CERUS CORP
Form 10-Q
August 07, 2015
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UNITED STATES

SECURITIES AND EXCHANGE COMMISSION

WASHINGTON, D.C. 20549

FORM 10-Q

(Mark One)

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

For the quarterly period ended June 30, 2015

or

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

For the transition period from:_____ to _____

Commission File Number 000-21937

CERUS CORPORATION

(Exact name of registrant as specified in its charter)

Delaware	**68-0262011**
(State or other jurisdiction of	**(I.R.S. Employer**
incorporation or organization)	**Identification No.)**
2550 Stanwell Dr.	
Concord, California	**94520**
(Address of principal executive offices)	**(Zip Code)**

(925) 288-6000

(Registrant s telephone number, including area code)

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

Indicate by check mark whether the registrant has submitted electronically and posted on its corporate Web site, if any, every Interactive Data File required to be submitted and posted pursuant to Rule 405 of Regulation S-T (§232.405 of this chapter) during the preceding 12 months (or for such shorter period that the registrant was required to submit and post such files). YES x NO ¨

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

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

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

As of July 24, 2015, there were 96,776,273 shares of the registrant s common stock outstanding.

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CERUS CORPORATION

QUARTERLY REPORT ON FORM 10-Q

THREE AND SIX MONTHS ENDED JUNE 30, 2015

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PART I: FINANCIAL INFORMATION

ITEM 1. FINANCIAL STATEMENTS

CERUS CORPORATION

CONDENSED CONSOLIDATED BALANCE SHEETS

(in thousands)

	June 30, 2015 (Unaudited)	December 31, 2014 [1]
ASSETS		
Current assets:		
Cash and cash equivalents	$ 35,059	$ 22,781
Short-term investments	75,854	28,513
Investment in Aduro Biotech, Inc.	12,032	
Accounts receivable	5,425	5,493
Inventories	13,681	14,956
Prepaid expenses	1,009	1,210
Other current assets	1,411	1,932
Total current assets	144,471	74,885
Non-current assets:		
Property and equipment, net	3,816	3,781
Goodwill	1,316	1,316
Intangible assets, net	1,041	1,142
Restricted cash	622	508
Other assets	140	144
Total assets	$ 151,406	$ 81,776
LIABILITIES AND STOCKHOLDERS EQUITY		
Current liabilities:		
Accounts payable	$ 5,765	$ 9,882
Accrued liabilities	6,914	8,444
Accrued taxes	2,467	
Deferred revenue current	577	376
Debt current	2,523	
Warrant liability	3,978	10,485
Total current liabilities	22,224	29,187
Non-current liabilities:		
Debt non-current	17,371	9,872

Deferred income taxes	122	115
Other non-current liabilities	1,160	1,081
Total liabilities	40,877	40,255
Commitments and contingencies		
Stockholders equity:		
Common stock	97	80
Additional paid-in capital	670,327	583,416
Accumulated other comprehensive income (loss)	7,481	(31)
Accumulated deficit	(567,376)	(541,944)
Total stockholders equity	110,529	41,521
Total liabilities and stockholders equity	$ 151,406	$ 81,776

(1) The financial information in this column was derived from audited consolidated financial statements included in the Company s 2014 Annual Report on Form 10-K.

See accompanying Notes to Unaudited Condensed Consolidated Financial Statements.

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CERUS CORPORATION

CONDENSED CONSOLIDATED STATEMENTS OF OPERATIONS

UNAUDITED

(in thousands, except per share data)

	Three Months Ended June 30,		Six Months Ended June 30,	
	2015	2014	2015	2014
Revenue	$ 8,830	$ 8,601	$ 16,522	$ 16,467
Cost of revenue	7,028	4,752	11,742	8,909
Gross profit on revenue	1,802	3,849	4,780	7,558
Operating expenses:				
Research and development	5,213	4,722	10,794	9,364
Selling, general and administrative	12,063	10,080	23,781	18,316
Amortization of intangible assets	51	51	101	101
Total operating expenses	17,327	14,853	34,676	27,781
Loss from operations	(15,525)	(11,004)	(29,896)	(20,223)
Non-operating (expense) income, net:				
(Loss) gain from revaluation of warrant liability	(2,707)	3,491	3,589	12,525
Foreign exchange gain (loss)	499	(25)	(614)	(4)
Interest expense	(301)	(34)	(556)	(84)
Other income, net	27	27	29	54
Total non-operating (expense) income, net	(2,482)	3,459	2,448	12,491
Loss before income taxes	(18,007)	(7,545)	(27,448)	(7,732)
(Benefit) provision for income taxes	(2,035)	44	(2,016)	82
Net loss	$ (15,972)	$ (7,589)	$ (25,432)	$ (7,814)
Net loss per share:				
Basic	$ (0.17)	$ (0.10)	$ (0.27)	$ (0.11)
Diluted	$ (0.17)	$ (0.16)	$ (0.30)	$ (0.28)
Weighted average shares outstanding used in the calculation of net loss per share:				
Basic	95,728	72,899	94,576	72,495
Diluted	95,728	74,517	95,682	74,927

See accompanying Notes to Unaudited Condensed Consolidated Financial Statements.

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CERUS CORPORATION

CONDENSED CONSOLIDATED STATEMENTS OF COMPREHENSIVE LOSS

UNAUDITED

(in thousands)

	Three Months Ended June 30,		Six Months Ended June 30,	
	2015	2014	2015	2014
Net loss	$ (15,972)	$ (7,589)	$ (25,432)	$ (7,814)
Other comprehensive gain (loss):				
Unrealized gains (losses) on available-for-sale investments, net of taxes of $4,552 for the three and six months ended June 30, 2015	7,493	(1)	7,512	(1)
Comprehensive loss	$ (8,479)	$ (7,590)	$ (17,920)	$ (7,815)

See accompanying Notes to Unaudited Condensed Consolidated Financial Statements.

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CERUS CORPORATION

CONDENSED CONSOLIDATED STATEMENTS OF CASH FLOWS

UNAUDITED

(in thousands)

	Six Months Ended June 30,	
	2015	**2014**
Operating activities		
Net loss	$ (25,432)	$ (7,814)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation and amortization	835	615
Stock-based compensation	3,179	2,286
Changes in revaluation of warrant liability	(3,589)	(12,525)
Non-cash interest expense	139	
Deferred income taxes	7	13
Tax benefit from other unrealized gain on available-for-sale securities	(2,085)	
Changes in operating assets and liabilities:		
Accounts receivable	69	1,647
Inventories	1,112	(1,411)
Other assets	739	(450)
Accounts payable	(4,176)	(2,625)
Accrued liabilities	(1,538)	743
Deferred revenue	256	85
Net cash used in operating activities	(30,484)	(19,436)
Investing activities		
Capital expenditures	(325)	(1,429)
Purchases of investments	(69,983)	(3,492)
Proceeds from maturities of investments	22,444	10,299
Restricted cash	(114)	
Net cash (used in) provided by investing activities	(47,978)	5,378
Financing activities		
Net proceeds from equity incentive plans and warrants	5,472	2,859
Net proceeds from public offering	75,324	3,847
Proceeds from loans, net of discount	10,000	9,848
Repayment of debt	(56)	(3,419)
Net cash provided by financing activities	90,740	13,135

Net increase (decrease) in cash and cash equivalents	12,278	(923)
Cash and cash equivalents, beginning of period	22,781	29,485
Cash and cash equivalents, end of period	$ 35,059	$ 28,562

See accompanying Notes to Unaudited Condensed Consolidated Financial Statements.

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CERUS CORPORATION

NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS

UNAUDITED

Note 1. Summary of Significant Accounting Policies

Principles of Consolidation and Basis of Presentation

The accompanying unaudited condensed consolidated financial statements include those of Cerus Corporation and its subsidiary, Cerus Europe B.V. (together with Cerus Corporation, hereinafter Cerus or the Company) after elimination of all intercompany accounts and transactions. These unaudited condensed consolidated financial statements have been prepared in accordance with accounting principles generally accepted in the United States (GAAP) for interim financial information and pursuant to the rules and regulations of the Securities and Exchange Commission (SEC). Accordingly, they do not include all of the information and footnotes required by GAAP for complete financial statements. In the opinion of management, all adjustments, consisting of normal recurring entries, considered necessary for a fair presentation have been made. Operating results for the three and six months ended June 30, 2015, are not necessarily indicative of the results that may be expected for the year ending December 31, 2015, or for any future periods.

These unaudited condensed consolidated financial statements and notes thereto should be read in conjunction with the Company s audited consolidated financial statements and notes thereto for the year ended December 31, 2014, which were included in the Company s 2014 Annual Report on Form 10-K, filed with the SEC on March 16, 2015. The accompanying condensed consolidated balance sheet as of December 31, 2014, has been derived from the Company s audited consolidated financial statements as of that date.

Use of Estimates

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

Reclassifications

Certain reclassifications have been made to prior period reported amounts to conform to the current period presentations. Previously the Company had presented the amortization of premium and accretion of any discount resulting from the purchase of fixed income securities as a component of Interest expense on the unaudited condensed consolidated statements of operations. For the three and six months ended June 30, 2014, the Company has reclassified approximately $0.1 million and $0.3 million, respectively, of the amortization of premium resulting from the purchase of fixed income securities as a component of Other income, net on the unaudited condensed consolidated statements of operations. This reclassification had no impact on net loss, total assets or total stockholders equity.

Revenue

The Company recognizes revenue in accordance with Accounting Standards Codification (ASC) Topic 605-25, *Revenue Recognition Arrangements with Multiple Deliverables,* as applicable. Revenue is recognized when (i) persuasive evidence of an agreement with the funding party exists; (ii) services have been rendered or product has been delivered; (iii) pricing is fixed or determinable; and (iv) collection is reasonably assured. The Company s source of revenues for the three and six months ended June 30, 2015 and 2014, was revenue from sales of the INTERCEPT Blood System for platelets and plasma (platelet and plasma systems).

Revenue related to sales is generally recognized when the Company fulfills its obligations for each element of an agreement. For all sales of the Company s INTERCEPT Blood System products, the Company uses a binding purchase order and signed sales contract as evidence of an arrangement. The Company sells its platelet and plasma systems 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 defective or non-conforming product. Deliverables and the units of accounting vary according to the provisions of each purchase order or sales contract. For revenue arrangements with multiple elements, the Company determines whether the delivered elements meet the criteria as separate units of accounting. Such criteria require that the deliverable have stand-alone value to the customer and that if a general right of return exists relative to the delivered item, delivery or performance of the undelivered item(s) is considered probable and substantially in the control of the Company. Once the Company determines if the deliverable meets the criteria for a separate unit of accounting, the Company must determine how the consideration should be allocated between the deliverables and how the separate units of

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accounting should be recognized as revenue. Consideration received is allocated to elements that are identified as discrete units of accounting. Because the Company has no vendor specific objective evidence or third party evidence for its products due to the Company s variability in its pricing across the regions into which it sells its products, the allocation of revenue is based on best estimated selling price for the products sold. The objective of best estimated selling price is to determine the price at which the Company would transact a sale, had the product been sold on a stand-alone basis. The Company determines best estimated selling price for its products by considering multiple factors, including, but not limited to, features and functionality of the system, geographies, type of customer, and market conditions. The Company regularly reviews best estimated selling price, as applicable.

Freight costs charged to customers are recorded as a component of revenue under ASC Topic 605, *Accounting for Shipping and Handling Fees and Costs.* Value-added-taxes (VAT) that the Company invoices to its customers and remits to governments are recorded on a net basis, which excludes such VAT from product revenue.

Research and Development Expenses

In accordance with ASC Topic 730, *Accounting for Research and Development Expenses,* research and development expenses are charged to expense when incurred. Research and development expenses include salaries and related expenses for scientific personnel, payments to consultants, supplies and chemicals used in in-house laboratories, costs of research and development facilities, depreciation of equipment and external contract research expenses, including clinical trials, preclinical safety studies, other laboratory studies, process development and product manufacturing for research use.

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

Cash Equivalents

The Company considers all highly liquid investments with original maturities of three months or less from the date of purchase to be classified as cash equivalents. These investments primarily consist of money market instruments, and are classified as available-for-sale.

Investments

Investments with original maturities of greater than three months primarily including corporate debt, U.S. government agency securities and marketable equity securities of Aduro Biotech, Inc. (Aduro), are designated as available-for-sale and classified as short-term investments, in accordance with ASC Topic 320, *Accounting for Certain Investments in Debt and Equity Securities* . Available-for-sale securities are carried at estimated fair value. Unrealized gains and losses derived by changes in the estimated fair value of available-for-sale securities are recorded in Net unrealized losses on available-for-sale securities, net of taxes on the Company s unaudited condensed consolidated statements of comprehensive loss. Realized gains (losses) from the sale of available-for-sale securities were recorded in Other income, net on the Company s unaudited condensed consolidated statements of operations. The cost of securities sold is based on the specific identification method. The Company reports the amortization of any premium and accretion of any discount resulting from the purchase of debt securities as a component of interest income.

The Company also reviews its marketable securities on a regular basis to evaluate whether any security has experienced an other-than-temporary decline in fair value. Other-than-temporary declines in market value, if any, are

recorded in Other income, net on the Company s unaudited condensed consolidated statements of operations.

Restricted Cash

The Company holds a certificate of deposit with a domestic bank for any potential decommissioning resulting from the Company s possession of radioactive material. The certificate of deposit is held to satisfy the financial surety requirements of the California Department of Health Services and is recorded in Restricted cash on the Company s unaudited condensed consolidated balance sheets. The Company also has non-US dollar denominated deposits recorded as Restricted cash in compliance with certain foreign contractual requirements.

Concentration of Credit Risk

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

Pursuant to the Company s investment policy, substantially all of the Company s cash, cash equivalents and non-equity short-term investments are maintained at major financial institutions of high credit standing. The Company monitors the financial credit worthiness of the issuers of its investments and limits the concentration in individual securities and types of investments that exist within its investment portfolio. Generally, all of the Company s investments are investment grade and carry high credit quality ratings, which is in accordance with its investment policy. At June 30, 2015, the fair value of the Company s marketable equity securities of Aduro is subject to the underlying volatility of Aduro s stock price. At June 30, 2015, the Company does not believe there is significant financial risk from non-performance by the issuers of the Company s cash equivalents.

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Concentrations of credit risk with respect to trade receivables exist. On a regular basis, including at the time of sale, the Company performs credit evaluations of its significant customers that it expects to sell to on credit terms. 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 establishes an allowance for doubtful accounts against the accounts receivable on its unaudited condensed consolidated balance sheets and records a charge on its unaudited condensed consolidated statements of operations as a component of selling, general and administrative expenses. At June 30, 2015 and December 31, 2014, the Company had not recorded any reserves for potentially uncollectible accounts.

The Company had two customers and one customer that accounted for more than 10% of the Company s outstanding trade receivables at each of June 30, 2015 and December 31, 2014, respectively. These customers cumulatively represented approximately 43% and 36% of the Company s outstanding trade receivables at June 30, 2015, and December 31, 2014, respectively. To date, the Company has not experienced collection difficulties from these customers.

