, No. 123R, Accounting for Stock-Based Compensation, or FAS 123R. We use the Black-Scholes option pricing model to determine the grant-date fair value of a stock award. We continue to apply the provisions of Emerging Issues Task Force, or EITF, 96-18, Accounting for Equity Instruments that are Issued to Other than Employees for Acquiring, or in Conjunctions with Selling, Goods or Services, for our non-employee stock-based awards. Under EITF 96-18, the measurement date at which the fair value of the stock-based award is measured is equal to the earlier of (i) the date at which a commitment for performance by the grantee to earn the equity instrument is reached or (ii) the date at which the grantee s performance is complete. We recognize stock-based compensation expense for the fair value of the vested portion of the non-employee awards in our condensed consolidated statements of operations.

The Black-Scholes option pricing model calculates the grant-date fair value using certain variables. These variables are impacted by our stock price, award exercise behaviors, the risk free interest rate and our expected dividends and many of these variables require us to use significant judgment.

Expected Term. We estimate the expected term of options granted using a variety of factors. Where possible, we estimate the expected term of options granted by analyzing employee exercise and post-vesting termination behavior. To make this estimation, we analyze the population of options granted by discreet homogeneous groups. For those homogeneous groups where we are unable to obtain sufficient information to estimate the expected term in this manner, we estimate the expected term of the options granted by taking the average of the vesting term and the contractual term of the option, as illustrated in the Securities and Exchange Commission Staff Accounting Bulletin No. 107 and 110, Share-Based Payment, or SAB 107 and SAB 110. The expected term of employee stock purchase plan shares is the term of each offering period.

Estimated Forfeiture Rate. We estimate the forfeiture rate of options at the time of grant and revise those estimates in subsequent periods if actual forfeitures differ from those estimates. We use historical data to estimate pre-vesting option forfeitures and record stock-based compensation expense only for those awards that are expected to vest. We estimate the historic pre-vesting forfeiture rates by groups that possess a degree of homogeneity regarding average time to vest and expected term. All stock-based payment awards are amortized on a straight-line basis over the requisite service periods of the awards, which are generally the vesting periods.

Estimated Volatility. We estimate the volatility of our common stock by using historical volatility of our common stock. We have used significant judgment in making these estimates and we will continue to monitor the availability of actively traded options on our common stock. If we determine that sufficient actively traded options on our common stock exist, we may consider a combination of historical and implied volatility, or solely implied volatility.

Risk-Free Interest Rate. We base the risk-free interest rate that we use in the option valuation model on United States Treasury zero-coupon issues with remaining terms similar to the expected term on the options.

Expected Dividend. We do not anticipate paying any cash dividends in the foreseeable future and therefore use an expected dividend yield of zero in the option valuation model.

If factors change and we utilize different assumptions in determining the grant-date fair value of stock compensation expense in the future, or if we utilize a different option pricing model in the future, then those results may differ significantly from what we have recorded in the current period and could materially affect our operating results. There is significant risk that the Black-Scholes option pricing model and the judgment we have used in ascertaining the variables will yield results that differ materially from the actual values realized upon the exercise, expiration, termination or forfeitures of the awards in the future. Historical results were utilized in deriving our variables, which may not be indicative of the future.

Income Taxes Since our inception we have accumulated significant net operating losses and research and development credits that may be used in future periods to offset future taxable income. We currently estimate that we may not be able to utilize all of our deferred tax assets. In addition, we may not generate future taxable income prior to the expiration of our net operating loss carry forwards and research and development credits. Timing and significance of any estimated future taxable income is highly subjective and is beyond the control of management due to uncertainties in market conditions, economic environments in which we operate, and timing of regulatory approval of our products. We do not recognize tax positions that have a lower than 50% likelihood of being recognized upon review by a taxing authority having full knowledge of all relevant information. Use of a valuation allowance as described in Financial Accounting Standard 109, Accounting for Income Taxes, or FAS 109, is not an appropriate substitute for the derecognition of a tax position. We did not have any recorded liabilities for unrecognized tax benefits at June 30, 2009 or December 31, 2008. We recognize interest accrued and penalties related to unrecognized tax benefits in our income tax expense. To date, we have not recognized any interest and penalties in our statements of operations, nor have we accrued for or made payments for interest and penalties. We continue to carry a full valuation allowance on all of our deferred tax assets. Although we believe it more likely than not that a taxing authority would agree with our current tax positions, there can be no assurance that the

tax positions we have taken will be substantiated by a taxing authority if reviewed.

Table of Contents

Results of Operations

Three and Six-Month Periods Ended June 30, 2009 and 2008

Revenue

(in thousands, except percentage)	Three months ended June 30, 2009	2008	Change		Six months ended June 30, 2009	2008	Change	
Product revenue	$ 3,871	$ 4,030	$ (159)	(4)%	$ 6,956	$ 8,882	$ (1,926)	(22)%
Government grants and cooperative agreement	335		335	%	738	117	621	531%
Total revenue	$ 4,206	$ 4,030	$ 176	4%	$ 7,694	$ 8,999	$ (1,305)	(15)%

Product revenue decreased $0.2 million to $3.9 million during the three months ended June 30, 2009, compared to $4.0 million during the comparable period in the prior year. The decrease was largely due to the recognition in 2008 of $0.3 million in revenue deferred in 2007 relating to the sale of INTERCEPT units to customers in 2007. We anticipate product revenue for both the platelet and plasma systems will increase in future periods as the INTERCEPT Blood System gains market acceptance in geographies where commercialization efforts are underway. These quarterly results may not be indicative of INTERCEPT Blood System revenue in the future.

We recognized $0.3 million of revenue from government grants and cooperative agreements for the three months ended June 30, 2009. No such revenue was recognized for the comparable period in 2008. The revenue recognized during the three months ended June 30, 2009 related to an award with the United States Department of Defense relating to the research and development of the red blood cell system. We anticipate recognizing $1.0 million, the remainder of the award, throughout 2009 and possibly into 2010. We anticipate applying for new awards with the Department of Defense to the extent such awards become available. However, we can provide no assurance that should such awards become available, our bids will be accepted by the Department of Defense or at what funding levels.

Product revenue decreased $1.9 million to $7.0 million during the six months ended June 30, 2009, compared to $9.0 million during the comparable period in the prior year. The decrease in product revenue was primarily due to the recognition in 2008 of $1.5 million in revenue originally deferred in 2007.

Government grant revenue increased by $0.6 million to $0.7 million during the six months ended June 30, 2009, compared to $0.1 million during the comparable period in the prior year. The increase in government grant revenue was primarily due to an award with the Department of Defense, received in 2009 relating to the research and development of the red blood cell system.

Cost of Product Revenue

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

(in thousands, except percentage)	Three months ended June 30, 2009	2008	Change		Six months ended June 30, 2009	2008	Change	
Cost of product revenue	$ 2,520	$ 3,077	$ (557)	(18)%	$ 4,614	$ 4,791	$ (177)	(4)%

Cost of product revenue decreased $0.6 million to $2.5 million during the three months ended June 30, 2009, from $3.1 million during the comparable period in the prior year. The decrease in cost of revenue was primarily due to the 2008 recognition of previously deferred cost of product revenue resulting from INTERCEPT units sold to customers in 2007. This increase was partially offset by an increase in the provision for obsolete slow-moving and scrapped inventory recorded in 2009 compared to 2008.

Similarly, cost of product revenue decreased $0.2 million to $4.6 million during the six months ended June 30, 2009, from $4.8 million during the comparable period in the prior year. The decrease in cost of product revenue was due to the lower number of consumable units sold during the six months ended June 30, 2009, partially offset by an increase in the provision for obsolete slow-moving and scrapped inventory recorded in

2009 compared to 2008.

We anticipate our cost of product revenue will increase in the future as a result of increased product sales volume. Our realized gross margins are affected by various factors, including manufacturing and supply chain costs, the mix of product sold, and the mix of customers to whom product is sold. Generally, distributors receive wholesale pricing.

Table of Contents

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, and costs associated with our infrastructure, and laboratory chemicals and supplies.

	Three months ended June 30,				Six months ended June 30,			
(in thousands, except percentage)	**2009**	**2008**	**Change**		**2009**	**2008**	**Change**	
Research and development	$ 1,625	$ 2,670	$ (1,045)	(39)%	$ 3,637	$ 5,454	$ (1,817)	(33)%

Research and development expenses decreased $1.0 million to $1.6 million for the three months ended June 30, 2009, from $2.7 million for the comparable period in 2008. Of our total research and development costs incurred, non-cash stock based compensation represented $0.1 million for each of the three months ended June 30, 2009 and 2008. The decrease in our research and development expenses during the three months ended June 30, 2009, compared to 2008 was the result of reduced research and development activities driven primarily by our March 2009 restructuring plan and the associated reduction in force.

Research and development expenses decreased $1.8 million to $3.6 million for the six months ended June 30, 2009, from $5.5 million for the comparable period in 2008. Of our total research and development expenses incurred, non-cash stock based compensation represented $0.3 million for the six months ended June 30, 2009 and 2008. The decrease in our research and development expenses during the six months ended June 30, 2009, compared to 2008 was a result of the effect of our March 2009 restructuring and the associated reduction in force.

We anticipate our research and development spending will continue at approximately the current level and at times may increase as a result of ongoing and later stage preclinical and clinical trials, and as potential new products move from development to preclinical and clinical trials. Because of the numerous risks and uncertainties associated with research and development activities, including but not limited to, the time and cost involved in obtaining regulatory approval and subsequent launch of our platelet and plasma systems in the United States, and the development of the red blood cell system and other development activities, including risks and uncertainties that could impact the rate of progress of our development activities, we are unable to estimate with certainty the amounts of increased capital outlays and operating expenditures that may ultimately be associated with our current and anticipated clinical trials and other research and development activities. We face numerous risks and uncertainties associated with the successful completion of our research and development projects, including the risks described in Risk Factors in Part II, Item 1A below.

Table of Contents

Selling, General, and Administrative Expenses

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

	Three months ended June 30,				Six months ended June 30,			
(in thousands, except percentage)	**2009**	**2008**	**Change**		**2009**	**2008**	**Change**	
Selling, general, and administrative	$ 5,409	$ 7,439	$ (2,030)	(27)%	$ 11,510	$ 14,540	$ (3,030)	(21)%

Selling, general, and administrative expenses decreased $2.0 million to $5.4 million for the three months ended June 30, 2009, from $7.4 million for the comparable period in 2008. Of these amounts, non-cash stock-based compensation represented $0.4 million and $0.3 million for each of the three months ended June 30, 2009 and 2008, respectively. Overall, the decrease in selling, general and administrative expenses from the three months ended June 30, 2009, was primarily due to the decreased personnel costs and lower marketing and public affairs costs driven primarily by our March 2009 restructuring plan and the associated reductions in force.

Selling, general, and administrative expenses decreased $3.0 million to $11.5 million for the six months ended June 30, 2009, from $14.5 million for the comparable period in 2008. Of the $11.5 million and $14.5 million of selling, general and administrative expenses recognized during the six months ended June 30, 2009 and 2008, respectively, $0.8 million and $0.7 million was due to non-cash stock-based compensation recognized during the respective periods. Overall, the decrease in selling, general and administrative expenses for the six months ended June 30, 2009, was primarily due to the decreased personnel costs and lower marketing and public affairs costs driven primarily by our March 2009 restructuring plan and the associated reductions in force. We anticipate that selling, general, and administrative expenses will continue to decline in the near term, as we implement our restructuring plan and focus available resources on commercialization of the INTERCEPT Blood System in Europe.

Restructuring

Restructuring costs during three and six months ended June 30, 2009, include one-time termination benefits, facility consolidation and related moving costs.

	Three months ended June 30,				Six months ended June 30,			
(in thousands, except percentage)	**2009**	**2008**	**Change**		**2009**	**2008**	**Change**	
Restructuring	$ 129	$	$ 129	100%	$ 841	$	$ 841	100%

In March 2009, pursuant to the Board of Directors approval, we began implementing a plan to focus resources on commercializing the INTERCEPT Blood System in Europe, to consolidate facilities, and to reduce our cost structure. During the three and six months ended June 30, 2009, we incurred costs for one-time termination benefits for employee positions that were eliminated under the restructuring plan. During the three months ended June 30, 2009, we also incurred costs associated with consolidating facilities and certain other costs associated with the restructuring plan. We anticipate continuing to implement our restructuring plan and incurring associated costs through the year ended December 31, 2009. Most costs accrued as one-time termination benefits as of March 31, 2009 were paid during the three months ended June 30, 2009. However, certain of these costs will be paid over an extended period of time, into 2010.

Other Income (Expense), Net

Other income (expense), net consists of interest earned from our short-term investment portfolio, foreign exchange gain (loss), and other non-operating gains and losses.

	Three months ended June 30,			Six months ended June 30,		
(in thousands, except percentage)	**2009**	**2008**	**Change**	**2009**	**2008**	**Change**

Other Income (Expense), Net	$ (735)	$ 209	$ (944)	(452)%	$ (701)	$ 899	$ (1,600)	(178)%

Other income (expense), net was $0.7 million of expense for the three months ended June 30, 2009, compared to $0.2 million of income during the comparable period in 2008. The decrease was primarily due to the unfavorable foreign currency variations between the Euro and U.S. dollar, our functional currency, as well as the decline in interest income resulting from lower cash and short-term investment balances and lower yields on those balances. These decreases were partially offset by realized gains which we recognized upon maturity of

Table of Contents

certain investments in our portfolio. Interest income was $0.1 million and $0.3 million for the three months ended June 30, 2009 and 2008, respectively. The decrease in interest income was primarily due to lower cash and investment balances maintained during the three months ended June 30, 2009, compared to the comparable period in 2008.

Other income (expense), net was $0.7 million of expense for the six months ended June 30, 2009, compared to $0.9 million of income during the comparable period in 2008. The decrease was primarily due to the unfavorable foreign currency variations between the Euro and U.S. dollar, our functional currency, as well as the decline in interest income resulting from lower cash and short-term investment balances and lower yields on those balances. These decreases were partially offset by realized gains which we recognized upon maturity of certain investments in our portfolio. Interest income was $0.2 million and $0.9 million for the six months ended June 30, 2009 and 2008, respectively. The decrease in interest income was primarily due to lower cash and investment balances maintained during the six months ended June 30, 2009, compared to the comparable period in 2008.

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.

Liquidity and Capital Resources

Our sources of capital to date have primarily consisted of public offerings and private placements of equity securities, payments received under our partnering agreements, United States government grants and cooperative agreements, and, to a lesser degree and more recently, contribution from product sales net of expenses and interest income.

At June 30, 2009, we had cash, cash equivalents and short-term investments of $12.9 million. Net cash used in operating activities was $9.5 million for the six months ended June 30, 2009, compared to $18.6 million during the comparable period in 2008. The decrease in net cash used in operating activities was primarily due to changes in our operating assets and liabilities, notably decreases in our inventory and accounts receivable balances. Net cash provided by investing activities during the six months ended June 30, 2009 was $6.9 million compared to $20.0 million during the comparable period in 2008. The decrease was primarily due to fewer purchases of short-term investments and maturities of short-term investments. Currently, as our investments mature, we have not reinvested the proceeds into similar investments, but have generally invested the proceeds in money market funds with original maturities less than 90 days. Net cash provided by financing activities during the six months ended June 30, 2009 was $43,000 compared to cash provided by financing activities of $1.3 million for the same period in 2008. The decrease in cash provided from financing activities in the six months ended June 30, 2009 was primarily due to less cash received from the exercise of stock options. Working capital decreased to $17.0 million at June 30, 2009, from $29.1 million at December 31, 2008, primarily due to lower cash, cash equivalents, short-term investments, inventory and accounts receivable balances.

Our near-term capital requirements are dependent on various factors, including operating costs and capital investments associated with commercializing the INTERCEPT Blood System, costs associated with planning and conducting clinical trials of our red blood cell system, timing and magnitude of payments under grants from the United States government, and costs related to creating, maintaining and defending our intellectual property. Our long-term capital requirements will also be dependent on competitive developments and regulatory factors. Until we are able to generate a sufficient amount of product revenue and generate positive cash flows from operations, meeting our long-term capital requirements is in large part subject to access to public and private equity and debt capital markets, as well as to additional collaborative arrangements with partners or government grants, augmented by cash generated from operations and interest income earned on the investment of our cash balances and short-term investments. Although our independent registered public accountants have indicated that substantial doubt exists as to our ability to continue as a going concern, we believe that our available cash balances will be sufficient to meet our capital requirements into 2010, by which time we may need to raise additional capital. We have based this estimate on assumptions that may prove to be wrong, and we could utilize our available capital resources sooner than we currently expect. We expect to prioritize continued commercialization of the platelet and plasma systems in Europe, Russia, the Middle East and in selected countries in other regions around the world over the pursuit of regulatory approval of the platelet system in the United States and development and commercialization of the red blood cell system. We expect to continue efforts to establish an acceptable pathway for U.S. regulatory approval of the platelet system. We also expect to complete a Phase I clinical trial of the INTERCEPT red blood cell system in 2009. Further efforts to gain U.S. regulatory approval of the platelet system and significant development of the red blood cell system are dependent upon securing adequate additional funding to support such activities. Because of the numerous risks and uncertainties associated with the commercialization of the platelet and plasma systems, the time and cost involved in obtaining regulatory approval and subsequent launch of our platelet and plasma systems in the United States, and the development of the red blood cell system and other development activities, including risks and uncertainties that could impact the rate of progress of our development activities, we are unable to estimate with certainty the amounts of increased capital outlays and operating expenditures that may ultimately be associated with our current and anticipated clinical trials and other research and development activities.

We may borrow additional capital from institutional and commercial sources to fund future growth on terms that may include restrictive covenants, including covenants that restrict the operation of our business, liens on assets, high effective interest rates and repayment provisions

that reduce cash resources and limit future access to capital markets. To the extent we raise additional capital by issuing equity securities, our stockholders may experience substantial dilution. To the extent that we raise additional funds through collaboration or partnering arrangements, we may be required to relinquish some of our rights to our technologies or product, or grant licenses on terms that are not favorable to us. Recently, the credit markets and the financial services industry have been experiencing a period of unprecedented turmoil and upheaval characterized by the bankruptcy, failure, collapse or sale of various financial institutions and

Table of Contents

an unprecedented level of intervention from the United States federal government. As a result of these and other factors, we do not know whether additional capital will be available when needed, or that, if available, we will be able to obtain additional capital on terms reasonable to us or our stockholders. If we are unable to raise additional capital due to the recent disruptions to the credit and financial markets in the United States and worldwide or other factors, we will need to curtail planned development activities and commercialization activities.