Inventories

At June 30, 2015 and December 31, 2014, inventory consisted of work-in-process and finished goods only. Finished goods include INTERCEPT disposable kits, UVA illumination devices (illuminators), and certain replacement parts for the illuminators. Platelet and plasma systems disposable kits generally have a two-year shelf life from the date of manufacture. Illuminators and replacement parts do not have regulated expiration dates. Work-in-process includes certain components that are manufactured before being sold to and ultimately incorporated and assembled by Fresenius Kabi Deutschland GmbH or Fresenius, Inc. (with their affiliates, Fresenius) into the finished INTERCEPT disposable kits. The Company maintains an inventory balance based on its current sales projections, and at each reporting period, the Company evaluates whether its work-in-process inventory would be sold to Fresenius for production of finished units in order to sell to existing and prospective customers within the next twelve-month period. It is not customary for the Company s production cycle for inventory to exceed twelve months. Instead, the Company uses its best judgment to factor in lead times for the production of its work-in-process and finished units to meet the Company s forecasted demands. If actual results differ from those estimates, work-in-process inventory could potentially accumulate for periods exceeding one year. At June 30, 2015 and December 31, 2014, the Company classified its work-in-process inventory as a current asset on its unaudited condensed consolidated balance sheets based on its evaluation that the work-in-process inventory would be sold to Fresenius for finished disposable kit production within each respective subsequent twelve-month period.

Inventory is recorded at the lower of cost, determined on a first-in, first-out basis, or market value. The Company uses significant judgment to analyze and determine if the composition of its inventory is obsolete, slow-moving or unsalable and frequently reviews such determinations. The Company writes-down specifically identified unusable, obsolete, slow-moving, or known unsalable inventory that has no alternative use in the period that it is first recognized by using a number of factors including product expiration dates, open and unfulfilled orders, and sales forecasts. Any write-down of its inventory to net realizable value establishes a new cost basis and will be maintained even if certain circumstances suggest that the inventory is recoverable in subsequent periods. Costs associated with the write-down of inventory are recorded in Cost of revenue on the Company s unaudited condensed consolidated statements of operations. At June 30, 2015 and December 31, 2014, the Company had $0.4 million and $0.1 million, respectively, recorded for potential obsolete, expiring or unsalable product.

Property and Equipment, net

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

Capitalization of Software Costs

The Company capitalizes certain significant costs incurred in the acquisition and development of software for internal use, including the costs of the software, materials, and consultants during the application development stage. Costs incurred prior to the application development stage, costs incurred once the application is substantially complete and ready for its intended use, and other costs not qualifying for capitalization, including training and maintenance costs, are charged to expense as incurred. The Company capitalized costs for enhancement of the enterprise resource planning software system and other internal use software of zero and $1.2 million during the six months ended June 30, 2015 and 2014, respectively. Capitalized software costs associated with the enterprise resource planning system are being amortized over the estimated useful life of five years.

Costs incurred in connection with the development of software products for sale are accounted for in accordance with the ASC 985 *Costs of Software to Be Sold, Leased or Marketed*. Costs incurred prior to the establishment of technological feasibility are charged to research and development expense. Software development costs are capitalized after a product is determined to be technologically feasible and is in the process of being developed for market.

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Goodwill and Intangible Assets, net

Intangible assets, net, which include a license for the right to commercialize the INTERCEPT Blood System in Asia, are subject to ratable amortization over the estimated useful life of ten years. The amortization of the Company s intangible assets, net, is recorded in Amortization of intangible assets on the Company s unaudited condensed consolidated statements of operations. Goodwill is not amortized but instead is subject to an impairment test performed on an annual basis, or more frequently if events or changes in circumstances indicate that goodwill may be impaired. Such impairment analysis is performed on August 31 of each fiscal year, or more frequently if indicators of impairment exist. The test for goodwill impairment may be assessed using qualitative factors to determine whether it is more likely than not that the fair value of a reporting unit is less than the carrying amount. If the Company determines that it is more likely than not that the fair value of a reporting unit is less than the carrying amount, the Company must then proceed with performing the quantitative two-step process to test goodwill for impairment; otherwise, goodwill is not considered impaired and no further testing is warranted. The Company may choose not to perform the qualitative assessment to test goodwill for impairment and proceed directly to the quantitative two-step process; however, the Company may revert to the qualitative assessment to test goodwill for impairment in any subsequent period. The first step of the two-step process compares the fair value of each reporting unit with its respective carrying amount, including goodwill. The Company has determined that it operates in one segment and has one reporting unit and estimates the fair value of its one reporting unit using the enterprise approach under which it considers the quoted market capitalization of the Company as reported on the Nasdaq Global Market. The Company considers quoted market prices that are available in active markets to be the best evidence of fair value. The Company also considers other factors, which include future forecasted results, the economic environment and overall market conditions. If the fair value of the reporting unit exceeds its carrying amount, goodwill of the reporting unit is not considered impaired and, therefore, the second step of the impairment test is unnecessary. The second step of the two-step process, which is used to measure the amount of impairment loss, compares the implied fair value of each reporting unit s goodwill with the respective carrying amount of that goodwill. If the carrying amount of the reporting unit s goodwill exceeds the implied fair value of that goodwill, an impairment loss is recognized in an amount equal to that excess.

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

Long-lived Assets

The Company evaluates its long-lived assets for impairment by continually monitoring events and changes in circumstances that could indicate carrying amounts of its long-lived assets may not be recoverable. When such events or changes in circumstances occur, the Company assesses recoverability by determining whether the carrying value of such assets will be recovered through the undiscounted expected future cash flows. If the expected undiscounted future cash flows are less than the carrying amount of these assets, the Company then measures the amount of the impairment loss based on the excess of the carrying amount over the fair value of the assets. The Company did not recognize impairment charges related to its long-lived assets during the three and six months ended June 30, 2015 and 2014.

Foreign Currency Remeasurement

The functional currency of the Company s foreign subsidiary is the United States dollar. Monetary assets and liabilities denominated in foreign currencies are remeasured in United States dollars using the exchange rates at the balance sheet date. Non-monetary assets and liabilities denominated in foreign currencies are remeasured in United States dollars using historical exchange rates. Revenues and expenses are remeasured using average exchange rates prevailing during the period. Remeasurements are recorded in the Company s unaudited condensed consolidated statements of operations.

Stock-Based Compensation

The Company accounts for stock-based compensation in accordance with ASC Topic 718, *Compensation Stock Compensation.* Stock-based compensation expense is measured at the grant-date based on the fair value of the award and is recognized as expense on a straight-line basis over the requisite service period, which is the vesting period, adjusted for estimated forfeitures. To the extent that stock options contain performance criteria for vesting, stock-based compensation is recognized once the performance criteria are probable of being achieved.

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For stock-based awards issued to non-employees, the Company follows ASC Topic 505-50, *Equity Based Payment to Non-Employees* and considers the measurement date at which the fair value of the stock-based award is measured to be the earlier of (i) the date at which a commitment for performance by the grantee to earn the equity instrument is reached or (ii) the date at which the grantee s performance is complete. The Company recognizes stock-based compensation expense for the fair value of the vested portion of the non-employee stock-based awards in its unaudited condensed consolidated statements of operations.

See Note 11 in the Notes to Unaudited Condensed Consolidated Financial Statements for further information regarding the Company s stock-based compensation assumptions and expenses.

Warrant Liability

In August 2009 and November 2010, the Company issued warrants to purchase an aggregate of 2.4 million and 3.7 million shares of common stock, respectively. The material terms of the warrants were identical under each issuance except for the exercise price, date issued and expiration date. In August 2014, all of the outstanding August 2009 warrants were exercised in full. The Company classifies warrants outstanding on the reporting date as a liability on its unaudited condensed consolidated balance sheets as the warrants contain certain material terms which require the Company to purchase the warrants for cash in an amount equal to the value of the unexercised portion of the warrants in connection with certain change of control transactions. In addition, the Company may also be required to pay cash to a warrant holder under certain circumstances if the Company is unable to timely deliver the shares acquired upon warrant exercise to such holder.

The fair value of outstanding warrants is calculated using the Black-Scholes model and was adjusted accordingly at December 31, 2014 and June 30, 2015.

Changes resulting from the revaluation of warrants to fair value are recorded in (Loss) gain from revaluation of warrant liability on the unaudited condensed consolidated statements of operations. Upon the exercise or modification to remove the provisions which require the warrants to be treated as a liability, the fair value of the warrants will be reclassified from a liability to stockholders equity on the Company s unaudited condensed consolidated balance sheets and no further adjustment to the fair value would be made in subsequent periods.

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

Income Taxes

The Company accounts for income taxes using an asset and liability approach in accordance with ASC Topic 740 *Accounting for Income Taxes.* Under this method, deferred tax assets and liabilities are determined based on differences between the financial reporting and tax bases of assets and liabilities and are measured using the enacted tax rates and laws that will be in effect when the differences are expected to reverse. ASC Topic 740 requires derecognition of tax positions that do not have a greater than 50% likelihood of being recognized upon review by a taxing authority having full knowledge of all relevant information. Use of a valuation allowance as described in ASC Topic 740 is not an appropriate substitute for derecognition of a tax position. The Company recognizes accrued interest and penalties related to unrecognized tax benefits in its income tax expense. To date, the Company has not recognized any interest and penalties in its unaudited condensed consolidated statements of operations, nor has its accrued for or made payments for interest and penalties. The Company continues to carry a full valuation allowance on all of its deferred tax assets. Although the Company believes it more likely than not that a taxing authority would agree with its current tax positions, there can be no assurance that the tax positions the Company has taken will be

substantiated by a taxing authority if reviewed. The Company s tax years 2010 through 2014 remain subject to examination by the taxing jurisdictions due to unutilized net operating losses and research credits.

Net Loss Per Share

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

Certain potential dilutive securities were excluded from the dilution calculation for the three and six months ended June 30, 2015 and 2014, as their inclusion would have been anti-dilutive.

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The following table sets forth the reconciliation of the numerator and denominator used in the computation of basic and diluted net loss per share for the three and six months ended June 30, 2015 and 2014 (in thousands, except per share amounts):

	Three Months Ended June 30,		Six Months Ended June 30,	
	2015	2014	2015	2014
Numerator for Basic and Diluted:				
Net loss used for basic calculation	$ (15,972)	$ (7,589)	$ (25,432)	$ (7,814)
Effect of revaluation of warrant liability		(4,007)	(3,589)	(13,041)
Adjusted net loss used for diluted calculation	$ (15,972)	$ (11,596)	$ (29,021)	$ (20,855)
Denominator:				
Basic weighted average number of shares outstanding	95,728	72,899	94,576	72,495
Effect of dilutive potential shares		1,618	1,106	2,432
Diluted weighted average number of shares outstanding	95,728	74,517	95,682	74,927
Net loss per share:				
Basic	$ (0.17)	$ (0.10)	$ (0.27)	$ (0.11)
Diluted	$ (0.17)	$ (0.16)	$ (0.30)	$ (0.28)

The table below presents shares underlying stock options, employee stock purchase plan rights, and warrants that are excluded from the calculation of the weighted average number of shares outstanding used for the calculation of diluted net loss per share. These are excluded from the calculation due to their anti-dilutive effect for the three and six months ended June 30, 2015 and 2014 (shares in thousands):

	Three Months Ended June 30,		Six Months Ended June 30,	
	2015	2014	2015	2014
Weighted average number of anti-dilutive potential shares:				
Stock options	6,910	12,160	5,793	11,587
Warrants	2,985			
Total	9,895	12,160	5,793	11,587

Guarantee and Indemnification Arrangements

The Company recognizes the fair value for guarantee and indemnification arrangements issued or modified by the Company. In addition, the Company monitors the conditions that are subject to the guarantees and indemnifications in order to identify if a loss has occurred. If the Company determines it is probable that a loss has occurred, then any such estimable loss would be recognized under those guarantees and indemnifications. Some of the agreements that

the Company is a party to contain provisions that indemnify the counter party from damages and costs resulting from claims that the Company s technology infringes the intellectual property rights of a third party or claims that the sale or use of the Company s products have caused personal injury or other damage or loss. The Company has not received any such requests for indemnification under these provisions and has not been required to make material payments pursuant to these provisions.

The Company generally provides for a one-year warranty on certain of its INTERCEPT blood-safety products covering defects in materials and workmanship. The Company accrues costs associated with warranty obligations when claims are probable. The Company has not experienced significant or systemic warranty claims nor is it aware of any existing current warranty claims and does not carry a warranty claim liability at June 30, 2015 and December 31, 2014.

Fair Value of Financial Instruments

The Company applies the provisions of fair value relating to its financial assets and liabilities. The carrying amounts of accounts receivables, accounts payable, and other accrued liabilities approximate their fair value due to the relative short-term maturities of such instruments. Based on the borrowing rates currently available to the Company for loans with similar terms, the Company believes the fair value of its debt also approximates its carrying amounts. The Company measures and records certain financial assets and liabilities at fair value on a recurring basis, including its available-for-sale securities and warrant liability. The Company classifies instruments within Level 1 if quoted prices are available in active markets for identical assets. The Company classifies instruments in Level 2 if the instruments are valued using observable inputs to quoted market prices, benchmark yields, reported trades, broker/dealer quotes or alternative pricing sources with reasonable levels of price transparency. The available-for-sale securities are held by a custodian who obtains investment prices from a third party pricing provider that uses standard inputs (observable in the market) to models which vary by asset class. The Company classifies instruments in Level 3 if one or more significant inputs or significant value drivers are unobservable, which include its warrant liability. The Company assesses any transfers among fair value measurement levels at the end of each reporting period.

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

New Accounting Pronouncements

In May 2014, the Financial Accounting Standards Board (FASB) issued Accounting Standards Update (ASU) No. 2014-09, *Revenue from Contracts with Customers* (Topic 606), which provides a single comprehensive model for entities to use in accounting for revenue arising from contracts with customers and will supersede most current revenue recognition guidance. This ASU is based on the principle that revenue is recognized to depict the transfer of goods or services to customers in an amount that reflects the consideration to which the entity expects to be entitled in exchange for those goods or services. The ASU also requires additional disclosure about the nature, amount, timing and uncertainty of revenue and cash flows arising from customer contracts, including significant judgments and changes in judgments and assets recognized from costs incurred to obtain or fulfill a contract. In July 2015, the FASB deferred the effective date for annual reporting periods beginning after December 15, 2017 (including interim periods within those periods). Early adoption is permitted to the original effective date of December 15, 2016 (including interim periods within those periods). The ASU s effective date for the Company will be the first quarter of fiscal year 2018, using one of two retrospective application methods. The Company has not selected a transition retrospective application method and is currently assessing the potential effects of this ASU on its unaudited condensed consolidated financial statements.

In August 2014, the FASB issued ASU No. 2014-15, *Presentation of Financial Statements Going Concern* (*Subtopic 205-40): Disclosure of Uncertainties about an Entity s Ability to Continue as a Going Concern*, which requires management to evaluate, in connection with preparing financial statements for each annual and interim reporting period, whether there are conditions or events, considered in the aggregate, that raise substantial doubt about an entity s ability to continue as a going concern within one year after the date that the financial statements are issued and provide related disclosures. This ASU will be effective for the Company in fiscal year 2016. Early adoption is permitted. The Company is currently assessing the future impact of this ASU on its unaudited condensed consolidated financial statements.

In April 2015, the FASB issued ASU No. 2015-03, *Interest Imputation of Interest (Subtopic 835-30): Simplifying the Presentation of Debt Issuance Costs*, which requires debt issuance costs related to a recognized debt liability to be presented in the balance sheet as a direct deduction from the corresponding debt liability rather than as an asset. This ASU will be effective for the Company in fiscal year 2016. Early adoption is permitted. The Company is currently assessing the future impact of this ASU on its unaudited condensed consolidated financial statements.