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

In late October 2008 we filed a shelf registration statement on Form S-3 to offer and sell up to $200.0 million of common stock, preferred stock, warrants, and/or debt securities. This shelf registration statement was declared effective by the SEC in December 2008. However, our ability to sell shares under this shelf registration statement may be limited due to applicable rules of the Securities Act. Consequently, any offering of common stock, preferred stock, warrants, and/or debt securities may need to be accompanied by a registration statement specific to the securities offered therein.

Table of Contents

Commitments and Off-Balance Sheet Arrangements

Commitments

Our commitments are as follows (in thousands):

	Total	Less than 1 year	1-3 years	4-5 years	After 5 years
Minimum purchase requirements	$ 2,290	$ 1,018	$ 807	$ 465	$
Operating leases	3,443	1,231	1,480	732	
Other commitment	80	22	45	13	
Total contractual obligations	$ 5,813	$ 2,271	$ 2,332	$ 1,210	$

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

Operating Leases

We 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 facility leases qualify as operating leases under FAS No. 13, Accounting for Leases and as such, are not included on our balance sheet.

Royalties

We are obligated to pay royalties on certain INTERCEPT product sales based on a percentage of net sales generated. The royalty rates vary by product, with rates of 10% of net sales for the platelet system, 3% for the plasma system, 5% for the red blood cell system, and 6.5% for UVA illuminators. As future product sales cannot be estimated, this royalty obligation is not included in the table above.

Credit Facility

In June 2008, we entered into a senior secured revolving credit facility with Wells Fargo Bank, N.A., or the Facility, which allowed us to borrow up to $10.0 million to be used for working capital and general operating needs. The initial term of the Facility was one year. At June 30, 2009, the Facility expired with no amount outstanding.

Financial Instruments

We maintain an investment portfolio of various issuers, types and maturities. These securities are generally classified as available-for-sale and, consequently, are recorded on the balance sheet at fair value with unrealized gains or losses reported as a separate component of stockholders equity. Our investment policy is to manage our marketable securities portfolio to preserve principal and liquidity while maximizing the return on the investment portfolio to assist us in funding our operations. Unrealized gains at June 30, 2009 and December 31, 2008, totaled $47,000 and $212,000 respectively.

We invest our cash, cash equivalents and short-term investments in a variety of financial instruments, consisting primarily of high credit, high liquidity United States government agency securities, asset-backed securities, corporate debt securities, money market funds and interest-bearing accounts with financial institutions. We maintain portfolio liquidity by ensuring that the securities have active secondary or resale markets. Certain of the investments in our portfolio are subject to general market risk and more specifically fluctuations resulting from turmoil from recent disruptions in the United States mortgage industry and financial institutions. As a result, we recognized other than temporary impairments for certain investments in our portfolio totaling $0.1 million during the six months ended June 30, 2008. There were no other-than-temporary impairments recognized during the three or six months ended June 30, 2009. The current global economic crisis has had, and may continue to have, a negative impact on the market values of the investments in our investment portfolio. There can be no assurance that the markets for these securities will not deteriorate further or that the institutions that these investments are with will be able to meet their debt obligations at the time

we may need to liquidate such investments or until such time as the investments mature.

Table of Contents

Off-Balance Sheet Arrangements

As of June 30, 2009, we had no contractual arrangements that create potential material risk for us and are not recognized in our condensed consolidated balance sheets.

ITEM 3. QUANTITATIVE AND QUALITATIVE DISCLOSURES ABOUT MARKET RISK

During the six months ended June 30, 2009, there were no material changes to our market risk disclosures as set forth in Part II, Item 7A, Quantitative and Qualitative Disclosures About Market Risk, of our Annual Report on Form 10-K for the year ended December 31, 2008.

ITEM 4. CONTROLS AND PROCEDURES

Evaluation of Disclosure Controls and Procedures. Our Chief Executive Officer and Vice President, Finance and Chief Accounting Officer (who perform the functions of the principal executive officer and principal financial officer, respectively) are responsible for establishing and maintaining disclosure controls and procedures (as defined in Rules 13a-15(e) and 15d-15(e) of the Securities Exchange Act of 1934, as amended) for our company. Based on their evaluation of our disclosure controls and procedures as of the end of the period covered by this report, our Chief Executive Officer and our Vice President, Finance and Chief Accounting Officer (in their capacities as principal executive officer and principal financial officer, respectively) have concluded that our disclosure controls and procedures were effective as of June 30, 2009.

Changes in Internal Control Over Financial Reporting. There were no changes in our internal control over financial reporting that occurred during our fiscal quarter ended June 30, 2009 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 controls are met. Because of the inherent limitations in all control systems, no evaluation of controls can provide absolute assurance that all control issues, if any, within a company have been detected. Accordingly, our disclosure controls and procedures are designed to provide reasonable assurance, not absolute assurance, that the objectives of our disclosure control system are met and, as set forth above, our chief executive officer and chief accounting officer have concluded, that based on their evaluation as of the end of the period covered by this report, that our disclosure controls and procedures were sufficiently effective to provide reasonable assurance that the objective of our disclosure control system were met.

PART II: OTHER INFORMATION

ITEM 1. LEGAL PROCEEDINGS

None.

ITEM 1A. RISK FACTORS

Risk Factors

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

If we fail to obtain the capital necessary to fund our future operations, we will need to curtail planned development or sales and commercialization activities.

Our near-term capital requirements are dependent on various factors, including operating costs and working capital investments associated with commercializing the INTERCEPT Blood System, costs associated with planning and conducting studies and clinical trials of our platelet and red blood cell systems, timing and magnitude of payments under grants from the United States government, and costs related to creating, maintaining and defending our intellectual property. Our long-term capital requirements will also be dependent on competitive developments and regulatory factors. Until we are able to generate a sufficient amount of product revenue and generate positive net cash flows from operations, meeting our long-term capital requirements is in large part subject to access to public and private equity and debt capital markets, as well as to additional collaborative arrangements with partners or government grants, augmented by cash generated from operations and interest income earned on the investment of our cash balances and short-term investments. We believe that we will be able to sustain our operations at levels that will result in sufficient capital to meet our capital requirements into 2010. If our assumptions prove to be incorrect, we could consume our available capital resources sooner than we currently expect.

Table of Contents

We may borrow additional capital from institutional and commercial banking sources to fund future growth on terms that may include restrictive covenants, including covenants that restrict the operation of our business, liens on assets, high effective interest rates and repayment provisions that reduce cash resources and limit future access to capital markets. To the extent we raise additional capital by issuing equity securities, our stockholders may experience substantial dilution. To the extent that we raise additional funds through collaboration or partnering arrangements, we may be required to relinquish some of our rights to our technologies or rights to market and sell our products in certain geographies, or grant licenses on terms that are not favorable to us. Our ability to raise additional capital by issuing equity securities may be limited by the number of authorized shares of capital stock under our current certificate of incorporation. If we are not able to increase the number of authorized shares of capital stock, we will be limited in our ability to issue equity securities to raise capital. Our ability to raise additional capital may also be adversely impacted by current economic conditions, including the effects of the recent disruptions to the credit and financial markets in the United States and worldwide. In addition, our independent registered public accountants have indicated that our recurring operating losses raise substantial doubt as to our ability to continue as a going concern. This opinion may make it more difficult for us to raise funds when needed. As a result of these and other factors, we do not know whether additional capital will be available when needed, or that, if available, we will be able to obtain additional capital on terms favorable to us or our stockholders. If we are unable to raise additional capital due to the recent disruptions to the credit and financial markets in the United States and worldwide or other factors, we will need to curtail planned development and commercialization activities. We expect to prioritize continued commercialization of the platelet and plasma systems in Europe, Russia, the Middle East and in selected countries in other regions around the world over pursuit of regulatory approval of the platelet system in the United States and development and commercialization of the red blood cell system.

Historically, we had received significant awards in funding under cooperative agreements with the DoD. Further funding awarded under Federal grants and cooperative agreements for the INTERCEPT Blood Systems may decline when compared to historic levels. It is subject to the authorization of funds and approval of our research plans by various organizations within the federal government, including the United States Congress. If we are unable to obtain Federal grant and cooperative agreement funding for future research and development activities at levels similar to past funding, we may need to reduce our operating expenses, which would delay progress in some of our development programs.

Our independent registered public accountants have indicated that our recurring operating losses raise substantial doubt as to our ability to continue as a going concern.

Our audited financial statements for the fiscal year ended December 31, 2008 were prepared on a going concern basis in accordance with United States generally accepted accounting principles, or GAAP. The going concern basis of presentation assumes that we will continue in operation for the foreseeable future and will be able to realize our assets and discharge our liabilities and commitments in the normal course of business. However, our independent registered public accountants have indicated that our recurring operating losses raise substantial doubt as to our ability to continue as a going concern. We may be forced to reduce our operating expenses and raise additional funds to meet our working capital needs, principally through the additional sales of our securities or debt financings. However, we cannot guarantee that will be able to obtain sufficient additional funds when needed or that such funds, if available, will be obtainable on terms satisfactory to us. In the event that these plans cannot be effectively realized, there can be no assurance that we will be able to continue as a going concern.

Prospective and existing customers may not adopt or may cease using the INTERCEPT Blood System due to our independent registered public accountants opinion which expressed doubt about our ability to continue as a going concern. Should this occur, it may in turn affect market acceptance and retention of customers. In addition, as a result of our independent registered public accountants opinion, we may face difficulties attracting and retaining key personnel, which may in turn affect our ability to successfully operate our business.