In July 2015, the FASB issued ASU No. 2015-11, *Inventory (Topic 330), Simplifying the Measurement of Inventory*, which simplifies the subsequent measurement of inventory by requiring inventory to be measured at the lower of cost and net realizable value. Net realizable value is defined as the estimated selling prices in the ordinary course of business, less reasonably predictable costs of completion, disposal and transportation. This ASU will be effective for the Company in fiscal year 2017. Early adoption is permitted. The Company is currently assessing the future impact of this ASU on its unaudited condensed consolidated financial statements.

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Note 2. Fair Value of Financial Instruments

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

Level 1: Quoted prices in active markets for identical instruments

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

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

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

To estimate the fair value of Level 2 debt securities as of June 30, 2015, the Company s primary service relies on inputs from multiple industry-recognized pricing sources to determine the price for each investment. Corporate debt and United States government agency securities are systematically priced by this service as of the close of business each business day. If the primary pricing service does not price a specific asset, a secondary pricing service is utilized.

The fair values of the Company s financial assets and liabilities were determined using the following inputs at June 30, 2015 (in thousands):

	Total	Quoted Prices in Active Markets for Identical Assets (Level 1)	Significant Other Observable Inputs (Level 2)	Significant Unobservable Inputs (Level 3)
Money market funds [1]	$ 18,588	$ 18,588	$	$
Corporate debt securities [2]	13,850		13,850	
United States government agency securities [2]	62,004		62,004	
Aduro equity securities [3]	12,032	12,032		
Total financial assets	$ 106,474	$ 30,620	$ 75,854	$

Warrant liability [4]	$ 3,978	$	$	$ 3,978
Total financial liabilities	$ 3,978	$	$	$ 3,978

(1) Included in cash and cash equivalents on the Company s unaudited condensed consolidated balance sheets.
(2) Included in short-term investments on the Company s unaudited condensed consolidated balance sheets.
(3) Included in investment in Aduro Biotech, Inc. on the Company s unaudited condensed consolidated balance sheets.
(4) Included in current liabilities on the Company s unaudited condensed consolidated balance sheets.

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The fair values of the Company s financial assets and liabilities were determined using the following inputs at December 31, 2014 (in thousands):

	Total	Quoted Prices in Active Markets for Identical Assets (Level 1)	Significant Other Observable Inputs (Level 2)	Significant Unobservable Inputs (Level 3)
Money market funds [1]	$ 3,912	$ 3,912	$	$
Corporate debt securities [2]	26,088		26,088	
United States government agency securities [2]	3,426		3,426	
Total financial assets	$ 33,426	$ 3,912	$ 29,514	$
Warrant liability [3]	$ 10,485	$	$	$ 10,485
Total financial liabilities	$ 10,485	$	$	$ 10,485

(1) Included in cash and cash equivalents on the Company s consolidated balance sheets.
(2) Included in short-term investments on the Company s consolidated balance sheets, except for approximately $1.0 million of corporate debt securities that are included in cash and cash equivalents on the Company s consolidated balance sheets.
(3) Included in current liabilities on the Company s consolidated balance sheets.

A reconciliation of the beginning and ending balances for warrant liability using significant unobservable inputs (Level 3) from December 31, 2014 to June 30, 2015, was as follows (in thousands):

Balance at December 31, 2014	$ 10,485
Decrease in fair value of warrants	(3,589)
Settlement of warrants exercised	(2,918)
Balance at June 30, 2015	$ 3,978

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

The Company did not have any transfers among fair value measurement levels during the three and six months ended June 30, 2015 or the year ended December 31, 2014.

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Note 3. Available-for-sale Securities

The following is a summary of available-for-sale securities at June 30, 2015 (in thousands):

	June 30, 2015			
	Amortized Cost	Gross Unrealized Gain	Gross Unrealized Loss	Fair Value
Money market funds	$ 18,588	$	$	$ 18,588
United States government agency securities	61,995	9		62,004
Corporate debt securities	13,858		(8)	13,850
Aduro equity securities		12,032		12,032
Total available-for-sale securities	$ 94,441	$ 12,041	$ (8)	$ 106,474

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

	December 31, 2014		
	Amortized Cost	Gross Unrealized Loss	Fair Value
Money market funds	$ 3,912	$	$ 3,912
United States government agency securities	3,427	(1)	3,426
Corporate debt securities	26,118	(30)	26,088
Total available-for-sale securities	$ 33,457	$ (31)	$ 33,426

Available-for-sale debt securities at June 30, 2015 and December 31, 2014, consisted of the following by original contractual maturity (in thousands):

	June 30, 2015		December 31, 2014	
	Amortized Cost	Fair Value	Amortized Cost	Fair Value
One year or less	$ 94,441	$ 94,442	$ 27,752	$ 27,727
Greater than one year and less than five years			5,705	5,699
Total available-for-sale debt securities	$ 94,441	$ 94,442	$ 33,457	$ 33,426

As of June 30, 2015, the Company considered the declines in market value of its marketable securities investment portfolio to be temporary in nature and did not consider any of its investments other-than-temporarily impaired. Fair values were determined for each individual security in the investment portfolio. When evaluating an investment for other-than-temporary impairment, the Company reviews factors such as the length of time and extent to which fair

value has been below its cost basis, the financial condition of the issuer and any changes thereto, changes in market interest rates, and the Company s intent to sell, or whether it is more likely than not it will be required to sell, the investment before recovery of the investment s cost basis. During the three and six months ended June 30, 2015 and 2014, the Company did not recognize any other-than-temporary impairment losses.

The Company recorded minimal gross realized gains from the sale or maturity of available-for-sale securities during the three and six months ended June 30, 2015, and did not record any gross realized gains from the sale or maturity of available-for-sale securities during the three and six months ended June 30, 2014. The Company did not record any gross realized losses from the sale or maturity of available-for-sale securities during the three and six months ended June 30, 2015 and 2014.

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Note 4. Inventories

Inventories at June 30, 2015 and December 31, 2014, consisted of the following (in thousands):

	June 30, 2015	December 31, 2014
Work-in-process	$ 4,096	$ 2,222
Finished goods	9,585	12,734
Total inventories	$ 13,681	$ 14,956

Note 5. Goodwill and Intangible Assets, net

Goodwill

During the three and six months ended June 30, 2015, the Company did not dispose of or recognize additional goodwill. The Company expects to perform its annual review of goodwill on August 31, 2015, unless indicators of impairment are identified prior to that date. As of June 30, 2015, the Company has not identified any indicators of goodwill impairment.

Intangible Assets, net

The following is a summary of intangible assets, net at June 30, 2015 (in thousands):

	June 30, 2015		
	Gross Carrying Amount	Accumulated Amortization	Net Carrying Amount
Acquisition-related intangible assets:			
Reacquired license INTERCEPT Asia	$ 2,017	$ (976)	$ 1,041
Total intangible assets	$ 2,017	$ (976)	$ 1,041

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

	December 31, 2014		
	Gross Carrying Amount	Accumulated Amortization	Net Carrying Amount
Acquisition-related intangible assets:			
Reacquired license INTERCEPT Asia	$ 2,017	$ (875)	$ 1,142

Total intangible assets	$ 2,017	$ (875)	$ 1,142

The Company recognized $0.05 million and $0.1 million in amortization expense related to intangible assets for each of the three and six months ended June 30, 2015 and 2014. During the three and six months ended June 30, 2015 and 2014, there were no impairment charges recognized related to the acquired intangible assets.

At June 30, 2015, the expected annual amortization expense of the intangible assets, net is $0.1 million for the remaining six months of 2015, $0.2 million annually beginning with the year ending December 31, 2016 through the year ending December 31, 2019, and $0.1 million for the year ending December 31, 2020.

Note 6. Long-Term Investments

The Company maintains an investment in Aduro historically carried under the cost basis of accounting and carried at zero on its unaudited condensed consolidated balance sheets. In April 2015, Aduro s common stock began trading on the NASDAQ Global Select Market, trading under the symbol ADRO . At the time of Aduro s initial public offering (IPO), the Company s preferred shares in Aduro converted to 396,700 shares of common stock, and the fair value of the Company s investment became readily determinable. As a result of the IPO, the Company no longer accounts for the investment in Aduro under the cost basis of accounting. The Company now reflects the investment in Aduro as an available-for-sale security on the consolidated balance sheet (Note 2) and will adjust the investment to fair value each quarterly reporting period, with changes in fair value recorded within other comprehensive income (loss), net of tax.

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Note 7. Accrued Liabilities

Accrued liabilities at June 30, 2015 and December 31, 2014, consisted of the following (in thousands):

	June 30, 2015	December 31, 2014
Accrued compensation and related costs	$ 3,495	$ 3,951
Accrued professional services	2,384	2,123
Accrued inventory costs	42	870
Accrued customer costs and deposits	344	385
Accrued insurance premiums	36	264
Other accrued expenses	613	851
Total accrued liabilities	$ 6,914	$ 8,444

Note 8. Debt

Debt at June 30, 2015, consisted of the following (in thousands):

	June 30, 2015		
	Principal	Unamortized Discount	Total
Loan and Security Agreement	$ 20,000	$ (106)	$ 19,894
Less: debt current	(2,568)	45	(2,523)
Debt non-current	$ 17,432	$ (61)	$ 17,371

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

	December 31, 2014		
	Principal	Unamortized Discount	Total
Loan and Security Agreement	$ 10,000	$ (128)	$ 9,872
Less: debt current			
Debt non-current	$ 10,000	$ (128)	$ 9,872

Principal and interest payments on debt at June 30, 2015, are expected to be as follows * (in thousands):

Year ended December 31,	Principal	Interest	Total

2015	$	$ 640	$ 640
2016	5,226	1,231	6,457
2017	5,603	854	6,457
2018	6,007	450	6,457
2019	3,164	1,465	4,629
Total	$ 20,000	$ 4,640	$ 24,640

* Unless interest only period extends to December 31, 2016, as described below.

Loan and Security Agreement

On June 30, 2014, the Company entered into a five year loan and security agreement with Oxford Finance LLC (the Term Loan Agreement) to borrow up to $30.0 million in term loans in three equal tranches (the Term Loans). On June 30, 2014, the Company received $10.0 million from the first tranche (Term Loan A). The second tranche of $10.0 million (Term Loan B) was drawn on June 15, 2015. The third tranche of $10.0 million (Term Loan C) will be available from July 1, 2015 through December 31, 2015, contingent upon the Company achieving trailing six months revenue at a specified threshold (the Revenue Event). Term Loan A bears an interest rate of 6.95%. Term Loan B bears an interest rate of 7.01%. Term Loan C will bear an interest rate calculated at the greater of 6.95% or 6.72% plus the three month U.S. LIBOR rate in effect three business days prior to the funding date. All of the Term Loans mature on June 1, 2019. The Company is required to make interest only payments through December 2015 followed by

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forty-two months of equal principal and interest payments thereafter; however, if the Revenue Event is achieved no later than November 30, 2015, then the interest-only period may be extended through December 31, 2016, and the amortization period will be reduced to thirty months. The Company is also required to make a final payment equal to 7% of the principal amounts of the Term Loans drawn payable on the earlier to occur of maturity or prepayment. The costs associated with the final payment are recognized as interest expense over the life of the Term Loans. The Company may prepay at any time the Term Loans subject to declining prepayment fees over the term of the Term Loan Agreement. The Company pledged all current and future assets, excluding its intellectual property and 35% of the Company s investment in its subsidiary, Cerus Europe B.V., as security for borrowings under the Term Loan Agreement. The Term Loan Agreement contains certain nonfinancial covenants, with which the Company was in compliance at June 30, 2015.

Note 9. Commitments and Contingencies

Operating Leases

The Company leases its office facilities, located in Concord, California and Amersfoort, the Netherlands, and certain equipment under non-cancelable operating leases with initial terms in excess of one year that require the Company to pay operating costs, property taxes, insurance and maintenance. The operating leases expire at various dates through 2019, with certain of the leases providing for renewal options, provisions for adjusting future lease payments, which is based on the consumer price index and the right to terminate the lease early. In June 2013, the Company entered into a new lease for additional space in Concord. The lease initially had a two-year term with four two-year options for the Company to renew, the first of which the Company exercised in March 2015 and obligates the Company to make rent payments for the remaining six months of 2015 of $82,544 and $172,592 and $105,056 in 2016 and 2017, respectively. The Company s leased facilities qualify as operating leases under ASC Topic 840, *Leases* and as such, are not included on its unaudited condensed consolidated balance sheets.

Financed Leasehold Improvements

In 2010, the Company financed $1.1 million of leasehold improvements at one of its facilities in Concord, California. The Company pays for the financed leasehold improvements as a component of rent and is required to reimburse its landlord over the remaining life of the lease. If the Company exercises its right to early terminate the Concord, California lease under which such improvements were made, which may occur at any time hereafter, the Company would be required to repay for any remaining portion of the landlord financed leasehold improvements at such time. At June 30, 2015, the Company had an outstanding liability of $0.6 million related to these leasehold improvements, of which $0.1 million was reflected in Accrued liabilities and $0.5 million was reflected in Other non-current liabilities on the Company s unaudited condensed consolidated balance sheets.

Purchase Commitments

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

Note 10. Stockholders Equity

Public Offering of Common Stock

In January 2015, the Company issued 14,636,363 shares of its common stock, par value $0.001 per share, in an underwritten public offering. The price to the public in the offering was $5.50 per share. The net proceeds from this offering were approximately $75.4 million, net of the underwriting discount and other issuance costs totaling $5.1 million.

Common Stock and Associated Warrant Liability

In August 2009, the Company issued warrants to purchase 2.4 million shares of common stock, exercisable at an exercise price of $2.90 per share (2009 Warrants). In August 2014, all outstanding 2009 Warrants were exercised in full.

In November 2010, the Company issued warrants to purchase 3.7 million shares of common stock, exercisable at an exercise price of $3.20 per share (2010 Warrants). The 2010 Warrants became exercisable on May 15, 2011, and are exercisable for a period of five years from the issue date.

The fair value of the 2010 Warrants were recorded on the unaudited condensed consolidated balance sheets as a liability pursuant to ASC Topic 480-10 *Distinguishing Liabilities from Equity* and adjusted to fair value at each financial reporting date thereafter until the earlier of exercise, expiration or modification to remove the provisions which require the warrants to be treated as a liability, at which time, these warrants would be reclassified into stockholders equity. The Company classified the 2010 Warrants as a liability as these warrants contain certain provisions that, under certain circumstances, which may be out of the Company s control, could require the Company to pay cash to settle the exercise of the warrants or may require the Company to redeem the warrants.

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The fair value of the 2010 warrants at June 30, 2015 and December 31, 2014, consisted of the following (in thousands):

	June 30, 2015	December 31, 2014
2010 Warrants	$ 3,978	$ 10,485

The fair value of the Company s warrants was based on an option valuation model using the following assumptions at June 30, 2015 and December 31, 2014:

	June 30, 2015	December 31, 2014
2010 Warrants:		
Expected term (in years)	0.36	0.86
Estimated volatility	52%	55%
Risk-free interest rate	0.01%	0.25%
Expected dividend yield	0%	0%

The Company recorded non-cash losses of $2.7 million and $3.5 million during the three months ended June 30, 2015 and June 30, 2014, respectively, and non-cash gains of $3.6 million and $12.5 million during the six months ended June 30, 2015 and 2014, respectively, in (Loss) gain from revaluation of warrant liability on its unaudited condensed consolidated statements of operations due to the changes in fair value of the warrants. Significant changes to the Company s market price for its common stock will impact the implied and/or historical volatility used to calculate the fair value the warrants. Any significant increases in the Company s stock price will likely create an increase in the fair value of warrant liability. Similarly, any significant decreases in the Company s stock price will likely create a decrease in the fair value of warrant liability. During the six months ended June 30, 2015, 1,369,123 shares of common stock were issued in connection with the exercise of outstanding 2010 Warrants. As of June 30 2015, 2010 Warrants to purchase approximately 2.0 million shares of common stock were outstanding.