Our financial condition may make us unable to obtain additional funds through debt financings, which will impair our ability to continue as a going concern.

Our lack of sufficient revenues to meet our working capital needs has caused our financial condition to decline. As a result, we may be unable to raise additional funds through debt financings or, if we are able to raise such funds, we may not be able to do so on terms satisfactory to us. If we fail to generate operating income or raise additional funds through sales of our securities or debt financings, we may not be able to continue as a going concern. Moreover, key vendors may restrict the amount of credit they extend to us, which in turn may result in the consumption of cash sooner than we expect.

The restructuring of our operations could result in management distractions, operational disruptions and other difficulties.

In March 2009, our Board of Directors committed to a restructuring plan that included the dismissal of 31 employees, or approximately 30% of our workforce. Employees whose positions were eliminated in connection with this reduction may seek future employment with our competitors. Although all employees are required to sign a confidentiality agreement with us at the time of hire, we cannot assure you that the confidential nature of our proprietary information will be maintained in the course of such future employment. In addition, our ongoing restructuring efforts could divert the attention of our management away from our operations and harm our reputation. We cannot assure you that we will not

undertake additional workforce reductions, that any of our restructuring efforts will be successful, or that we will be able to realize the cost savings and other anticipated benefits from our previous or future restructuring plans. In addition, if we continue to reduce our workforce, it may adversely impact our ability to continue our commercialization efforts with respect to the INTERCEPT Blood System in Europe or retain key employees.

Table of Contents

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

We may never achieve a profitable level of operations. Our development and selling, general, and administrative expenses have resulted in substantial losses each year since our inception with the exception of the year ended December 31, 2005. At June 30, 2009, we had an accumulated deficit of approximately $399.5 million. Through June 30, 2009, we have only recognized modest revenue from product sales. The platelet and plasma systems are not yet approved in the United States or in many other countries around the world. The red blood cell system is in early stage clinical development and may never emerge from the clinical development stage as a marketed product. We may be required to reduce the sales price for our products in order to make our products economically attractive to our customers and to governmental and private payors, which may reduce or altogether eliminate our gross profit on sales. Pricing levels may differ widely from country to country, depending on economic, social and industry practices specific to each country. At our present low unit sales levels of the platelet and plasma systems, our costs to manufacture, distribute, market, sell, support and administer the systems are in excess of revenue. We may be unable to increase sales to a level sufficient to generate profit contribution. Because the contracts with large, public-sector customers, such as the EFS in France, for the INTERCEPT Blood System may not be confidential due to the public tender process, their terms may set contractual precedents that would not be acceptable to us if applied to contracts with our other customers. Historically, we received substantially all of our revenue from our agreements with our development partners and from federal research grants and cooperative agreements and were required to conduct significant research, development, clinical testing and regulatory compliance activities for each of these products. Contribution from product sales is unlikely to exceed the costs we incur in research, development, and commercialization of the INTERCEPT Blood System for the foreseeable future. We expect our losses to continue at least until the INTERCEPT Blood System is commercialized more broadly and achieves more significant market acceptance. To the extent that we are able to secure funding from partners or government agencies for the red blood cell system, costs of developing and testing the red blood cell system in later stage human clinical trials would extend the period during which we expect to operate at a loss.

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

Our cash equivalent and short-term investment portfolio as of June 30, 2009 consisted primarily of high credit, high liquidity United States government agency securities, asset backed securities, corporate debt securities, money market funds and interest-bearing accounts with financial institutions. We follow an established investment policy and set of guidelines to monitor, manage and limit our exposure to interest rate and credit risk.

As a result of current adverse financial market conditions, investments in some financial instruments, such as structured investment vehicles, sub-prime mortgage-backed securities, auction rate securities and collateralized debt obligations, may pose risks arising from liquidity and credit concerns. We have limited holdings of these investments in our portfolio; however, the current disruptions in the credit and financial markets have negatively affected investments in many industries, including those in which we invest. We did not recognize any other-than-temporary impairments on our investment portfolio during the three or six months ended June 30, 2009. The current global economic crisis has had, and may continue to have, a negative impact on the market values of the investments in our investment portfolio. We cannot predict future market conditions or market liquidity and there can be no assurance that the markets for these securities will not deteriorate further or that the institutions that these investments are with will be able to meet their debt obligations at the time we may need to liquidate such investments or until such time as the investments mature.

The INTERCEPT Blood System may not achieve broad market acceptance.

We may encounter governmental and blood banking community resistance to commercial adoption for any or all of our products. Some potential customers may await further safety information or additional studies before choosing whether to adopt our products. In addition to blood banks, our direct customers, we must also address issues and concerns from broad constituencies involved in the healthcare system, from patients who may ultimately benefit from INTERCEPT-treated blood components, to transfusing physicians, hospitals, private and public sector payors, regulatory bodies and public health authorities. Any one of these constituencies may be able to delay or block adoption of the INTERCEPT Blood System. We may be unable to adequately demonstrate to these constituencies that the INTERCEPT Blood System is safe, efficacious and cost effective.

For logistical and financial reasons, the transfusion industry has not always integrated new technologies into its processes, even those with the potential to improve the safety of the blood supply, such as the INTERCEPT Blood System. Our products may require significant changes to our potential customers blood component collection methods, space and staffing requirements and potential customers may not believe that the benefits of using the INTERCEPT Blood System justify their cost. There is some loss of platelets as a result of our pathogen inactivation process. If the loss of platelets leads to increased costs, or our process requires changes in blood center or clinical regimens, customers may not adopt our platelet system. Certain studies have indicated that transfusion of conventionally prepared platelets may yield higher post-transfusion platelet counts (according to a measurement called corrected count increment) than transfusion of INTERCEPT-treated platelets. While studies also demonstrate that INTERCEPT-treated platelets retain therapeutic function comparable to conventional platelets, customers may choose not

to adopt our platelet system due to considerations relating to corrected count increment.

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

Table of Contents

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

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

Our products may not demonstrate economic value sufficient to offset their price, imposing a financial burden on the healthcare system that may limit market acceptance. We may need to develop new product configurations to address market needs, which may be technically challenging, expensive and negatively affect potential contribution from product sales. If customers experience operational or technical problems with the use of INTERCEPT Blood System products, market acceptance may be reduced. For example, if adverse events arise from incomplete inactivation of pathogens, improper processing or user error, or if testing of INTERCEPT-treated blood samples fails to reliably confirm pathogen inactivation, whether or not directly attributable to a shortcoming of the INTERCEPT Blood System, customers may refrain from purchasing the products. In addition, there is a risk that further studies we or our customers may conduct will show results inconsistent with previous studies. For example, the largest branch of the German Red Cross is planning to conduct an observational clinical study of use of our platelet system prior to implementing it in routine practice. If that customer is not satisfied with the results of the study, it may not purchase our products, and adoption of our product may also be adversely affected in other blood centers. We are also conducting a study to evaluate the use of INTERCEPT-treated platelets after storage for seven days. If that study does not demonstrate acceptable platelet activity and safety, market acceptance could be adversely affected. Should this happen, potential customers may delay or choose not to adopt our products, and existing customers may cease use of our products.

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

Product revenue in Europe and other regions may be negatively affected because we do not have FDA approval for any of our products. In addition, failure to gain approval or achieve widespread product adoption in key European countries for reasons within and outside our control may limit adoption in other countries. If the INTERCEPT Blood System products fail to achieve market acceptance, we may never become profitable.

The market for the INTERCEPT Blood System is highly concentrated with few customers, including often-dominant regional or national blood collection entities. Even if our products receive regulatory approval and reimbursement is available, failure to properly market, promote, distribute, price or sell our products to any of these large customers could significantly diminish potential product revenue in those geographies. The market for our pathogen inactivation systems in the United States is highly concentrated, dominated by a small number of blood collection organizations. In many countries in Western Europe and in Japan, various national blood transfusion services or Red Cross organizations collect, store and distribute virtually all of their respective nations blood and blood components supply. In Europe, the largest markets for our products are in England, Germany and France. Decisions on product adoption in England are centralized with the National Blood Service. In Germany, decisions on product adoption and subsequent reimbursement are expected to be on a regional or even blood center-by-blood center basis, but depend on both local and centralized regulatory approval from the Paul Ehrlich Institute, or PEI. Product characteristics relating to platelet dose of INTERCEPT-treated platelets that have received marketing authorization from the PEI may be incompatible with market requirements. While INTERCEPT-treated platelets and plasma have received in-country regulatory approval and reimbursement rates have been established in France, adoption throughout France has been delayed. The Japanese Red Cross controls a significant majority of blood transfusions in Japan and exerts a high degree of influence on the adoption and use of blood safety measures in Japan. The Japanese Red Cross has been reviewing preclinical and clinical data on pathogen inactivation of blood over a number of years and has yet to make a formal determination to adopt the INTERCEPT Blood System or any other competitive approach. If approvals are not obtained to market our products in these countries, or if the products are not adopted in these countries, our potential product revenue will be significantly impaired.

Our products, 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 regulatory authorities to grant marketing approval, we will be unable to commercialize our products and generate revenue. Our red blood cell system requires extensive additional testing and development.

Our products, both those sold commercially and those under development are subject to extensive and rigorous regulation by local, state and federal regulatory authorities in the United States and by foreign regulatory bodies. These regulations are wide-ranging and govern, among other things:

development;

Table of Contents

testing;

manufacturing;

labeling;

storage;

pre-market clearance or approval;

sales and distribution;

use standards and documentation;

post-launch surveillance;

quality;

advertising and promotion; and

reimbursement.