Sales Agreements

On March 21, 2014, the Company entered into Amendment No. 1 to the Controlled Equity Offering℠ Sales Agreement, dated August 31, 2012 (as amended, the Amended Cantor Agreement) with Cantor Fitzgerald & Co. (Cantor) that provides for the issuance and sale of shares of its common stock over the term of the Amended Cantor Agreement having an aggregate offering price of up to an aggregate of $70.0 million through Cantor. Under the Amended Cantor Agreement, Cantor also acts as the Company s sales agent and receives compensation based on an aggregate of 2% of the gross proceeds on the sale price per share of its common stock. The issuance and sale of these shares by the Company pursuant to the Amended Cantor Agreement are deemed an at-the-market offering and are registered under the Securities Act of 1933, as amended. During the year ended December 31, 2014, approximately 4.3 million shares of the Company s common stock were sold under the Amended Cantor Agreement for aggregate net proceeds of $18.6 million. During the six months ended June 30, 2015, the Company had no sales of its common stock under the Amended Cantor Agreement. At June 30, 2015, the Company had approximately $22.5 million of common stock available to be sold under the Amended Cantor Agreement.

Note 11. Stock-Based Compensation

The Company maintains an equity compensation plan to provide long-term incentives for employees, contractors, and members of its Board of Directors. The Company currently grants equity awards from one plan, the 2008 Equity Incentive Plan (the 2008 Plan). The 2008 Plan allows for the issuance of non-statutory and incentive stock options, restricted stock, restricted stock units, stock appreciation rights, other stock-related awards, and performance awards which may be settled in cash, stock, or other property. The Company continues to have equity awards outstanding under its previous stock plans: 1998 Non-Officer Stock Option Plan and 1999 Equity Incentive Plan (collectively, the Prior Plans) and 1996 Equity Incentive Plan (the 1996 Plan). Equity awards issued under the Prior Plans and the 1996 Plan continue to adhere to the terms of those respective stock plans and no further options may be granted under those previous plans. However, at June 2, 2008, any shares that remained available for future grants under the Prior Plans became available for issuance under the 2008 Plan. On June 10, 2015, the Company s stockholders approved an amendment and restatement of the 2008 Plan that increased the aggregate number of shares of common stock authorized for issuance under the 2008 Plan by 5,000,000 shares. At June 30, 2015, the Company had an aggregate of approximately 21.8 million shares of its common stock reserved for issuance under the Amended 2008 Plan, the Prior Plans and the 1996 Plan, of which approximately 14.1 million shares were subject to outstanding options and other stock-based awards, and approximately 7.7 million shares were available for future issuance under the Amended 2008 Plan.

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The Company maintains an Employee Stock Purchase Plan (the Purchase Plan), which is intended to qualify as an employee stock purchase plan within the meaning of Section 423(b) of the Internal Revenue Code. Under the Purchase Plan, the Company s Board of Directors may authorize participation by eligible employees, including officers, in periodic offerings. Under the Purchase Plan eligible employee participants may purchase shares of common stock of the Company at a purchase price equal to 85% of the lower of the fair market value per share on the start date of the offering period or the fair market value per share on the purchase date. The Purchase Plan consists of a fixed offering period of 12 months with two purchase periods within each offering period. On June 10, 2015, the Company s stockholders approved an amendment and restatement of the Purchase Plan that increased the aggregate number of shares of common stock authorized for issuance under the Purchase Plan by 1,500,000 shares. At June 30, 2015, the Company had 1,784,130 shares of its common stock available for future issuance under the Purchase Plan.

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

	Number of Options Outstanding	Weighted Average Exercise Price per Share
Balances at December 31, 2014	11,323	$ 4.13
Granted	3,151	4.54
Forfeited	(74)	4.51
Expired	(3)	5.87
Exercised	(261)	2.90
Balances at June 30, 2015	14,136	4.24

The Company uses the Black-Scholes option pricing model to determine the grant-date fair value of stock options and Purchase Plan shares. The Black-Scholes option pricing model is affected by the Company s stock price, as well as assumptions regarding a number of complex and subjective variables, which include the expected term of the grants, actual and projected employee stock option exercise behaviors, including forfeitures, the Company s expected stock price volatility, the risk-free interest rate and expected dividends. The Company recognizes the grant-date fair value of the stock award as stock-based compensation expense on a straight-line basis over the requisite service period, which is the vesting period, and is adjusted for estimated forfeitures.

Stock-based compensation recognized on the Company s unaudited condensed consolidated statements of operations for the three and six months ended June 30, 2015 and 2014, was as follows (in thousands):

	Three Months Ended June 30,		Six Months Ended June 30,	
	2015	2014	2015	2014
Stock-based compensation expense by caption:				

Research and development	$ 340	$ 276	$ 623	$ 459
Selling, general and administrative	1,364	1,065	2,556	1,827
Total stock-based compensation expense	$ 1,704	$ 1,341	$ 3,179	$ 2,286

Note 12. Income Taxes

Intraperiod tax allocation rules require the Company to allocate the provision for income taxes between continuing operations and other categories of earnings, such as other comprehensive income. In periods in which the Company has a year-to-date pre-tax loss from continuing operations and pre-tax income in other categories of earnings, such as other comprehensive income, the Company must allocate the tax provision to the other categories of earnings. The Company then records a related tax benefit in continuing operations. During the six months ended June 30, 2015, we recorded unrealized gains on our investments in available-for-sale securities in other comprehensive income, net of taxes. As a result, for the three and six months ended June 30, 2015, the Company recorded a $2.0 million tax benefit.

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Note 13. Development and License Agreements

Agreements with Fresenius

The Company has certain agreements with Fresenius which require the Company to pay royalties on future INTERCEPT Blood System product sales at royalty rates that vary by product: 10% of product sales for the platelet system and 3% of product sales for the plasma system. During the three months ended June 30, 2015 and 2014, the Company made royalty payments to Fresenius of $0.5 million and $0.6 million, respectively. During each of the six months ended June 30, 2015 and 2014, the Company made royalty payments to Fresenius of $1.3 million. At both June 30, 2015 and December 31, 2014, accrued royalties due to Fresenius were $0.7 million.

Until 2014, the Company and Fresenius operated under a supply agreement (the Original Supply Agreement) for the manufacture of the Company s platelet and plasma systems. Under the Original Supply Agreement, the Company paid Fresenius a set price per kit, which was established annually, plus a fixed surcharge per kit. In addition, volume driven manufacturing overhead was to be paid or refunded if actual manufacturing volumes were lower or higher than the estimated production volumes.

In November 2013, the Company amended the Original Supply Agreement with Fresenius, with the new terms effective January 1, 2014 (the 2013 Amendment). Under the 2013 Amendment, Fresenius is obligated to sell, and the Company is obligated to purchase, up to a certain specified annual volume of finished disposable kits for the platelet and plasma systems from Fresenius for both clinical and commercial use. Once the specified annual volume of disposable kits is purchased from Fresenius, the Company is able to purchase additional quantities of disposable kits from other third-party manufacturers. The 2013 Amendment also provides for fixed pricing for finished kits with successive decreasing pricing tiers at various annual production volumes. In addition, the 2013 Amendment requires the Company to purchase additional specified annual volumes of sets per annum if and when an additional Fresenius manufacturing site is identified and qualified to make INTERCEPT disposable kits subject to mutual agreement on pricing for disposable kits manufactured at the additional site. Fresenius is also obligated to purchase and maintain specified inventory levels of the Company s proprietary inactivation compounds and adsorption media from the Company at fixed prices. During the three and six months ended June 30, 2015, the Company sold $0.5 million and $0.9 million, respectively, of such components to Fresenius. During the three and six months ended June 30, 2014, respectively, the Company sold $1.1 million and $3.8 million of such components to Fresenius. The Company maintains the amounts due from the components sold to Fresenius as a current asset on its accompanying unaudited condensed consolidated balance sheets until such time as the Company purchases finished disposable kits using those components. The term of the 2013 Amendment extends through December 31, 2018, subject to termination by either party upon thirty months prior written notice, in the case of Fresenius, or twenty-four months prior written notice, in the Company s case. The Company and Fresenius each have normal and customary termination rights, including termination for material breach.

The Company made payments to Fresenius of $4.7 million and $4.9 million relating to the manufacturing of the Company s products during the three months ended June 30, 2015 and 2014, respectively, and $9.4 million and $9.5 million during the six months ended June 30, 2015 and 2014, respectively. At June 30, 2015 and December 31, 2014, accrued amounts due to Fresenius were $2.5 million and $5.1 million, respectively, for INTERCEPT disposable kits manufactured. At June 30, 2015 and December 31, 2014, amounts due from Fresenius were $0.8 million and $1.3 million, respectively.

Note 14. Segment, Customer and Geographic Information

The Company continues to operate in only one segment, blood safety. The Company s chief executive officer is the chief operating decision maker who evaluates performance based on the net revenues and operating loss of the blood safety segment. The Company considers the sale of all of its INTERCEPT Blood System products to be similar in nature and function, and any revenue earned from services is minimal.

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

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The Company had the following significant customers that accounted for more than 10% of the Company s total product revenue, all of which operate in a country outside of the United States of America, during the three and six months ended June 30, 2015 and 2014 (in percentages):

	Three Months Ended June 30,		Six Months Ended June 30,	
	2015	2014	2015	2014
Etablissement Francais du Sang	25%	24%	25%	24%
Advanced Technology Company KSC	*	18%	*	*
Medical Device APS	*	10%	*	*

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

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

This discussion and analysis should be read in conjunction with our unaudited condensed consolidated financial statements and the accompanying notes included in this Quarterly Report on Form 10-Q and the audited consolidated financial statements and accompanying notes included in our Annual Report on Form 10-K for the year ended December 31, 2014. Operating results for the three and six months ended June 30, 2015 are not necessarily indicative of results that may occur in future periods.

This Quarterly Report on Form 10-Q contains forward-looking statements within the meaning of Section 27A of the Securities Act of 1933, as amended, and Section 21E of the Securities and Exchange Act of 1934, as amended, that involve risks and uncertainties. The forward-looking statements are contained principally in this Item 2, Management s Discussion and Analysis of Financial Condition and Results of Operations and in Item 1A, Risk Factors. These statements relate to future events or to our future operating or financial performance and involve known and unknown risks, uncertainties and other factors that may cause our actual results, performance or achievements to be materially different from any future results, performances or achievements expressed or implied by the forward-looking statements. Examples of forward-looking statements include, but are not limited to, statements about:

- *future sales of and our ability to effectively commercialize and achieve market acceptance of the INTERCEPT Blood System, including our ability to comply with applicable United States and foreign laws, regulations and regulatory requirements;*
- *our ability to manage the growth of our business and attendant cost increases, including in connection with the commercialization of the INTERCEPT Blood System in the United States, as well as our ability to manage the risks attendant to our international operations;*
- *our ability to transition distribution of the INTERCEPT Blood System from third parties to a direct sales model in certain international markets;*
- *the timing or likelihood of regulatory submissions and approvals and other regulatory actions or interactions;*
- *our ability to obtain and maintain regulatory approvals of the INTERCEPT Blood System;*
- *our ability to obtain adequate clinical and commercial supplies of the INTERCEPT Blood System from our sole source suppliers;*
- *the initiation, scope, rate of progress, results and timing of our ongoing and proposed preclinical and clinical trials of the INTERCEPT Blood System;*

the successful completion of our research, development and clinical programs and our ability to manage cost increases associated with preclinical and clinical development of the INTERCEPT Blood System;

the ability of our products to inactivate the Ebola virus and other pathogens that we may target in the future;

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 and our need for additional funding.

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In some cases, you can identify forward-looking statements by terms such as anticipate, will, believe, estimate, ex plan, may, should, could, would, project, predict, potential, and similar expressions intended to identify 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 any of the events anticipated by forward-looking statements will occur or, if any of them do occur, what impact they will have on our business, results of operations and financial condition. Certain important factors could cause actual results to differ materially from those discussed in such statements, including the rate of customer adoption in the U.S. and our ability to achieve market acceptance of our products in the U.S. and international markets, whether our preclinical and clinical data or data from commercial use will be considered sufficient by regulatory authorities to grant marketing approval for our products or for product extensions or additional claims for our products, our ability to obtain reimbursement approval for our products, our ability to complete, our ability to complete development and testing of additional configurations of our products, our need for additional financing, the impacts of regulation of our products by domestic and foreign regulatory authorities, our limited experience in sales, marketing and regulatory support for the INTERCEPT Blood System, our reliance on Fresenius Kabi AG and third parties to manufacture certain components of the INTERCEPT Blood System, incompatibility of our platelet system with some commercial platelet collection methods, our need to complete certain of our product components commercial design, more effective product offerings by, or clinical setbacks of, our competitors, product liability, our use of hazardous materials in the development of our products, business interruption due to earthquake, our expectation of continuing losses, protection of our intellectual property rights, volatility in our stock price, legal proceedings, and on-going compliance with the requirements of the Sarbanes-Oxley Act of 2002. We discuss many of these risks in this Quarterly Report on Form 10-Q in greater detail in the section entitled Risk Factors under Part II, Item 1A below and in our other documents filed with the Securities and Exchange Commission. Given these uncertainties, you should not place undue reliance on these forward-looking statements. Also, forward-looking statements represent our estimates and assumptions only as of the date of this Quarterly Report on Form 10-Q. You should read this Quarterly Report on Form 10-Q and the documents that we incorporate by reference in and have filed as exhibits to this Quarterly Report on Form 10-Q, completely and with the understanding that our actual future results may be materially different from what we expect. Except as required by law, we assume no obligation to update any forward-looking statements publicly, or to update the reasons actual results could differ materially from those anticipated in any forward-looking statements, even if new information becomes available in the future.

Overview

Since our inception in 1991, we have devoted substantially all of our efforts and resources to the research, development, clinical testing and commercialization of the INTERCEPT Blood System. The INTERCEPT Blood System is designed for three blood components: platelets, plasma and red blood cells. The INTERCEPT Blood System for platelets, or platelet system, and the INTERCEPT Blood System for plasma, or plasma system, have received CE marks and are being marketed and sold in a number of countries around the world.

In December 2014, we received approval of our premarket applications, or PMAs, from the United States Food and Drug Administration, or FDA, for the INTERCEPT Blood System for platelets, and our INTERCEPT Blood System for plasma. The platelet system is approved in the United States for *ex vivo* preparation of pathogen-reduced apheresis platelet components in order to reduce the risk of transfusion-transmitted infection, or TTI, including sepsis, and to potentially reduce the risk of transfusion-associated graft versus host disease, or TA-GVHD. The plasma system is approved in the United States for *ex vivo* preparation of plasma in order to reduce the risk of TTI when treating patients requiring therapeutic plasma transfusion.

We also submitted and received approval from the FDA for a Phase I clinical study protocol under an investigational device exemption, or IDE, to treat plasma derived from convalesced patients that were previously infected with the

Ebola virus and have recovered from the disease according to the criteria set by the Centers for Disease Control and Prevention. The transfusion of convalesced plasma from Ebola survivors is believed to pass on antibodies to the disease from the survivor to the recipient of the plasma transfusion. INTERCEPT use under this IDE is limited to pathogen reduction claims that rely on existing clinical data that we have regarding reduction of certain pathogens in donated plasma, and we do not have any clinical or commercial data on the efficacy of INTERCEPT to inactivate the Ebola virus and therefore do not know the effectiveness of INTERCEPT to inactivate the Ebola virus. In addition, we have submitted and received approval from the FDA for a separate, expanded use IDE, to conduct a study using INTERCEPT to treat platelet donations in areas of the U.S. that have outbreaks of the chikungunya and dengue viruses. Both of these studies are ongoing.

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Our red blood cell system is currently in development and has not been commercialized anywhere in the world. We completed our European Phase III clinical trial of our red blood cell system for acute anemia patients and have another European Phase III clinical trial of our red blood cell system for chronic anemia patients underway. Although we plan to undertake additional development and CMC activities to support an anticipated CE mark submission for the red blood cell system planned for the second half of 2016, such studies, including any additional studies required by the FDA prior to its review of any proposed U.S. Phase III clinical trial protocol, could prolong development of the red blood cell system, and we do not expect to receive any regulatory approvals of our red blood cell system for a few years, if ever. We understand that while the acute anemia Phase III clinical trial in Europe may be sufficient to receive CE mark approval in Europe, a successful outcome with potentially more safety data in the ongoing Phase III chronic anemia clinical trial may also be required for our red blood cell system to achieve broad market acceptance. In addition, the trials may need to be supplemented by additional, successful Phase III clinical trials for approval in certain countries. If such additional Phase III clinical trials are required, they would likely need to demonstrate equivalency of INTERCEPT-treated red blood cells compared to conventional red blood cells and significantly lower lifespan for INTERCEPT-treated red blood cells compared to non-treated red blood cells may limit our ability to obtain regulatory approval for the product. As part of our development and CMC activities, we will need to complete a number of *in vitro* studies, finalize development of the final commercial configuration of the red blood cell system and manufacture and validate sufficient quantities of the final red blood cell system prior to receiving any regulatory approvals in Europe and may have to complete additional activities prior to receiving regulatory approvals in the U.S. Many of these activities may require capital beyond that which we currently have, and we may be required to obtain additional capital in order to complete the development of and obtain any regulatory approvals for the red blood cell system. If we continue to experience delays in testing, conducting trials or obtaining approvals, our product development costs will increase.

Our near-term capital requirements are dependent on various factors, including operating costs and working capital investments associated with commercializing the INTERCEPT Blood System, including in connection with the continuing U.S. commercial launch of our platelet and plasma systems, costs associated with planning, enrolling and completing the ongoing studies under our IDEs and the post-approval study we are required to conduct in connection with the FDA approval of the platelet system, costs associated with pursuing potential regulatory approvals in other geographies where we do not currently sell our platelet and plasma systems, costs associated with conducting *in vitro* studies and clinical development of our red blood cell system in Europe and the U.S., including our ongoing European Phase III clinical trial of our red blood cell system for chronic anemia patients, and costs related to creating, maintaining and defending our intellectual property. Our long-term capital requirements will also be dependent on the success of our sales efforts, competitive developments, the timing, costs and magnitude of our longer-term clinical trials and other development activities related to our platelet, plasma and red blood cell systems, including the post-approval study for the platelet system, market preparedness and product launch activities for any of our products in geographies where we do not currently sell our products, and regulatory factors. Until we are able to generate a sufficient amount of product revenue and generate positive net cash flows from operations, which we may never do, meeting our long-term capital requirements is in large part reliant on access to public and private equity and debt capital markets, as well as on collaborative arrangements with partners, augmented by cash generated from operations and interest income earned on the investment of our cash balances. We believe that our available cash and cash equivalents and short-term investments, as well as cash received from product sales, will be sufficient to meet our capital requirements for at least the next twelve months. We have based our cash sufficiency estimate on assumptions that may prove to be incorrect. If our assumptions prove to be incorrect, we could consume our available capital resources sooner than we currently expect or in excess of amounts than we currently expect, which could adversely affect our commercialization and clinical development activities.

We have borrowed and in the future may borrow additional capital from institutional and commercial banking sources to fund future growth, including pursuant to our loan and security agreement with Oxford Finance as described below

or potentially pursuant to new arrangements with different lenders. We may borrow funds on terms that may include restrictive covenants, including covenants that restrict the operation of our business, liens on assets, high effective interest rates and repayment provisions that reduce cash resources and limit future access to capital markets. In addition, we expect to continue to opportunistically seek access to the equity capital markets to support our development efforts and operations. To the extent that we raise additional capital by issuing equity securities, our stockholders may experience substantial dilution. To the extent that we raise additional funds through collaboration or partnering arrangements, we may be required to relinquish some of our rights to our technologies or rights to market and sell our products in certain geographies, grant licenses on terms that are not favorable to us, or issue equity that may be substantially dilutive to our stockholders.

As a result of economic conditions, general global economic uncertainty and other factors, we do not know whether additional capital will be available when needed, or that, if available, we will be able to obtain additional capital on reasonable terms. If we are unable to raise additional capital due to disruptions to the global credit and financial markets, general economic uncertainty or other factors, we may need to curtail planned development or commercialization activities. Apart from the ongoing studies under our IDEs, we do not plan on conducting any additional randomized controlled clinical trials of the red blood cell, platelet or plasma systems unless and until we can obtain sufficient additional funding or, at such time, our existing operations provide sufficient cash flow to conduct these trials.

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Although we have begun the combined commercial launch of the plasma and platelet systems in the United States and announced the first customer contracts for the sale of the INTERCEPT Blood System for platelets and plasma since the beginning of 2015, we do not expect to recognize meaningful revenues from sales in the United States in 2015, and our commercial activities for 2015 in the United States will continue to be focused on supporting initial customer adoption and implementation. Significant revenue from customers in the U.S. may not occur until we have been able to successfully implement INTERCEPT and demonstrate that it is economic, safe and efficacious for potential customers. We recognize product revenues from the sale of our platelet and plasma systems in a number of countries around the world including those in Europe, the CIS and the Middle East. If we are unable to gain widespread commercial adoption in markets where our blood safety products are approved for commercialization, including the U.S., we will have difficulties achieving profitability. In order to commercialize all of our products and product candidates, we will be required to conduct significant research, development, preclinical and clinical evaluation, commercialization and regulatory compliance activities for our products and product candidates, which, together with anticipated selling, general and administrative expenses, are expected to result in substantial losses. Accordingly, we may never achieve a profitable level of operations in the future.

Aduro Biotech

We maintain an investment in Aduro Biotech, Inc., or Aduro, historically carried under the cost basis of accounting and carried at zero on our unaudited condensed consolidated balance sheets. In April 2015, Aduro s common stock began trading on the NASDAQ Global Select Market under the symbol ADRO . At the time of Aduro s initial public offering, our preferred shares in Aduro converted to 396,700 shares of common stock. The initial public offering price was $17.00 per share. As a result of the initial public offering, we no longer account for the investment in Aduro under the cost basis of accounting but reflect the investment as an available-for-sale security on our consolidated balance sheet. We will adjust the investment to fair value each quarterly reporting period with changes in fair value recorded within other comprehensive income (loss), net of tax.

Fresenius

We pay royalties to Fresenius Kabi AG, or Fresenius, on INTERCEPT Blood System product sales under certain agreements that arose from the sale of the transfusion therapies division of Baxter International Inc., or Baxter, in 2007 to Fenwal Inc., or Fenwal (Fenwal was subsequently acquired by Fresenius in 2012), at rates that vary by product: 10% of product sales for the platelet system and 3% of product sales for the plasma system. Fresenius has assumed Fenwal s rights and obligations under those agreements, including our manufacturing and supply agreement. In this report, references to Fresenius include references to its predecessors-in-interest, Fenwal and Baxter.

In November 2013, we amended our manufacturing and supply agreement with Fresenius with the new terms effective January 1, 2014. Under the amended agreement, Fresenius is obligated to sell, and we are obligated to purchase up to a certain specified annual volume of finished disposable kits for the platelet and plasma systems from Fresenius for both clinical and commercial use. Once the specified annual volume of disposable kits is purchased from Fresenius, we are able to purchase additional quantities of disposable kits from other third-party manufacturers. The amended terms also provide for fixed pricing for finished kits with successive decreasing pricing tiers at various annual production volumes. At the current and expected near term production volumes, pricing is expected to be at the lowest tier. In addition, the amendment requires us to purchase additional specified annual volumes of sets if and when an additional Fresenius manufacturing site is identified and qualified to make INTERCEPT disposable kits, subject to mutual agreement on pricing for disposable kits manufactured at the additional site. Fresenius is also obligated to purchase and maintain specified inventory levels of our proprietary inactivation compounds and compound adsorption devices from us at fixed prices. The term of the amended manufacturing and supply agreement with Fresenius extends through December 31, 2018, subject to termination by either party upon thirty months prior written notice, in the case

of Fresenius, or twenty-four months prior written notice, in our case. We and Fresenius each have normal and customary termination rights, including termination for material breach. In October 2014, Fresenius announced plans to cease manufacturing certain of its non-Cerus product lines and to significantly reduce its workforce at the manufacturing facility at which our products are made. We do not currently have plans to terminate our amended manufacturing and supply agreement with Fresenius and understand that Fresenius currently plans to continue operating under the amended agreement. However, in the event Fresenius refuses or is unable to continue operating under the amended agreement, we may be unable to maintain inventory levels or otherwise meet customer demand, and our business and operating results would be materially and adversely affected. Likewise, if we conclude that supply of the INTERCEPT Blood System or components from Fresenius and others is uncertain, we may choose to build and maintain inventories of raw materials, work-in-process components, or finished goods, which would consume capital resources faster than we anticipate and may cause our supply chain to be less efficient.

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Equity and Debt Agreements

Cantor

On March 21, 2014, we entered into Amendment No. 1 to the Controlled Equity Offering℠ Sales Agreement, dated August 31, 2012, which we refer to as the Amended Cantor Agreement, with Cantor Fitzgerald & Co. or Cantor, that provides for the issuance and sale of shares of our common stock over the term of the Amended Cantor Agreement having an aggregate offering price of up to $70.0 million through Cantor. Under the Amended Cantor Agreement, Cantor acts as our sales agent and receives compensation based on an aggregate of 2% of the gross proceeds on the sale price per share of our common stock. The issuance and sale of these shares by us pursuant to the Amended Cantor Agreement are deemed an at-the-market offering and are registered under the Securities Act of 1933, as amended. At June 30, 2015, we had approximately $22.5 million of common stock available to be sold under the Cantor Agreement, subject to the continued effectiveness of our current shelf registration statement or an effective replacement registration statement.

Debt Agreement

On June 30, 2014, we entered into a five year loan and security agreement with Oxford Finance, or the Term Loan Agreement, to borrow up to $30.0 million in term loans in three equal tranches, or the Term Loans. On June 30, 2014, we received $10.0 million from the first tranche, or Term Loan A. On June 15, 2015, we received $10.0 million from Term Loan B. The third tranche of $10.0 million, or Term Loan C, will be available from July 1, 2015 through December 31, 2015, contingent upon our achieving trailing six months revenue at a specified threshold, or Revenue Event. Term Loan A bears an interest rate of 6.95%, and Term Loan B bears an interest rate of 7.01%. Term Loan C will bear an interest rate calculated at the greater of 6.95% or 6.72% plus the three month U.S. London Interbank Offered Rate, or LIBOR in effect three business days prior to the applicable funding date. All of the Term Loans mature on June 1, 2019. We are required to make interest only payments through December 2015 followed by forty-two months of equal principal and interest payments thereafter; however, if the Revenue Event is achieved no later than November 30, 2015, then the interest-only period may be extended through December 31, 2016, and the amortization period will be reduced to thirty months. We are also required to make a final payment equal to 7% of the principal amounts of the Term Loans drawn payable on the earlier to occur of maturity or prepayment. We pledged all current and future assets, excluding our intellectual property and 35% of our investment in our subsidiary, Cerus Europe B.V., as security for borrowings under the Term Loan Agreement. The Term Loan Agreement contains certain nonfinancial covenants, with which we were in compliance at June 30, 2015. For additional discussion on the Term Loan Agreement, see *Commitments and Off-Balance Sheet Arrangements Debt*.

Critical Accounting Policies and Management Estimates

Critical accounting policies are those that require significant judgment and/or estimates by management at the time that the financial statements are prepared such that materially different results might have been reported if other assumptions had been made. We consider certain accounting policies related to revenue recognition, inventory, accrued expenses, goodwill and intangible assets, warrants, stock-based compensation and income taxes to be critical policies. There have been no changes to our critical accounting policies since we filed our 2014 Form 10-K with the SEC on March 16, 2015. For a description of our critical accounting policies, please refer to our 2014 Annual Report on Form 10-K.

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Results of Operations

Three and Six Months Ended June 30, 2015 and 2014

Revenue

(in thousands, except percentages)	Three Months Ended June 30, 2015	2014	Change		Six Months Ended June 30, 2015	2014	Change	
Revenue	$ 8,830	$ 8,601	$ 229	3%	$ 16,522	$ 16,467	$ 55	0%

Revenue increased slightly during the three and six months ended June 30, 2015, compared to the three and six months ended June 30, 2014, primarily as a result of higher unit sales volume of our disposable platelet and plasma system kits, partially offset by the deterioration in the Euro relative to the U.S. dollar in 2015 as compared to 2014 of approximately 19% for three and six months ended June 30, relative to the corresponding prior periods as most revenue has been invoiced and transacted in Euro, and accordingly reported revenues is in U.S. dollars.

We anticipate product revenue for both our platelet and plasma systems will increase in future periods as the INTERCEPT Blood System gains market acceptance in geographies where commercialization efforts are underway, including anticipated contribution from U.S. sales. However, continued deterioration in the Euro relative to the U.S. dollar would continue to adversely impact product revenue. As a result of these and other factors, the historical results may not be indicative of INTERCEPT Blood System revenue in the future.

Cost of Revenue

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

(in thousands, except percentages)	Three Months Ended June 30, 2015	2014	Change		Six Months Ended June 30, 2015	2014	Change	
Cost of revenue	$7,028	$4,752	$2,276	48%	$11,742	$8,909	$2,833	32%

Cost of revenue increased during the three and six months ended June 30, 2015 compared to the three and six months ended June 30, 2014. These increases were primarily the result of higher unit sales volume coupled with inventory produced during periods of less favorable foreign currency exchange rates, and increased obsolescence and manufacturing charges in the current period.

Our realized gross margin on product sales was 20% during the three months ended June 30, 2015, down from 45% during the three months ended June 30, 2014. Our realized gross margin on product sales was 29% during the six months ended June 30, 2015, down from 46% during the six months ended June 30, 2014. The decrease in gross margins on sales was primarily due to the deterioration in the Euro relative to the U.S. dollar on current period cost of revenues which were recorded at foreign exchange rates in effect at the time the inventory was purchased. In addition, increased obsolescence and manufacturing charges resulted in the overall decrease in gross margins for three and six months ended June 30, 2015, relative to the corresponding prior periods.