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

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

The FDA and other agencies in the United States and in foreign countries impose substantial requirements upon the manufacturing and marketing of products such as those we are developing. The process of obtaining FDA and other required regulatory approvals is long, expensive and uncertain, and typically takes a number of years, depending on the type, complexity and novelty of the product. In addition, we may be required to obtain approval from the Food and Drug Branch of the California State Department of Health for any product manufactured by us in California, including for clinical trial use. We may encounter significant delays or excessive costs in our efforts to secure necessary approvals or licenses, or we may not be successful at all.

We have received CE mark approval for the INTERCEPT platelet and plasma systems, which, is sufficient to allow us to sell our platelet and plasma systems in the European Union and allows us to sell the INTERCEPT platelet and plasma systems under import licenses to many countries outside of the European Union. However, in Germany and France, additional regulatory approval of the blood products treated by our products has been required before those blood products can be transfused into a human patient. We have obtained those additional regulatory approvals from the Paul Ehrlich Institute in Germany for two German blood centers, and the Agence Française de Sécurité Sanitaire Des Produits de Santé, or Afssaps, in France. We also understand that certain other countries, including Australia and Japan will require similar approvals of INTERCEPT-treated blood products. We have not received regulatory approval for commercial sale of the INTERCEPT Blood System in the United States and many other countries around the world. Our products are in various stages of development and regulatory approval, and we face the risks of failure inherent in developing medical devices and biotechnology products based on new technologies. Our products must satisfy rigorous standards of safety and efficacy and we must adhere to quality standards regarding manufacturing and customer-facing business processes before the FDA and international regulatory authorities can approve them for commercial use. We must provide the FDA and international regulatory authorities with preclinical, clinical and manufacturing data demonstrating that our products are safe, effective and in compliance with government regulations before the products can be approved for commercial sale.

Before the FDA determines whether to approve the INTERCEPT Blood System products, we expect our approval applications to be reviewed by the Blood Products Advisory Committee, or BPAC. BPAC would then make a recommendation to the FDA for, or against, approval. Even if BPAC were to recommend approval of one or more of our products, the FDA would not necessarily approve those products. If BPAC were to recommend against approval of one or more of our products, it is likely that the FDA would not approve those products. If our product candidates receive approval for commercial sale, their marketing and manufacturing will be subject to continuing FDA and other regulatory requirements, such as requirements to comply with Good Manufacturing Practice and ISO 13485, a quality management system standard applicable to the products we sell in Europe. The failure to comply with these requirements on an ongoing basis could result in delaying or precluding commercialization efforts in certain geographies, including the United States, and could result

Table of Contents

in an enforcement action, which could harm our business. The current manufacturing sites we rely upon for producing the platelet and plasma system products for international distribution and sale are not FDA-qualified facilities. Regulatory authorities may also require post-marketing testing, which can involve significant expense. Governments or regulatory authorities may impose new regulations or other changes or we may discover that we are subject to additional regulations that could further delay or preclude regulatory approval and subsequent adoption of our potential products. We cannot predict the impact of adverse governmental regulation that might arise from future legislative or administrative action.

Distribution of our products in markets outside the United States also is subject to extensive government regulation. These regulations vary by country, including the requirements for approvals or clearance to market, the time required for regulatory review and the sanctions imposed for violations. In some countries, we may be required to register as a medical device manufacturer, even though we outsource manufacturing to third parties. In addition to CE mark documentation, countries outside the European Union may require clinical data submissions, registration packages, import licenses or other documentation with which we have little or no familiarity.

In countries that do not recognize the CE mark as being adequate for commercializing the INTERCEPT Blood System, we may also be required to conduct additional testing in order to obtain regulatory approval. The level of additional product testing varies by country, but could be expensive or take a long time to complete. Failure to obtain necessary regulatory approvals or any other failure to comply with regulatory requirements could result in lost product revenue and profitability. In addition, regulatory agencies are able to withdraw or suspend previously issued approvals.

We completed our Phase III clinical trial of the platelet system in the United States in March 2001 and submitted data from this trial, along with several other modules of our pre-market approval application, to the FDA. Based on discussions with the FDA, we performed an additional blinded analysis of the clinical trial data, under the direction of an independent expert physician panel, to determine if apparent differences between treatment groups in the category of pulmonary adverse events reported in the study were attributable to inconsistent event reporting. The reassessment of primary patient records by the expert physician panel showed no statistically significant differences between groups. This reassessment differed from the earlier analysis of adverse events that was based on clinical trial case report forms, which showed statistically significant differences in specific pulmonary events. We submitted a report of the analysis to the FDA for review. We have had several interactions with the FDA subsequent to the final report submission. We understand that our reassessment of our previously completed Phase III clinical trial data will not be sufficient to address the apparent differences observed in that trial between the treatment groups in the category of pulmonary adverse events. Contrary to prior interactions with the FDA, in which we understood that the FDA might consider non-randomized, un-blinded, and non-controlled data gathered from monitoring patients transfused with INTERCEPT-treated platelets in the context of standard medical practice in Europe in conjunction with data from the previously completed Phase III trials, we now understand that a Europe-based study is not likely to answer all the questions the FDA has posed, while adhering to study logistics and protocols that the agency is recommending. The FDA has clarified in recent teleconferences with us the nature of the data needed to address the FDA s open clinical questions. From these recent interactions with FDA, we have determined that the most feasible pathway to gain regulatory approval of the platelet system in the U.S. would be to conduct a second randomized Phase III clinical trial using U.S. sites for which we submitted a proposal for a clinical trial protocol to the FDA in July 2009. There is no assurance that we will be able to reach agreement with the FDA on the data to be collected and endpoints to be monitored, that transfusing physicians with patients in the study will adhere to post diagnostic medical procedures that may be mandated in the agreed upon study protocol, that we will be able to collect such data, or that the FDA will find such data adequate to answer questions that the FDA has concerning the safety and efficacy of the platelet system. We may conclude that the cost of gathering such data or the time required to do so is too great or that gathering such data is not logistically achievable. We understand that the FDA will likely require a larger, randomized, blinded clinical trial than we and Baxter completed in 2001 before a product license application can be finalized and the platelet system considered for approval in the United States. The dimensions of such a Phase III trial may be prohibitively large due either to prospective cost, logistics or both. We have no plans to initiate such a trial unless adequate funding from partners or government agencies is secured. The additional Phase III clinical trial will need to be completed and data submitted to the FDA before we can complete our regulatory submission. In addition, the FDA will require that certain manufacturing and distribution facilities operated by the third parties with whom we contract to produce the platelet system be compliant with Good Manufacturing Practice, or GMP, regulations and Quality System Regulations, or QSR, before the FDA would consider the applications for approval.

We have completed Phase IIIa, Phase IIIb and Phase IIIc clinical trials of the plasma system, in the United States, reports for which were filed with the FDA during 2005. We obtained a CE mark approval in Europe of the plasma system in November 2006 and final French approval in May 2007 based on data from those trials of the plasma system. We have not submitted any applications for regulatory approval of the plasma system in the United States or any other regions other than Europe. In some countries, including several in Europe, we or our customers may be required to perform additional clinical studies or submit manufacturing and marketing applications in order to obtain regulatory approval.

We have conducted many toxicology studies to demonstrate the INTERCEPT platelet and plasma systems safety, and we have conducted and plan to conduct toxicology studies for the INTERCEPT red blood cell system throughout the product development process. At any time, the FDA and other regulatory authorities may require further toxicology or other studies to further demonstrate our products safety, which could

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

Table of Contents

benefits, which may be less compelling in light of improved safety in the blood supply. We expect the FDA to require us to demonstrate a very low level of potential side effects in non-randomized data from standard medical practice in Europe or in additional randomized Phase III trials of the platelet system we may conduct in the United States or elsewhere. Trials of this type may be too large and expensive to be practical.

As a result of the termination of Phase III clinical trials of our red blood cell system due to the detection of antibody reactivity to red blood cells treated with the INTERCEPT red blood cell system in one patient in the chronic arm of the trials, we have been conducting additional research activities on our red blood cell system to determine if the system can be reconfigured to reduce the potential for antibody reactivity to treated red blood cells. Based upon an internal evaluation of the results from these additional research activities and after consulting with regulatory authorities, we initiated a new Phase I trial in 2006 in the United States using a modified red blood cell system before potentially progressing to later-stage clinical trials. We utilized a manual processing system in the Phase I trial conducted in 2006, which system is not in a commercially feasible form. Results of the Phase I trial suggested that the modified process in combination with a conventional additive solution results in conditions not suitable for long-term storage of red blood cells treated with the INTERCEPT system, adversely impacting their lifespan. Consequently, we conducted *in vitro* and *in vivo* studies and initiated a new Phase I clinical trial in the fourth quarter of 2008 to test further modifications to the red blood cell system. A number of trial design, process and product design issues that could impact efficacy, regulatory approval and market acceptance will need to be resolved prior to the initiation of further clinical trials. While those clinical trials are being conducted and further clinical work is planned, including determining the appropriate design of additional Phase I, subsequent Phase II clinical trials, if deemed necessary, and Phase III clinical trials, we will need to develop a commercially feasible red blood cell system. In the aggregate, these activities will require significant funding beyond our current resources. We will not commence the next phase of activities until we have secured adequate funds. We expect that we can continue some level of program advancement with minimal spending, by leveraging grant funding from the Department of Defense and existing and potential partners. A delay in completing such activities could result in a delay in the timely progression to later stage trials. If we are unsuccessful in advancing a modified red blood cell system through clinical trials, resolving process and product design issues or in obtaining subsequent regulatory approvals and acceptable reimbursement rates, we may never realize a return on our development expenses incurred to date in the red blood cell system program.