Changes in our gross margins are affected by various factors, including the exchange rate of the Euro relative to the U.S. dollar, manufacturing and supply chain costs, the mix of product sold, and the mix of customers to which product is sold. Generally, we offer our distributors tiered volume discounts of varying magnitudes, depending on their annual purchases. We may encounter unforeseen manufacturing difficulties which, at a minimum, may lead to higher than anticipated costs, scrap rates, manufacturing overhead variances or delays in manufacturing products. Our gross margins may be impacted in the future based on all of these criteria.

We expect to maintain inventory levels that will be sufficient to meet forecasted demand for a relatively short time period and plan to manufacture at levels above those produced in 2014. Manufacturing disposable kits at levels above the levels produced in 2014 should result in a continuing lower per unit cost of goods sold when the product is ultimately sold; however, actual manufacturing levels may differ from our assumptions.

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Research and Development Expenses

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

	Three Months Ended June 30,				Six Months Ended June 30,			
(in thousands, except percentages)	**2015**	**2014**	**Change**		**2015**	**2014**	**Change**	
Research and development	$5,213	$4,722	$491	10%	$10,794	$9,364	$1,430	15%

Research and development expenses increased during the three and six months ended June 30, 2015, compared to the three and six months ended June 30, 2014, primarily due to increased costs associated with pursuing potential label claim extensions for the platelet and plasma systems and conducting our IDE studies in 2015.

We anticipate our research and development spending will continue to increase over the near term as we attempt to accelerate and complete enrollment in our Phase III chronic anemia clinical trial in Europe and as we undertake research and development activities, including additional *in vitro* studies, to potentially expand our label claims in the United States and further develop additional configurations or redesigns of our existing products, including a full or partial redesign of the INTERCEPT illuminator. In addition, we have undertaken and plan to perform certain additional clinical development in the U.S. which would result in further increased research and development spending. Due to the inherent uncertainties and risks associated with developing biomedical products, including, but not limited to, intense and changing government regulation, uncertainty of future preclinical studies and clinical trial results and uncertainty associated with manufacturing, it is not possible to reasonably estimate the costs to complete these research and development projects. We face numerous risks and uncertainties associated with the successful completion of our research and development projects, which risks and uncertainties are discussed in further detail under Item 1A *Risk Factors* in Part II of this Quarterly Report on Form 10-Q.

Selling, General, and Administrative Expenses

Selling, general, and administrative expenses include salaries and related expenses for administrative personnel, non-cash stock based compensation, expenses for our commercialization efforts in a number of countries around the world including those in U.S., Europe, the CIS and the Middle East, Asia, Latin America, and expenses for accounting, tax, and internal control, legal and facility and infrastructure related expenses, and insurance premiums.

	Three Months Ended June 30,				Six Months Ended June 30,			
(in thousands, except percentages)	**2015**	**2014**	**Change**		**2015**	**2014**	**Change**	
Selling, general and administrative	$12,063	$10,080	$1,983	20%	$23,781	$18,316	$5,465	30%

Selling, general, and administrative expenses increased during the three and six months ended June 30, 2015, compared to the three and six months ended June 30, 2014, primarily due to increased spending related to general corporate services activities for the U.S. launch of our plasma and platelet products.

We anticipate our selling, general, and administrative spending to increase over the coming year, as we continue to on-board commercial capabilities in the U.S., including incremental back-office support, sales and marketing and medical science liaisons to educate hospitals and physicians on our products.

Amortization of Intangible Assets

Amortization of intangible assets relates to a license to commercialize the INTERCEPT Blood System in certain Asian countries. These intangible assets are being amortized over an estimated useful life of ten years and will be reviewed for impairment.

	Three Months Ended June 30,				Six Months Ended June 30,			
(in thousands, except percentages)	**2015**	**2014**	**Change**		**2015**	**2014**	**Change**	
Amortization of intangible assets	$51	$51	$	0%	$101	$101	$	0%

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Amortization of intangible assets remained flat during the three and six months ended June 30, 2015, compared to the three and six months ended June 30, 2014.

We expect that the amortization of our intangible assets to remain relatively consistent in future periods, unless facts and circumstances arise which may result in our intangible assets being impaired.

Non-Operating (Expense) Income, Net

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

	Three Months Ended June 30,				Six Months Ended June 30,			
(in thousands, except percentages)	**2015**	**2014**	**Change**		**2015**	**2014**	**Change**	
(Loss) gain from revaluation of warrant liability	$ (2,707)	$ 3,491	$ (6,198)	(178)%	$ 3,589	$ 12,525	$ (8,936)	(71)%
Foreign exchange gain (loss)	499	(25)	524	(2,096)%	(614)	(4)	(610)	15,250%
Interest expense	(301)	(34)	(267)	785%	(556)	(84)	(472)	562%
Other income, net	27	27		0%	29	54	(25)	(46)%
Total non-operating (expense) income, net	$ (2,482)	$ 3,459	$ (5,941)	(172)%	$ 2,448	$ 12,491	$ (10,043)	(80)%

Gain from revaluation of Warrant liability

In August 2009 and November 2010, we issued warrants to purchase an aggregate of 2.4 million and 3.7 million shares of common stock, respectively, in connection with offerings of our common stock. In August 2014, all 2.4 million warrants issued in August 2009 were exercised. The fair value of the November 2010 outstanding warrants, which uses the Black-Scholes model, is classified as a liability on our unaudited condensed consolidated balance sheets and is adjusted at each subsequent reporting period, until such time the instruments are exercised or otherwise modified to remove the provisions which require this treatment. Upon the exercise or modification to remove the provisions which require the warrants to be treated as a liability, the fair value of the warrants will be reclassified from liabilities to stockholders equity and no further adjustment to the fair value would be made in subsequent periods. Further changes in stock price will result in similar adjustment as needed.

We recorded a $2.7 million non-cash loss from the revaluation of the warrant liability during the three months ended June 30, 2015, compared to a $3.5 million non-cash gain during the three months ended June 30, 2014, and a $3.6 million non-cash gain during the six months ended June 30, 2015, compared to a $12.5 million non-cash gain during the six months ended June 30, 2014.

Foreign exchange (loss) gain

We recorded a foreign exchange gain during the three months ended June 30, 2015, compared to a foreign exchange loss during the three months ended June 30, 2014, primarily attributable to favorable foreign currency variations

between the Euro and U.S. dollar. Foreign exchange loss increased during the six months ended June 30, 2015, compared to the six months ended June 30, 2014, primarily attributable to unfavorable foreign currency variations between the Euro and U.S. dollar.

Other income, net

Other income, net remained flat for the three months ended June 30, 2015 compared to the three months ended June 30, 2014 and decreased slightly for the six months ended period over period, primarily as a result of higher Delaware Franchise tax costs period over period.

Interest expense

Interest expense increased for the three and six months ended June 30, 2015 compared to the three and six months ended June 30, 2014, primarily due a higher effective interest rate and larger outstanding debt balance under our Term Loan Agreement (see Debt section below), which we entered into on June 30, 2014 and June 15, 2015, compared to the credit facility that was outstanding in the prior periods.

Provision for Income Taxes

For the three months ended June 30, 2015, we recorded a tax benefit of $2.0 million and for the three months ended June 30, 2014, we recorded a tax provision of approximately $40,000. For the six months ended June 30, 2015, we recorded a tax benefit of $2.0 million and for the six months ended June 30, 2014, we recorded a tax provision of $0.1 million. The tax benefits recognized during the three and six months ended June 30, 2015 are the result of intra period allocation rules associated with the unrealized increase in the fair value of our investment in Aduro. These tax benefits are partially offset by the tax provision recorded in other comprehensive income which is also associated with the increased value of our Aduro investment.

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We do not provide for U.S. income taxes on undistributed earnings of our foreign operations as we intend to permanently reinvest such earnings outside the U.S. Due to our history of cumulative operating losses, management has concluded that, after considering all the available objective evidence, it is not likely that all our net deferred tax assets will be realized. Accordingly, all of our U.S. deferred tax assets continue to be subject to a valuation allowance as of June 30, 2015.

As of June 30, 2015, there have been no material changes to our total amount of unrecognized tax benefits.

Liquidity and Capital Resources

In recent years, our sources of capital have primarily consisted of public issuance of common stock, debt instruments, and to a lesser extent, contribution from product sales.

At June 30, 2015, we had cash and cash equivalents of $35.1 million, compared to $22.8 million at December 31, 2014. We had $87.9 million of short-term investments at June 30, 2015, and $28.5 million at December 31, 2014. We also had total indebtedness under our Term Loan Agreement of approximately $19.9 million at June 30, 2015, and $9.9 million at December 31, 2014. Our cash equivalents primarily consist of money market instruments, which are classified for accounting purposes as available-for-sale. Excess cash is typically invested in highly liquid instruments of short-term investments with high-quality credit rated corporate and government agency fixed-income securities in accordance with our investment policy. In addition, at June 30, 2015, the Company s short-term investments included $12.0 million related to the Company s investment in Aduro.

Operating Activities

Net cash used in operating activities was $30.5 million during the six months ended June 30, 2015, compared to $19.4 million during the six months ended June 30, 2014. The increase in net cash used in operating activities was primarily related to the level of cash spent for development activities for our red blood cell program, support of our IDE studies, and selling and administrative expenses related to the U.S. commercial launch of our platelet and plasma systems. Also impacting this increase in net cash used in operating activities were changes in working capital resulting from a net decrease in the combined total for our accounts payable and accrued liabilities due to of the timing of payments and increased activities, and a decrease in accounts receivable collections during the six months ended June 30, 2015, as compared to the corresponding period in 2014.

Investing Activities

Net cash used in investing activities was $48.0 million for the six months ended June 30, 2015, compared to $5.4 million net cash provided by investing activities during the six months ended June 30, 2014. The period-over-period change was primarily the result of investing the proceeds from our January 2015 public offering, offset by fewer capital expenditures during the six months ended June 30, 2015, as compared to the corresponding period in 2014.

Financing Activities

Net cash provided by financing activities was $90.7 million during the six months ended June 30, 2015, compared to $13.1 million during the six months ended June 30, 2014. The increase in net cash provided by financing activities was primarily due to the proceeds received from common stock sales related to our January 2015 public offering. The net proceeds from this offering were approximately $75.3 million, net of underwriting discounts and other issuance costs. This was further increased by our drawdown of Term Loan B of $10.0 million in June 2015, and by higher proceeds from our warrant exercises and equity incentive plans during the six months ended June 30, 2015, as

compared to the corresponding period in 2014.

Working Capital

Working capital increased to $122.2 million at June 30, 2015, from $45.7 million at December 31, 2014, primarily due to increases in short term investments due to the investment of funds from the January 2015 public offering and our equity investment in Aduro common stock resulting from Aduro s initial public offering in April 2015, coupled with a decrease in the fair value of our warrant liability.

Capital Requirements

Our near-term capital requirements are dependent on various factors, including operating costs and working capital investments associated with commercializing the INTERCEPT Blood System, including in connection with the continuing U.S. commercial launch of our platelet and plasma systems, costs associated with planning, enrolling and completing the ongoing studies under our IDEs and the post-approval study we are required to conduct in connection with the FDA approval of the platelet system, costs associated with pursuing potential regulatory approvals in other geographies where we do not currently sell our platelet and plasma systems, costs associated with conducting *in vitro* studies and clinical development of our red blood cell system in Europe and the U.S., including our

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ongoing European Phase III clinical trial of our red blood cell system for chronic anemia patients, and costs related to creating, maintaining and defending our intellectual property. Our long-term capital requirements will also be dependent on the success of our sales efforts, competitive developments, the timing, costs and magnitude of our longer-term clinical trials and other development activities related to our platelet, plasma and red blood cell systems, including the post-approval study for the platelet system, market preparedness and product launch activities for any of our products in geographies where we do not currently sell our products, and regulatory factors. Until we are able to generate a sufficient amount of product revenue and generate positive net cash flows from operations, which we may never do, meeting our long-term capital requirements is in large part reliant on access to public and private equity and debt capital markets, as well as on collaborative arrangements with partners, augmented by cash generated from operations and interest income earned on the investment of our cash balances. We believe that our available cash and cash equivalents and short-term investments, as well as cash received from product sales, will be sufficient to meet our capital requirements for at least the next twelve months. We have based our cash sufficiency estimate on assumptions that may prove to be incorrect. If our assumptions prove to be incorrect, we could consume our available capital resources sooner than we currently expect or in excess of amounts than we currently expect, which could adversely affect our commercialization and clinical development activities.

We have borrowed and in the future may borrow additional capital from institutional and commercial banking sources to fund future growth, including pursuant to our loan and security agreement with Oxford Finance as described below or potentially pursuant to new arrangements with different lenders. We may borrow funds on terms that may include restrictive covenants, including covenants that restrict the operation of our business, liens on assets, high effective interest rates and repayment provisions that reduce cash resources and limit future access to capital markets. In addition, we expect to continue to opportunistically seek access to the equity capital markets to support our development efforts and operations. To the extent that we raise additional capital by issuing equity securities, our stockholders may experience substantial dilution. To the extent that we raise additional funds through collaboration or partnering arrangements, we may be required to relinquish some of our rights to our technologies or rights to market and sell our products in certain geographies, grant licenses on terms that are not favorable to us, or issue equity that may be substantially dilutive to our stockholders.

As a result of economic conditions, general global economic uncertainty and other factors, we do not know whether additional capital will be available when needed, or that, if available, we will be able to obtain additional capital on reasonable terms. If we are unable to raise additional capital due to disruptions to the global credit and financial markets, general economic uncertainty or other factors, we may need to curtail planned development or commercialization activities. Apart from the ongoing studies under our IDEs, we do not plan on conducting any additional randomized controlled clinical trials of the red blood cell, platelet or plasma systems unless and until we can obtain sufficient additional funding or, at such time, our existing operations provide sufficient cash flow to conduct these trials.

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Commitments and Off-Balance Sheet Arrangements

Off-balance sheet arrangements

We did not have any off-balance sheet arrangements as of June 30, 2015.

Contractual Commitments

The following summarizes our contractual commitments at June 30, 2015:

	Total	< 1 year	1-3 years	4-5 years	After 5 years
Minimum purchase requirements	$ 6,891	$ 5,001	$ 1,890	$	$
Debt	24,640	3,868	12,915	7,857	
Operating leases	2,007	945	889	173	
Other commitments	670	179	287	204	
Total contractual obligations	$ 34,208	$ 9,993	$ 15,981	$ 8,234	$

Minimum purchase requirements

Our minimum purchase commitments include certain components of our INTERCEPT Blood System which we purchase from third party manufacturers.

Operating leases

We generally lease our office facilities and certain equipment under non-cancelable operating leases with initial terms in excess of one year that require us to pay operating costs, property taxes, insurance and maintenance. The operating leases expire at various dates through 2019, with certain of the leases providing for renewal options, provisions for adjusting future lease payments, which is based on the consumer price index and the right to terminate the lease early. In June 2013 we entered into a lease for additional space in Concord. The lease initially had a two-year term with four two-year options we may renew, the first of which we exercised in March 2015. Our leased facilities qualify as operating leases under ASC Topic 840, *Leases* and as such, are not included on our consolidated balance sheets.

Other commitments

Our other commitments primarily consist of obligations for landlord financed leasehold improvements, which are in addition to the operating leases we have for office and laboratory space. We pay for the financed leasehold improvements as a component of rent and are required to reimburse our landlords over the remaining life of the respective leases. If we exercise our right to early terminate the Concord, California lease, we would be required to pay for any remaining portion of the landlord financed leasehold improvements at such time. At June 30, 2015, we had an outstanding liability of $0.6 million related to these leasehold improvements. Our agreements with Fresenius require us to pay royalties on sales of the INTERCEPT Blood System at rates that vary by product: 10% of product sales for the platelet system and 3% of product sales for the plasma system. Such royalties are calculated based on future product sales and are not provided for in the table above as they are dependent on events that have not yet occurred.

Debt

On June 30, 2014, we entered into the Term Loan Agreement with Oxford Finance to borrow up to $30.0 million in term loans in three equal tranches of Term Loans. On June 30, 2014, we received $10.0 million from Term Loan A. On June 15, 2015, we received $10.0 million from Term Loan B. The third tranche of $10.0 million, Term Loan C, will be available from July 1, 2015 through December 31, 2015, contingent upon our achieving the Revenue Event. Term Loan A bears an interest rate of 6.95%, and Term Loan B bears an interest rate of 7.01%. Term Loan C will bear an interest rate calculated at the greater of 6.95% or 6.72% plus the three month U.S. LIBOR rate in effect three business days prior to the applicable funding date. All of the Term Loans mature on June 1, 2019. We are required to make interest only payments through December 2015 followed by forty-two months of equal principal and interest payments thereafter; however, if the Revenue Event is achieved no later than November 30, 2015, then the interest-only period may be extended through December 31, 2016, and the amortization period will be reduced to thirty months. We are also required to make a final payment equal to 7% of the principal amounts of the Term Loans drawn payable on the earlier to occur of maturity or prepayment. The costs associated with the final payment will be recognized as interest expense over the principle life of the Term Loans. We may prepay the Term Loans subject to declining prepayment fees over the term of the Term Loan Agreement. We paid the lender a $0.2 million commitment fee related to the Term Loan Agreement which has been recorded as a discount on the Term Loans and is being amortized to interest expense using the effective interest method over the life of the Term Loans. The Term Loan Agreement contains certain nonfinancial covenants, with which we were in compliance at June 30, 2015. We pledged all current and future assets, excluding our intellectual property and 35% of our investment in our subsidiary, Cerus Europe B.V., as security for borrowings under the Term Loan Agreement. All principal and interest payments related to Term Loan have been included in the table above.

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Our ability to access the final $10.0 million under the loan and security agreement is subject to our ability to achieve the Revenue Event, which condition we may not be able to meet, which could adversely affect our liquidity. In addition, although we expect to borrow the final $10.0 million from Term Loan C, subject to achievement of the Revenue Event, before we do so, we must first satisfy ourselves that we will have access to future alternate sources of capital, including cash flow from our own operations, equity capital markets or debt capital markets in order to repay any principal borrowed, which we may be unable to do, in which case, our liquidity and ability to fund our operations may be substantially impaired.

Financial Instruments

Our investment policy is to manage our marketable securities portfolio to preserve principal and liquidity while maximizing the return on the investment portfolio to assist us in funding our operations. We currently invest our cash and cash equivalents in money market funds and interest-bearing accounts with financial institutions. Our money market funds are classified as Level 1 in the fair value hierarchy, in which quoted prices are available in active markets, as the maturity of money market funds are relatively short and the carrying amount is a reasonable estimate of fair value. As a result of Aduro s IPO in April 2015, our common shares of Aduro are designated as available-for-sale securities and classified as Level 1 in the fair value hierarchy using its stock price in the market. Historically, our available-for-sale securities related to corporate debt and U.S. government agency securities were classified as Level 2 in the fair value hierarchy, which uses observable inputs to quoted market prices, benchmark yields, reported trades, broker/dealer quotes or alternative pricing sources with reasonable levels of price transparency. We maintain portfolio liquidity by ensuring that the securities have active secondary or resale markets. We did not record any other-than-temporary impairment losses during the three and six months ended June 30, 2015 or the year ended December 31, 2014. Adverse global economic conditions, including the sovereign debt crisis in Europe, have had, and may continue to have, a negative impact on the market values of potential investments.

New Accounting Pronouncements

In May 2014, the Financial Accounting Standards Board, or FASB, issued Accounting Standards Update, or ASU, No. 2014-09, *Revenue from Contracts with Customers* (Topic 606), which provides a single comprehensive model for entities to use in accounting for revenue arising from contracts with customers and will supersede most current revenue recognition guidance. This ASU is based on the principle that revenue is recognized to depict the transfer of goods or services to customers in an amount that reflects the consideration to which the entity expects to be entitled in exchange for those goods or services. The ASU also requires additional disclosure about the nature, amount, timing and uncertainty of revenue and cash flows arising from customer contracts, including significant judgments and changes in judgments and assets recognized from costs incurred to obtain or fulfill a contract. In July 2015, the FASB deferred the effective date for annual reporting periods beginning after December 15, 2017 (including interim periods within those periods). Early adoption is permitted to the original effective date of December 15, 2016 (including interim periods within those periods). The ASU s effective date for us will be the first quarter of fiscal year 2018, using one of two retrospective application methods. We have not selected a transition method and are currently assessing the potential effects of this ASU on our unaudited condensed consolidated financial statements.

In August 2014, the FASB issued ASU No. 2014-15, *Presentation of Financial Statements Going Concern* (Subtopic 205-40): Disclosure of Uncertainties about an Entity s Ability to Continue as a Going Concern, which requires management to evaluate, in connection with preparing financial statements for each annual and interim reporting period, whether there are conditions or events, considered in the aggregate, that raise substantial doubt about an entity s ability to continue as a going concern within one year after the date that the financial statements are issued and provide related disclosures. This ASU will be effective for us in fiscal year 2016. Early adoption is permitted. We are currently assessing the future impact of this ASU on our unaudited condensed consolidated financial statements.

In April 2015, the FASB issued ASU No. 2015-03, *Interest Imputation of Interest* (Subtopic 835-30): *Simplifying the Presentation of Debt Issuance Costs*, which requires debt issuance costs related to a recognized debt liability to be presented in the balance sheet as a direct deduction from the corresponding debt liability rather than as an asset. This ASU will be effective for us in fiscal year 2016. Early adoption is permitted. We are currently assessing the future impact of this ASU on our unaudited condensed consolidated financial statements.

In July 2015, the FASB issued ASU No. 2015-11, *Inventory (Topic 330), Simplifying the Measurement of Inventory*, which simplifies the subsequent measurement of inventory by requiring inventory to be measured at the lower of cost and net realizable value. Net realizable value is defined as the estimated selling prices in the ordinary course of business, less reasonably predictable costs of completion, disposal and transportation. This ASU will be effective for us in fiscal year 2017. Early adoption is permitted. We are currently assessing the future impact of this ASU on its unaudited condensed consolidated financial statements.

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ITEM 3. QUANTITATIVE AND QUALITATIVE DISCLOSURES ABOUT MARKET RISK

During the six months ended June 30, 2015, there were no material changes to our market risk disclosures as set forth under, Item 7A *Quantitative and Qualitative Disclosures About Market Risk*, in Part II of our Annual Report on Form 10-K for the year ended December 31, 2014.

ITEM 4. CONTROLS AND PROCEDURES

Evaluation of Disclosure Controls and Procedures. Our principal executive officer and principal financial officer are responsible for establishing and maintaining disclosure controls and procedures (as defined in Rules 13a-15(e) and 15d-15(e), promulgated under the Securities Exchange Act of 1934, as amended) for our company. Based on their evaluation of our disclosure controls and procedures as of the end of the period covered by this Quarterly Report on Form 10-Q, our principal executive officer and principal financial officer have concluded that, due to reported material weaknesses in internal control over financial reporting, as previously disclosed in our Annual Report on Form 10-K for the year ended December 31, 2014 and as described below, our disclosure controls and procedures were not effective as of June 30, 2015.

Previously Reported Material Weaknesses

A material weakness is a deficiency, or a combination of deficiencies, in internal control over financial reporting, such that there is a reasonable possibility that a material misstatement of our annual or interim financial statements will not be prevented or detected on a timely basis. As previously reported in our Annual Report on Form 10-K for the fiscal year ended December 31, 2014, we identified deficiencies related to the design and operating effectiveness of certain controls over (i) the valuation of our inventory and cost of product revenue as reported on our consolidated balance sheets and statements of operations; and (ii) the timeliness and accuracy of recording adjustments to certain accrued liabilities reported on our consolidated balance sheets and statements of operations, in each case, as further described below.

We are in the process of implementing plans to remediate our material weaknesses. In this regard, we are in the process of developing specific controls to: (i) provide reasonable assurance that inventory is valued under a first-in-first-out basis and utilizes appropriate historical foreign exchange rates at the time inventory is purchased if still on hand at each balance sheet date and further to ensure that product sold during any reporting period is recorded under appropriate first-in-first-out accounting at historical rates; and (ii) modify and expand our internal controls over timely and accurate identification of adjustments to accruals based on information received after year-end. The successful remediation of these material weaknesses will require review and evidence of the effectiveness of the related internal controls as part of our next annual assessment of our internal controls over financial reporting as of December 31, 2015. As we continue these remediation efforts, we may determine that additional measures should be taken to address these or other control deficiencies, and/or that we should modify the remediation plan described above. Once the new controls are placed in operation for a sufficient period of time, we will subject the new controls procedures to appropriate tests, in order to determine whether they are operating effectively.

Changes in Internal Control over Financial Reporting. Except as described above under Previously Reported Material Weaknesses, there were no changes in our internal control over financial reporting which occurred during our fiscal quarter ended June 30, 2015, which has materially affected, or is reasonably likely to materially affect, our internal control over financial reporting.

Limitations on the Effectiveness of Controls. A control system, no matter how well conceived and operated, can provide only reasonable, not absolute, assurance that the objectives of the control system are met. Because of the

inherent limitations in all control systems, no evaluation of controls can provide absolute assurance that all control issues, if any, within a company have been detected. Our disclosure controls and procedures are designed to provide reasonable assurance of achieving their objectives; however, as noted above, our principal executive officer and principal financial officer have concluded that our disclosure controls and procedures were not effective at the reasonable assurance level as of June 30, 2015.

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PART II: OTHER INFORMATION

ITEM 1. LEGAL PROCEEDINGS

None.

ITEM 1A. RISK FACTORS

Risk Factors

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

We depend substantially upon the commercial success of the INTERCEPT Blood System for platelets and plasma in the United States, and our inability to successfully commercialize the INTERCEPT Blood System in the United States would have a material adverse affect on our business, financial condition, results of operations and growth prospects.

We have invested a significant portion of our efforts and financial resources on the development of the INTERCEPT Blood System for platelets and plasma for the United States market. As a result, our business is substantially dependent on our ability to successfully commercialize the INTERCEPT Blood System in the United States in a timely manner. We only recently received U.S. regulatory approval of the INTERCEPT Blood System for platelets and plasma and although the INTERCEPT Blood System is now commercially available in the United States, we have no prior experience commercializing any products in the United States and we may be unable to commercialize the INTERCEPT Blood System in the United States successfully or in a timely manner, or at all. Based on our experience in other foreign jurisdictions, potential customers in the United States may first choose to validate our technology or conduct experience studies of the INTERCEPT Blood System, among other things, prior to purchasing or deciding whether to adopt the INTERCEPT Blood System for commercial use, which may never occur. In addition, potential customers must obtain site-specific licenses from the Center for Biologics Evaluation and Research, or CBER, prior to engaging in interstate transport of blood components processed using the INTERCEPT Blood System, which could significantly delay or preclude our ability to successfully commercialize the INTERCEPT Blood System to those customers for the portion of their business involved in interstate commerce. Further, the hospital customers of any of our new blood center customers will need to go through the administrative process of generating internal tracking codes to integrate INTERCEPT-treated products into their inventories, which may result in further delay of customer adoption in the United States. If we are not successful in achieving market adoption of the INTERCEPT Blood System in the United States, we may never generate substantial revenue, and our business, financial condition, results of operations and growth prospects would be materially and adversely affected.

Our ability to successfully commercialize the INTERCEPT Blood System for platelets and plasma in the United States will depend on our ability to:

achieve market acceptance and generate product sales through execution of sales agreements on commercially reasonable terms;

enter into and maintain sufficient manufacturing arrangements for the U.S. market with our third party suppliers;

create market demand for the INTERCEPT Blood System through our education, marketing and sales activities;

hire, train, deploy and support a qualified U.S.-based commercial organization and field sales force;

expand the labeled indications of use for the INTERCEPT Blood System and/or design, develop and test new product configurations;

comply with requirements established by the FDA, including post-marketing requirements and label restrictions; and

comply with other U.S. healthcare regulatory requirements.

In addition to the other risks described herein, our ability to successfully commercialize the INTERCEPT Blood System for platelets and plasma in the United States is subject to a number of risks and uncertainties, including those related to:

the highly concentrated U.S. blood collection market that is dominated by a small number of blood collection organizations;

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- regulatory and licensing requirements, including the CBER licensing process that U.S.-based blood centers will need to follow in order to obtain the required site-specific licenses to engage in interstate transport of blood components processed using the INTERCEPT Blood System;

- changed or increased regulatory restrictions or requirements;

- obtaining reimbursement codes under the Healthcare Common Procure Coding System, or HCPCS, and pricing for outpatient use of INTERCEPT-treated blood components;

- any supply or manufacturing problems or delays arising with any of our suppliers, many of whom are our sole suppliers for the particular product or component they manufacture, including the ability of such suppliers to maintain FDA approval to manufacture the INTERCEPT Blood System and to comply with FDA-mandated current Good Manufacturing Practice, or cGMP, and Quality System Regulation, or QSR, requirements;

- changes in healthcare laws and policy, including changes in requirements for blood product coverage by U.S. federal healthcare programs; and

- acceptance of the INTERCEPT Blood System as safe, effective and economical from the broad constituencies involved in the healthcare system.

In addition to the above, our ability to successfully commercialize the INTERCEPT Blood System in the United States is dependent on our ability to operate without infringing on the intellectual property rights of others. For example, we are aware of a United States patent issued to a third-party that covers methods to remove psoralen compounds from blood products. We have reviewed the patent and believe there exists substantial questions concerning its validity. We cannot be certain, however, that a court would hold the patent to be invalid or not infringed by our platelet or plasma systems. In this regard, whether or not we infringe this patent will not be known with certainty unless and until a court interprets the patent in the context of litigation. In the event that we are found to infringe any valid claim of this patent, we may, among other things, be required to pay damages, cease the use and sale of our platelet and plasma systems and/or obtain a license from the owner of the patent, which we may not be able to do at a reasonable cost or at all.

These and the other risks described below related to the commercialization of the INTERCEPT Blood System could have a material adverse effect on our ability to successfully commercialize the INTERCEPT Blood System for platelets and plasma in the United States.

The INTERCEPT Blood System may not achieve broad market adoption.

In order to increase market adoption of the INTERCEPT Blood System and to create market demand in the United States, we must address issues and concerns from broad constituencies involved in the healthcare system, from blood centers to patients, transfusing physicians, key opinion leaders, hospitals, private and public sector payors, regulatory bodies and public health authorities. We may be unable to demonstrate to these constituencies that the INTERCEPT Blood System is safe, effective and economical or that the benefits of using the INTERCEPT Blood System products justify their cost and outweigh their risks.