Regulatory delays can also materially impact our product development costs. If we experience delays in testing, conducting trials or approvals, our product development costs will increase. For example, we may need to repeat clinical trials to address regulatory or clinical questions. We may also need to retain third-party investigators and organizations in an attempt to facilitate regulatory review and approval. If the delays are significant, our financial results and the commercial prospects for our products will be harmed, and our ability to become profitable will be delayed.

Regulatory agencies may limit the uses, or indications, for which any of our products are approved. For example, we believe that the INTERCEPT Blood System products will be able to claim the inactivation of particular pathogens only to the extent we have laboratory data to support such claims. After regulatory approval for the initial indications, further studies may be necessary to gain approval for the use of the product for additional indications.

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

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

Since February 2006, we have been fully responsible for sales, marketing, distribution and regulatory support of the INTERCEPT Blood System worldwide, except in those Asian territories covered by our agreements with BioOne for the platelet and plasma systems. We no longer rely upon Baxter or Fenwal for these activities. If we fail in our efforts to develop or maintain such internal competencies or establish acceptable relationships with third parties on a timely basis, our attempts to commercialize the INTERCEPT Blood System may be irreparably harmed.

We operate a small organization, headquartered in the Netherlands, dedicated primarily to selling and marketing the platelet and plasma systems in geographies where the INTERCEPT platelet and plasma systems are approved. We will need to maintain and continue to increase our competence in a number of functions, including sales, marketing, regulatory, inventory and logistics, customer service, credit and collections,

risk management, and quality assurance systems. Many of these competencies require compliance with EU and local standards and practices, with which we have limited experience.

We have entered into contracts, generally on a geographically exclusive basis, with distributors in countries where we have limited abilities to commercialize our pathogen inactivation products directly. We have entered into national distribution agreements in Spain, Italy, Portugal and Chile, Russia, Poland, Greece, Kuwait and Qatar. We rely on these distributors to market and sell the INTERCEPT Blood

Table of Contents

System, obtain any necessary in-country regulatory approvals beyond the CE marks, provide customer support, maintain inventories, and adhere to our quality system in all material respects, among other activities. While our contracts generally require distributors to exercise diligence, these distributors may fail to commercialize the INTERCEPT Blood System in their respective territories or may do so on terms which are not economic to us. They may fail to sell product inventory they have purchased from us to end customers. Initial purchases of UVA illuminators or disposable kits by these third parties may not lead to follow-on purchases of disposable platelet and plasma system kits. We have limited visibility into the identity and requirements of blood banking customers these distributors may have. These third parties may irreparably harm relationships with local existing and prospective customers and our standing with the blood banking community in general. We may have little recourse, short of termination, in the event that a distributor fails to execute according to our expectations.

We must develop regulatory capabilities for clinical-stage and post-approval trials involving the INTERCEPT Blood System globally.

Failure to develop regulatory capabilities in support of international commercialization of the INTERCEPT Blood System may slow the rate of adoption of the platelet and plasma systems. We may not have adequate internal resources and capabilities to manage clinical-stage and post-approval trials and to respond appropriately to possible customer complaints or required regulatory reporting of adverse events arising from the use of the platelet and plasma systems. We will need to increase our regulatory and trial management resources or contract with independent regulatory consultants, which we may be unable to do on a timely basis. Adding regulatory and trial management resources will result in increased costs and may potentially delay regulatory filings. Delays or inabilities to complete regulatory filings and obtain approvals will also delay or prevent us from being able to recognize sales of our products and attaining profitability.

We rely on third parties for manufacturing and supplying components of our platelet and plasma systems. We are dependent on Fenwal to manufacture disposable kits for the platelet and plasma systems through the end of 2013. Over a longer period, we may need to identify, select and qualify alternate third party sources of supply for the INTERCEPT Blood System, including the INTERCEPT red blood cell system if our agreement with Fenwal cannot be extended or broadened.

In March 2007 Baxter sold its Transfusion Therapies business, the unit of Baxter that has performed many of the manufacturing and supply chain activities related to our relationship with Baxter, to a new company, Fenwal, Inc. Fenwal has agreed, through an agreement signed with us in December 2008, to manufacture disposable kits for the platelet and plasma systems for us through the end of 2013. However, Fenwal may fail to manufacture an adequate supply of disposable kits and Intersol additive solution or to do so on a cost effective basis, which would subject us to loss of revenue and reduced contribution margin. In addition, because the components of the INTERCEPT Blood System are manufactured and assembled at multiple facilities owned by both Fenwal and Baxter leading up to final assembly, Fenwal and Baxter will remain interdependent with respect to the INTERCEPT Blood System supply chain. Fenwal and Baxter may fail to coordinate or meet interdependent supply chain obligations, leading to a failure to manufacture an adequate supply of components or devices of the INTERCEPT Blood System, which would also subject us to the risks described below. We contract with independent suppliers, including NOVA Biomedical Corporation, or NOVA, for the manufacture of UVA illuminators and certain components of the INTERCEPT Blood System which are manufactured or assembled at facilities not owned by Fenwal or Baxter. 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. We understand that certain manufacturing operations affecting our products will be transferred from a Baxter facility to a Fenwal facility in the near-term. If this transfer involves unexpected production delays or other issues our supply chain may be adversely affected. If we conclude that supply of the INTERCEPT Blood System or components from Fenwal and others is uncertain, we may choose to build and maintain inventories of raw materials, work-in-process components, or finished goods, which would consume capital resources and may cause our supply chain to be less efficient. Future supply of illuminators is limited to availability of components, some of which are in short supply or are no longer manufactured. We may be required to redesign the illuminator used in the platelet and plasma systems to manage the risk of obsolete components. Such redesign may be expensive and lead to regulatory delays in obtaining approvals to market the redesigned device.

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

We will also be dependent on Baxter and Fenwal to transfer know-how relevant to the INTERCEPT Blood System; however, certain of Fenwal s materials, manufacturing processes and methods are proprietary to Fenwal or Baxter. We may be unable to establish alternate sources of supply to Fenwal, NOVA, or other suppliers without having to redesign certain elements of the platelet and plasma systems. Such redesign may be costly, time consuming and require further regulatory review, which would delay our ability to commercialize the platelet and plasma systems. Fenwal is not obligated to provide support for development and testing of improvements or changes we may make to the INTERCEPT Blood System. We may be unable to identify, select, and qualify such manufacturers or those third parties able to provide support for development and testing activities on a timely basis or enter into contracts with them on reasonable terms, if at all. We have recently contracted directly with third-party suppliers of certain components of the platelet and plasma systems which Fenwal had used historically in an effort to make the

supply of components more reliable, though doing so will increase our investment in raw material and work-in-process inventories and subject us to minimum purchase requirements. Raw material and component suppliers may not meet quality specifications we have set, which would cause a disruption in supply and may lead to lost sales and irreparable damage to our customer relationships. Moreover, the inclusion of components manufactured by new suppliers could require us to seek new or updated approvals from regulatory authorities, which could result in delays in product delivery. We may not receive any such required regulatory approvals.

Table of Contents

Our potential remedies against Fenwal or other manufacturers may be inadequate in assuring that these manufacturing partners meet their contractual obligations.

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

The platelet system is not compatible with some commercial platelet collection methods and platforms and platelet storage solutions.

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

Our system for platelets is designed to work with platelets collected using platelet storage solutions, called Intersol and SSP+, and for platelets suspended in plasma. For platelets collected by apheresis, the INTERCEPT platelet system is most compatible with Fenwal s apheresis platelet collection system, because it facilitates the use of Intersol. For platelets prepared from whole blood, our platelet system is most compatible with the buffy coat collection method, again because this method facilitates the use of Intersol as an additive solution to the platelet concentrate. As a result, we have conducted most of our clinical studies using either Fenwal s equipment or buffy coat platelets. We have received approval for the use of the platelet system in combination with other collection and preparation platforms, with SSP+ and with platelets suspended in plasma. Fenwal may be required to obtain separate regulatory approval for Intersol in the United States and in countries which do not recognize CE mark approval before customers would be permitted to use Intersol with the INTERCEPT Blood System in those countries.

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

Fenwal has committed to us to make Intersol collection and pooling products and conversion kits available to customers. However, Fenwal may not make such products or its apheresis collection system available for sale in certain countries and has elected to discontinue sales efforts for its apheresis collection system in Japan.

Other manufacturers supplying blood component collection platforms to the market may resist our efforts to make the INTERCEPT Blood System compatible with their platforms. Attaining compatibility with collection platforms manufactured by others may require adaptations to either the INTERCEPT Blood System or to the collection platforms, which may be difficult to engineer, expensive to implement and test, require additional clinical trials, cause delays in regulatory approval and/or be commercially unattractive to pursue. These development activities will increase our costs significantly, and may not be successful. Market acceptance of the INTERCEPT Blood System may be delayed until the system receives regulatory approval for use on such other equipment, if required.

Because the INTERCEPT Blood System products have not been manufactured on more than a limited commercial scale, we face manufacturing uncertainties that could limit their commercialization. If our third-party manufacturers fail to produce our products or compounds satisfactorily, at acceptable cost and in sufficient quantities, we may incur delays, shortfalls and additional expenses, which may in turn result in permanent harm to our customer relations.

The INTERCEPT Blood System products, including many of the components, have been manufactured on a commercial scale on only a limited basis. Fenwal relies on third parties, including Baxter, to manufacture and assemble some of the platelet and plasma system components, many of which are customized and have not been manufactured on a commercial scale. Fenwal has produced some pathogen inactivation systems in modest commercial quantities, but may not be able to manufacture and assemble other systems or in larger quantities, or do so economically. Because of low sales volumes and other reasons, Fenwal s costs to manufacture commercial components for the platelet and plasma systems have

been greater than we previously anticipated and may continue to rise. It is uncertain what effect Fenwal s independence from Baxter will have on its cost structure or on transfer prices from Baxter to Fenwal and costs ultimately passed on to us. These issues may result in reducing our potential gross profit margin from platelet and plasma system sales.

We are in the early stages of commercializing the INTERCEPT Blood System and may not accurately forecast demand for the INTERCEPT Blood System. We have contracted with third parties to supply platelet and plasma systems and components to meet forecasted demand. However, such forecasts may prove to be either higher or lower than actual commercial demand. As a result, we may carry excess work-in-process or finished goods inventory, which would consume capital resources and may become obsolete, or be

Table of Contents

inadequate to meet customer demand. If Fenwal or third-party manufacturers fail to produce our products or Intersol products satisfactorily, at acceptable costs and in sufficient quantities, we may incur delays, shortfalls and additional expenses, which may in turn result in permanent harm to our customer relations.

Fenwal and we purchase certain key components of the INTERCEPT Blood System from a limited number of suppliers. It would be expensive and time-consuming to establish additional or replacement suppliers for these components. Some components of the INTERCEPT Blood System, including components of the UVA illuminator device, are no longer manufactured, which will require us to identify and qualify replacement components and may require that we conduct additional studies, which could include clinical trials, to demonstrate equivalency or validate any required design or component changes. If Fenwal or we are unable to identify and supply replacement components, we may be unable to supply products to our customers. If we were required to redesign the products, our development costs would increase, and our programs and commercialization efforts could be delayed significantly.

We use third-party manufacturers to produce commercial quantities of the chemical compounds used in our products. We currently do not have any third-party manufacturing agreements in place for commercial production of compounds used in our red blood cell system, which is in early stages of clinical development. Any new or additional commercial manufacturer will need to develop new methods and processes to manufacture these compounds on a commercial scale and demonstrate to us, the FDA and foreign regulatory authorities that its commercial scale manufacturing processes comply with government regulations and that its compounds are equivalent to originally licensed compounds in order for us to maintain commercial licensure of our products. It may be difficult or impossible to economically manufacture our products on a commercial scale.

Our platelet and plasma system disposables have received regulatory approval for two-year shelf lives. We and our distributors may be unable to ship product to customers prior to the expiration of product shelf life, which would require that we destroy or consume the outdated inventory in product demonstration activities Product expiration may in turn lead to elevated product demonstration costs or reduced gross margins.

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

The system disposables and instruments of our red blood cell system that we used in our preclinical studies and clinical trials in the United States historically and those we are now using in the current Phase I red blood cell trial are prototypes of systems to be used in the final products. As a result, we expect regulatory authorities will require us to perform additional preclinical and clinical studies using the commercial versions of the systems to demonstrate the acceptability of the commercial configuration and the equivalence of the prototypes and the commercial products, which may increase our expenses and delay the commercialization of our products. We have tested additional modifications of the red blood cell system to improve the lifespan of treated red blood cells. *In vitro* and *in vivo* studies of such modifications to the red blood cell system may not be indicative of red blood cell lifespan in humans. Additional early-stage trials will be necessary to determine whether our modifications, including these new approaches, may lead to a product with acceptable commercial characteristics. We also are assessing whether such modifications would be acceptable clinically, economically and/or operationally to potential customers. We may determine that although the modified red blood cell system may overcome technical issues encountered in the past, it may not be commercially feasible from potential customers perspectives. If we fail to develop commercial versions of the INTERCEPT red blood cell system on schedule, our potential revenue would be delayed or diminished and our potential competitors may be able to bring products to market before we do.

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

Fenwal is not obligated to provide manufacturing services related to the red blood cell system. It will be time-consuming for other manufacturers to develop the capability to manufacture the INTERCEPT Blood System products and blood component storage solutions economically and to gain regulatory approval to do so for commercial use. We may be unable to identify and contract with manufacturers that can make our products cost-effectively, which would delay our efforts to commercialize the red blood cell system, even if we successfully complete clinical development.

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

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

Table of Contents

BioOne has made little progress to date in commercializing the platelet and plasma systems in Asian territories. Because we only have a minority investment interest in BioOne, we lack the ability to significantly influence BioOne, and are dependent on BioOne s performance to realize milestone and royalty revenue from commercialization of our platelet and plasma systems in those countries. In Japan, regulatory authorities may require our platelet and plasma systems to be widely adopted commercially in Europe or approved by the FDA before the platelet and plasma systems are considered for approval in Japan, which would delay or prevent BioOne from achieving significant product revenue. In July 2007, BioOne raised limited additional capital in order to fund curtailed operations. At these reduced operating levels, we expect that BioOne s abilities to commercialize the platelet and plasma systems in its Asian territories will be compromised. We understand that BioOne may need to raise additional capital to continue its operations beyond the near term. There is no assurance that BioOne will be able to attract additional required capital in the future to successfully commercialize those products licensed from Fenwal and us. Even if BioOne fails to commercialize the INTERCEPT Blood System in its territories, we may be unable to assert contractual rights to regain commercialization rights on satisfactory terms, if at all.

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

We expect our products to encounter significant competition. The INTERCEPT Blood System products compete with other approaches to blood safety currently in use, and may compete with future products that may be developed by others. Our success will depend in part on our ability to respond quickly to medical and technological changes brought about by the development and introduction of new products. Product development is risky and uncertain, and we cannot assure you that we will develop our products successfully. Competitors products or technologies may make our products obsolete or non-competitive before we are able to generate any significant revenue. In addition, competitors or potential competitors may have substantially greater financial and other resources than we have. They may also have greater experience in preclinical testing, human clinical trials and other regulatory approval procedures.

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

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. Continued delays in commercialization of our platelet and plasma systems in France and Germany may impact our ability to compete with bacterial testing for platelets. Other competitors are developing rapid, point-of-care bacterial tests, synthetic blood product substitutes and products to stimulate the growth of platelets. Development and commercialization of any of these or other related technologies could limit the potential market for our products.

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

We are exposed to potential liability risks inherent in the testing and marketing of medical devices and pharmaceutical products. We may be liable if any of our products cause injury, illness or death. Although we will have completed rigorous preclinical and clinical safety testing prior to marketing our products, there may be harmful effects caused by our products that we are unable to identify in preclinical or clinical testing. In particular, unforeseen, rare reactions or adverse side effects related to long-term use of our products may not be observed until the products are in widespread commercial use. Because of the limited duration and number of patients receiving blood components treated with the INTERCEPT Blood System products in clinical trials, it is possible that harmful effects of our products not observed in clinical and preclinical testing could be discovered after a marketing approval has been received. For example, in cases where we have obtained regulatory approval for our products, we have demonstrated pathogen inactivation to specified levels based on well-established tests. However, there is no way to determine, after treatment by our products, whether our products have completely inactivated all of the pathogens that may be present in blood components. There is also no way to determine whether any residual amount of a pathogen remains in the blood component treated by our products and there is no way to exclude that such residual amount would be enough to cause disease in the transfused patient. For ethical

reasons, we cannot conduct human testing to determine whether an individual who receives a transfusion of a blood component containing a pathogen that was inactivated using the INTERCEPT Blood System might show positive results if tested for an antibody against that pathogen. While we believe, based on the clinical experience of our scientists, that the level of inactivated pathogens would likely be too small to induce a detectable antibody response in diagnostic tests, we cannot exclude that a transfused patient might show positive results if tested for an antibody against that pathogen. We could be subject to a claim from a patient that tests positive, even though that patient did not contract a disease. Later discovery of problems with a product, manufacturer or facility may result in additional restrictions on the product or manufacturer, including withdrawal of the product from the market. We are subject to risks and costs of product recall, which include not only potential out-of-pocket costs, but also potential interruption to our supply chain. In such an event, our customer relations would be harmed and we would incur unforeseen losses.

Table of Contents

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.

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

Virtually all of our research and development activities and the significant majority of our general and administrative activities are performed in or managed from our facilities in Concord, California, which are within an active earthquake fault zone. Should a severe earthquake occur, we might be unable to occupy our facilities or conduct research and development and general and administrative activities in support of our business and products until such time as our facilities could be repaired and made operational. Our property and casualty and business interruption insurance in general does not cover losses caused by earthquakes. While we have taken certain measures to protect our scientific, technological and commercial assets, a lengthy or costly disruption due to an earthquake would have a material adverse effect on us. We have also taken measures to limit damage that may occur from the loss of computerized data due to power outage, system or component failure, or corruption of data files. However, we may lose critical computerized data, which may be difficult or impossible to recreate, which may harm our business. We may be unable to make timely filings with regulatory agencies in the event of catastrophic failure of our data storage and backup systems, which may subject us to fines or adverse consequences, up to and including loss of our abilities to conduct business.

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

In November 2007, we spun-off our immunotherapy business to Anza. In exchange for contributed tangible and intangible assets, we received preferred stock representing an equity interest of approximately 20% of Anza s preferred equity. We were informed that Anza had ceased operations by March 31, 2009. The terms of sale provided Anza a right to redeem up to 1,000,000 of such shares for a nominal amount upon the failure to occur of certain circumstances relating to possible research grant funding from the DoD. We were advised that based upon such provision, Anza may seek to redeem 1,000,000 shares held by us. If such shares are redeemed by Anza, we would own fewer shares of Anza s preferred stock, reducing our preferred equity interest to approximately 16.0% of Anza s outstanding preferred equity. There is no assurance that the equity will have monetary value at such time we are allowed to sell it or that we will receive any proceeds upon liquidation or sale of Anza. We are evaluating whether such clause is applicable in the present circumstances.

We may not be able to protect our intellectual property or operate our business without infringing intellectual property rights of others.

Our commercial success will depend, in part, on obtaining and maintaining patent protection on our products and successfully defending our products against third-party challenges. Our technology will be protected from unauthorized use only to the extent that it is covered by valid and enforceable patents or effectively maintained as trade secrets. As a result, our success depends in part on our ability to:

obtain patents;

protect trade secrets;

operate without infringing upon the proprietary rights of others; and

prevent others from infringing on our proprietary rights.

We cannot be certain that our patents or patents that we license from others will be enforceable and afford protection against competitors. Our patents or patent applications, if issued, may be challenged, invalidated or circumvented. Our patent rights may not provide us with proprietary protection or competitive advantages against competitors with similar technologies. Others may independently develop technologies similar to ours or independently duplicate our technologies. For example, a United States patent issued to a third-party covers methods to remove psoralen compounds from blood products. We have reviewed the patent and believe there exist substantial questions concerning its validity. We cannot be certain, however, that a court would hold the patent to be invalid or not infringed by our platelet or plasma systems, if and when those products are sold in the United States. Our key blood safety patents generally expire at various dates between 2013 and 2018. Recent patent applications will, if granted, result in patents with later expiration dates. In addition, we have a license from Fenwal to United States and foreign patents relating to the INTERCEPT Blood System, which expire from 2010 to 2022. 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.

We may face litigation to defend against claims of infringement, assert claims of infringement, enforce our patents, protect our trade secrets or know-how or determine the scope and validity of others proprietary rights. Patent litigation is costly. In addition, we may require interference proceedings before the United States Patent and Trademark Office to determine the priority of inventions relating to our patent applications. Litigation or interference proceedings could be expensive and time consuming, and we could be unsuccessful in our efforts to enforce our intellectual property rights.

We may rely, in certain circumstances, on trade secrets to protect our technology. However, trade secrets are difficult to protect. We protect our proprietary technology and processes, in part, by confidentiality agreements with employees and certain contractors. These agreements may be breached and we may not have adequate remedies for any breach or our trade secrets may otherwise become known or be independently discovered by competitors. To the extent that our employees, consultants or contractors use intellectual property owned by others, disputes also may arise as to the rights in related or resulting know-how and inventions.

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

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

Product sales of our blood safety products are typically made in Europe and generally are invoiced to customers in Euros. In addition, we purchase finished disposable kits for our platelet and plasma systems and incur operating expenses in Euros and other foreign currencies. Our exposure to foreign exchange rate volatility is a direct result of our product sales, cash collection and expenses to support our international operations. Foreign exchange rate fluctuations are recorded as a component of interest (expense) and other, net on our condensed consolidated statements of operations. Significant fluctuations in the volatility of foreign currencies relative to the United States dollar may materially affect our results of operations. Currently we do not have any near-term plans to enter into a formal hedging program to mitigate the effects of foreign currency volatility.

The market price of our stock may be highly volatile.

The market prices for our securities and those of other emerging medical device and biotechnology companies have been, and may continue to be, volatile. For example, during the period from January 1, 2007 to June 30, 2009, the sale price of our common stock as quoted on the Nasdaq Global Market fluctuated within a range from a low of $0.55 to a high of $10.29. Announcements may have a significant impact on the market price of our common stock. Such announcements may include:

- decisions regarding reimbursement and commercial adoption by customers, national blood services or governmental bodies;
- biological or medical discoveries;
- technological innovations discovered or new commercial services offered by us or our competitors;
- developments concerning proprietary rights, including patents and litigation matters;

regulatory developments in both the United States and foreign countries;

status of development partnerships;

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

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

public concern as to the safety of new technologies;

general market conditions;

comments made by analysts, including changes in analysts estimates of our financial performance; and

quarterly fluctuations in our revenue and financial results.

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

Our stock price may not meet the minimum bid price for continued listing on The NASDAQ Global Market. Our ability to publicly or privately sell equity securities and the liquidity of our common stock could be adversely affected if we are delisted from The NASDAQ Global Market or if we are unable to transfer our listing to another stock market.

Our common stock is currently listed on The NASDAQ Global Market. The NASDAQ Stock Market LLC, or NASDAQ, has minimum requirements that a company must meet in order to remain listed on The NASDAQ Global Market. These requirements include maintaining a minimum closing bid price of $1.00 per share. If our common stock does not maintain a minimum closing bid price of $1.00 per share, we may be subject to delisting by NASDAQ for failure to meet the continued listing requirements. Delisting from The NASDAQ Global Market could adversely affect our ability to raise additional financing through the public or private sale of equity securities, would

Table of Contents

significantly affect the ability of investors to trade our securities and would negatively affect the value and liquidity of our common stock. Delisting could also have other negative results, including the potential loss of confidence by employees, the loss of investor interest and fewer business development opportunities.

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

Section 404 of the Sarbanes-Oxley Act of 2002 requires annual management assessments of the effectiveness of our internal controls over financial reporting and a report by our independent registered public accountants attesting to the effectiveness of our internal controls. These requirements extend to the operations of our subsidiary in Europe. If we fail to maintain the adequacy of our internal controls over financial reporting, as such standards are modified, supplemented or amended from time to time, we may not be able to ensure that we can conclude in future periods that we have effective internal controls over financial reporting in accordance with Section 404 of the Sarbanes-Oxley Act of 2002. If we cannot favorably assess, or our independent registered public accountants are unable to provide an unqualified attestation report on the effectiveness of our internal controls over financial reporting, investor confidence in the reliability of our financial reports may be adversely affected, which could have a material adverse effect on our stock price.

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

None.

ITEM 3. DEFAULTS UPON SENIOR SECURITIES

None.

ITEM 4. SUBMISSION OF MATTERS TO A VOTE OF SECURITY HOLDERS

The following proposals were submitted to a vote of, and adopted by our stockholders at the 2009 Annual Meeting of Stockholders on June 1, 2009, or the Annual Meeting:

1. Stockholders approved the proposal to elect two (2) directors, each for a three-year term. The vote tabulation was as follows:

Director	Votes For	Votes Withheld
B.J. Cassin	28,048,876	991,706
William R. Rohn	28,079,521	961,061

Timothy Anderson, Claes Glassell, Bruce C. Cozadd, Gail Schulze, and Laurence M. Corash continued to serve as directors after the Annual Meeting.

2. Stockholders approved the proposal to ratify the selection of Ernst & Young LLP as the Company s independent registered public accounting firm to perform the audit of Cerus Corporation s financial statements for fiscal year ending December 31, 2009 by a vote of 28,121,820 for and 814,493 against, with 104,268 abstentions.

ITEM 5. OTHER INFORMATION

None.

ITEM 6. EXHIBITS

3.1.1(1)	Restated Certificate of Incorporation of Cerus Corporation, as amended to date.
3.2(2)	Amended and Restated Bylaws of Cerus.
4.2(3)	Specimen Stock Certificate.
4.3	Stockholder Rights Plan, dated November 3, 1999 and as amended as of August 6, 2001, by and between Cerus and Wells Fargo Bank MN, N.A. (formerly Norwest Bank Minnesota, N.A.).
10.41(4)(6)	Form of Indemnity Agreement entered into between Cerus and each of its directors and executive officers, adopted April 24, 2009.
10.42(6)	Employment Letter for Kevin D. Green, dated May 1, 2009.
10.43(5)(6)	Form of Severance Benefits Agreement.

Table of Contents

31.1	Certification of the Chief Executive Officer of Cerus pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.
31.2	Certification of the Vice President, Finance and Chief Accounting Officer of Cerus pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.
32.1(*)	Certification of the Chief Executive Officer and Vice President, Finance and Chief Accounting Officer pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.

(1) Incorporated by reference to Cerus Current Report on Form 8-K (No. 000-21937), dated November 3, 1999.
(2) Incorporated by reference to Cerus Current Report on Form 8-K (No. 000-21937), dated April 26, 2007
(3) Incorporated by reference to Cerus Registration Statement on Form S-1 (File No. 333-11341) and amendments thereto.
(4) Incorporated by reference to Cerus Current Report on Form 8-K (No. 000-21937), dated April 28, 2009.
(5) Incorporated by reference to Cerus Current Report on Form 8-K (No. 000-21937), dated May 26, 2009.
(6) Management contract or compensatory arrangement.
Filed herewith.
(*) This certification accompanies the Form 10-Q to which it relates, is not deemed filed with the Securities and Exchange Commission, and is not incorporated by reference into any filing of Cerus Corporation under the Securities Act of 1933, as amended, or the Securities Exchange Act of 1934, as amended (whether made before or after the date of the Form 10-Q), irrespective of any general incorporation language contained in such filing.

Table of Contents

SIGNATURES

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

CERUS CORPORATION

Date: August 10, 2009

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

(on behalf of registrant and as Principal Financial Officer)

Table of Contents

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