The use of the platelet system results in some processing loss of platelets. If the loss of platelets leads to increased costs for our customers, our customers or prospective customers believe that the loss of platelets reduces the efficacy of the transfusion unit, or our process requires changes in blood center or clinical regimens, prospective customers may not adopt our platelet system. Certain studies have indicated that transfusion of conventionally prepared platelets may yield higher post-transfusion platelet counts (according to a measurement called corrected count increment) and may be more effective than transfusion of INTERCEPT-treated platelets. Although certain other studies demonstrate that INTERCEPT-treated platelets retain therapeutic function comparable to conventional platelets, prospective customers may choose not to adopt our platelet system due to considerations relating to corrected count increment or efficacy.

The INTERCEPT Blood System does not inactivate all known pathogens, and the inability of the INTERCEPT Blood System to inactivate certain pathogens may limit its market adoption. For example, our products have not been demonstrated to be effective in the reduction of certain non-lipid-enveloped viruses, including hepatitis A and E viruses, due to these viruses biology. In addition, our products have not demonstrated a high level of reduction for human parvovirus B-19, which is also a non-lipid-enveloped virus. Although we have shown high levels of reduction of a broad spectrum of lipid-enveloped viruses, prospective customers may choose not to adopt our products based on considerations concerning inability to inactivate, or limited reduction, of certain non-lipid-enveloped viruses. Similarly, although our products have been demonstrated to effectively inactivate spore-forming bacteria, our products have not shown to be effective in inactivating bacterial spores once formed. In addition, our products do not inactivate prions since prions do not contain nucleic acid. While transmission of prions has not been a major problem in blood transfusions, and we are not aware of any competing products that inactivate prions, the inability to inactivate prions may limit market adoption of our products. Furthermore, due to limitations of detective tests, we cannot exclude that a sufficient quantity of pathogen or pathogens may still be present in active form, which could present a risk of infection to the transfused patient. Such uncertainty may limit the market adoption of our products.

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We submitted and received approval from the FDA for a Phase I clinical study protocol under an investigational device exemption, or IDE, to treat plasma derived from convalesced patients that were previously infected with the Ebola virus and have recovered from the disease according to the criteria set by the Centers for Disease Control and Prevention. The transfusion of convalesced plasma from Ebola survivors is believed to pass on antibodies to the disease from the survivor to the recipient of the plasma transfusion. INTERCEPT use under this IDE is limited to pathogen reduction claims that rely on existing clinical data that we have regarding reduction of certain pathogens in donated plasma, and we do not have any clinical or commercial data on the efficacy of INTERCEPT to inactivate the Ebola virus and therefore do not know the effectiveness of INTERCEPT to inactivate the Ebola virus. This may negatively impact a customer s desire to adopt INTERCEPT in those countries where addressing the Ebola virus outbreak is the primary concern.

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

If customers experience operational or technical problems with the use of INTERCEPT Blood System products, market acceptance may be reduced or delayed. For example, if adverse events arise from incomplete reduction of pathogens, improper processing or user error, or if testing of INTERCEPT-treated blood samples fails to reliably confirm pathogen reduction, whether or not directly attributable to the INTERCEPT Blood System, customers may refrain from purchasing our products. In addition, there is a risk that further studies that we or others may conduct, including the post-approval study we are required to conduct as a condition to the FDA approval of the platelet system, will show results inconsistent with previous studies. Should this happen, potential customers may delay or choose not to adopt our products and existing customers may cease use of our products. In addition, some hospitals may decide to purchase and transfuse both INTERCEPT-treated blood components and conventional blood components. Managing such a dual inventory of blood products may be challenging; hospitals may need to amend their product labels and inventory management systems before being able to move forward with INTERCEPT. This may require coordination with hospital suppliers and our customers, the blood centers, which in-turn may cause delay in market adoption. Further, in certain markets, potential customers may require us to develop, sell, and support a data management application for their operations before they would consider adopting INTERCEPT. Such development efforts may be costly or we may be unsuccessful in developing a data management application that would be broadly accepted. Failure to do so may limit market adoption in geographies where we commercialize the INTERCEPT Blood System, including the United States.

Market adoption of our products is affected by blood center and healthcare facility budgets and the availability of reimbursement from governments, managed care payors, such as insurance companies, and/or other third parties. In many jurisdictions, due to the structure of the blood products industry, we have little control over budget and reimbursement discussions, which generally occur between blood centers, healthcare facilities such as hospitals, and national or regional ministries of health and private payors. Even if a particular blood center is prepared to adopt the INTERCEPT Blood System, its hospital customers may not accept or may not have the budget to purchase INTERCEPT-treated blood products. Since blood centers would likely not eliminate the practice of screening donors or testing blood for some pathogens prior to transfusion, even after implementing our products, some blood centers may not be able to identify enough cost offsets or hospital pricing increases to afford to purchase our products. Budgetary concerns may be further exacerbated by the economic austerity programs implemented in European countries and by proposals by legislators at both the U.S. federal and state levels, regulators, healthcare facilities and

third party payors to keep healthcare costs down, which may limit the adoption of new technologies, including our products. In some jurisdictions, including the United States, commercial use of our products is not yet subject to reimbursement by governmental or commercial third party payors for health care services and may never be subject to reimbursement. The costs and expenses incurred by the blood center related to donor blood are typically included in the price that the blood center charges a hospital for a unit of blood. Even after blood components treated with our products are approved for reimbursement by governmental or commercial third party payors, the costs and expenses related to use of the INTERCEPT Blood System will not be directly reimbursed, but instead may be incorporated within the reimbursement structure for medical procedures and/or products at the site of patient care. If the costs to the hospital for INTERCEPT-processed blood products cannot be easily, readily, or fully incorporated into the existing reimbursement structure, hospital billing and/or reimbursement for these products could be impacted, thus negatively impacting hospitals acceptance and uptake of our products.

The market for the INTERCEPT Blood System is highly concentrated with few customers, including often-dominant regional or national blood collection entities. Even where our products receive regulatory approval and reimbursement is available, failure to effectively market, promote, distribute, price or sell our products to any of these customers could significantly delay or even diminish potential product revenue in those geographies. In addition, the lack of widespread adoption of the INTERCEPT Blood System has adversely affected and may in the future adversely affect further market adoption of the INTERCEPT Blood System. Moreover, the market for pathogen reduction systems in the United States is highly concentrated and dominated by a small number of blood collection organizations. In the United States, the American Red Cross represents the largest single portion of the blood collection market. Although we currently have an agreement with the American Red Cross to support our IDE study in Puerto Rico to treat

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platelet donations with the INTERCEPT Blood System, there is no guarantee that the American Red Cross will continue to use our products commercially in conjunction with or following our IDE study, even if we successfully enroll and complete this study. In many countries in Western Europe and in Japan, various national blood transfusion services or Red Cross organizations collect, store and distribute virtually all of their respective nations blood and blood components supply. In Europe, the largest markets for our products are in Germany, France, and England. In Germany, decisions on product adoption and subsequent reimbursement are made on a regional or even blood center-by-blood center basis, but depend on both local approvals and centralized regulatory approvals from the Paul Ehrlich Institute, or PEI. Product specifications that receive marketing authorization from the PEI may differ from product specifications that have been adopted in other territories where we rely on CE mark approval, thereby necessitating market specific modifications to the commercial product, which may not be economical or technically feasible for us. While INTERCEPT-treated platelets and plasma have received in-country regulatory approval and reimbursement rates have been established in France, adoption throughout France has been limited to certain blood centers. In 2011, we entered into a two-year contract with the EFS, a public organization responsible for all collection, testing preparation and distribution of blood products in France, to supply platelet and plasma disposable kits, which was extended until November 2015. We understand that the EFS is considering taking action to further protect platelet components from bacterial contamination, including potential use of bacterial culture detection methods or broader use of the platelet system. We cannot provide any assurance that a new supply agreement with the EFS will be entered into prior to the expiration of the current agreement in a timely manner or with reasonable terms, if at all. If we fail to enter into a new supply agreement with the EFS or we enter into a new supply agreement with the EFS with less favorable terms, including pricing, our financial results may be adversely impacted. Decisions on product adoption in England are centralized with the National Blood Service which has implemented bacterial detection testing for platelets instead of pathogen reduction. In Japan, the Japanese Red Cross controls a significant majority of blood transfusions 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 reduction of blood over a number of years and has yet to make a formal determination to adopt any pathogen reduction approach. We also understand that the Japanese Red Cross has begun formal evaluation of a competing technology. Before the Japanese Red Cross considers our products, we understand that we may need to commit to making certain product configuration changes, which may not be economically or technologically feasible for us to accomplish.

We expect to continue to generate losses.

We may never achieve a profitable level of operations. Our research and development and selling, general and administrative expenses have resulted in substantial losses since our inception. The platelet and plasma systems have only recently been approved in the United States and are not approved in many countries around the world. The red blood cell system is in the development stage and may never emerge from the 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, or to compete favorably with other pathogen reduction technologies, which may reduce or altogether eliminate our gross profit on sales. At our present and expected near-term sales levels of the platelet and plasma systems, our costs to manufacture, distribute, market, sell, and support the systems are and are expected to continue to be in excess of our revenue. We expect our losses to continue at least until we are able to gain widespread commercial adoption, which may never occur. In addition to increased selling, general and administrative expenses in connection with the commercial launch of the platelet and plasma systems in the United States, we expect to incur additional research and development costs associated with planning, enrolling and completing our required post-approval study and the ongoing studies under our IDEs, pursuing potential regulatory approvals in other geographies where we do not currently sell our platelet and plasma systems, planning and conducting *in vitro* studies and clinical development of our red blood cell system in Europe and the United States, and completing chemistry, manufacturing and control, or CMC, activities to support a potential CE Mark submission for our red blood cell system in Europe, which is planned for the second half of 2016, which costs

could be substantial and could extend the period during which we expect to operate at a loss.

In certain countries, governments have issued regulations relating to the pricing and profitability of medical products and medical product companies. Healthcare reform in the United States has also placed downward pressure on the pricing of medical products that could have a negative impact our profit margins.

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

Sales of our products are dependent on purchasing decisions of and/or reimbursement from government health administration authorities, distribution partners and other organizations. As a result of adverse conditions affecting the global economies and credit and financial markets, including the sovereign debt crisis in certain countries in Europe and disruptions due to political instability or otherwise, these organizations may defer purchases, may be unable to satisfy their purchasing or reimbursement obligations, or may delay payment for the INTERCEPT Blood System. In addition, there have been concerns for the overall stability and suitability of the Euro as a single currency given the economic and political challenges facing individual Eurozone countries. Continuing deterioration in the creditworthiness of Eurozone countries, the withdrawal of one or more member countries from the European Union, or the failure of the Euro as a common European currency or an otherwise diminished value of the Euro could materially and adversely affect our product revenue.

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Additionally, a meaningful amount of our revenue currently comes from sales to our distributor in Russia. Low worldwide oil prices and the current political conflict stemming from tensions in the Ukraine have significantly devalued the Russian Ruble and may continue to have a negative impact on the Russian economy, particularly if sanctions continue to be levied against Russia or are strengthened from those currently in place from either the European Union, United States or both. While our agreement with our Russian distributor calls for sales, invoicing and collections to be denominated in Euros, if significant sanctions continue or are strengthened, if worldwide oil prices continue to remain low and/or if measures taken by the Russian government to support the Ruble fail, the Russian economy and value of the Ruble may further weaken, and our business in Russia and elsewhere may be negatively impacted.

Our products, blood products treated with the INTERCEPT Blood System and we are subject to extensive regulation by domestic and foreign authorities. If our preclinical and clinical data are not considered sufficient by a country s regulatory authorities to grant marketing approval, we will be unable to commercialize our products and generate revenue in that country. Our investigational red blood cell system requires extensive additional testing and development.

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

development;

testing;

manufacturing;

labeling;

storage;

clinical trials;

product safety;

pre-market clearance or approval;

sales and distribution;

use standards and documentation;

conformity assessment procedures;

product traceability and record keeping procedures;

post-launch surveillance and post-approval studies;

quality;

advertising and promotion;

product import and export; and

reimbursement.

Our products must satisfy rigorous standards of safety and efficacy and we must adhere to quality standards regarding manufacturing and customer-facing business processes in order for the FDA and international regulatory authorities to approve them for commercial use. For our product candidates, we must provide the FDA and international regulatory authorities with preclinical, clinical and manufacturing data demonstrating that our products are safe, effective and in compliance with government regulations before the products can be approved for commercial sale. The process of obtaining required regulatory approvals is expensive, uncertain and typically takes a number of years. We may continue to encounter significant delays or excessive costs in our efforts to secure necessary approvals or licenses, or we may not be successful at all. In addition, our labeling claims may not be consistent across markets. For instance, in Europe, our label permits storage of platelets treated with the INTERCEPT Blood System in both storage solution as well as suspended in 100% plasma, both of which are common practices with the preparation of conventional platelet components. Our approved label from the FDA for the platelet system only permits storage in platelet additive solutions, which may result in limited market adoption in the United States. If we are unable to provide sufficient data to the FDA or if the FDA requires us to collect and provide more data to support a label expansion request to include platelets suspended in 100% plasma, market acceptance of our products may be delayed or negatively impacted and our growth prospects would be delayed or materially and adversely affected.

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Clinical and Preclinical

Clinical trials are particularly expensive and have a high risk of failure. Any of our trials may fail or may not achieve results sufficient to attain market acceptance, which could prevent us from achieving profitability. We do not know whether we will begin or complete clinical trials on schedule, if at all. Clinical trials can be delayed for a variety of reasons, including delays in obtaining regulatory approval to commence a study, delays in reaching agreement on acceptable clinical study agreement terms with prospective clinical sites, delays in obtaining institutional review board, ministry of health or ethical committee approval to conduct a study at a prospective clinical site, delays in recruiting subjects to participate in a study and delays in the conduct of the clinical trial by personnel at the clinical site. Each of these factors has adversely impacted our ongoing European Phase III trial for the red blood cell system in chronically transfused recipients. Significant delays in clinical testing could also materially impact our clinical trials. Criteria for regulatory approval in blood safety indications are evolving, reflecting competitive advances in the standard of care against which new product candidates are judged, as well as changing market needs and reimbursement levels. Clinical trial design, including enrollment criteria, endpoints and anticipated label claims are thus subject to change, even if original objectives are being met. As a result, we do not know whether any clinical trial will result in marketable products. Typically, there is a high rate of failure for product candidates in preclinical studies and clinical trials and products emerging from any successful trial may not reach the market for several years.

Enrollment criteria for certain of our clinical trials may be quite narrow, further delaying the clinical trial process. For instance, clinical trials previously conducted using INTERCEPT-treated plasma for patients with thrombotic thrombocytopenic purpura lasted approximately four years due in part to the difficulties associated with enrolling qualified patients. In addition, enrollment criteria have impacted the speed with which we have been able to enroll patients for our ongoing Phase III red blood cell system trial in chronic anemia in Europe. Consequently, we may be unable to recruit suitable patients into clinical trials on a timely basis, if at all, which may lead to higher costs or the inability to complete the clinical trials. We cannot rely on interim results of trials to predict their final results, and acceptable results in early trials might not be repeated in later trials. Any trial may fail to produce results satisfactory to the FDA or foreign regulatory authorities. In addition, preclinical and clinical data can be interpreted in different ways, which could delay, limit or prevent regulatory approval. Negative or inconclusive results from a preclinical study or clinical trial, or adverse medical events during a clinical trial could cause a preclinical study or clinical trial to be repeated, require other studies to be performed or cause a program to be terminated, even if other studies or trials relating to a program are successful.

We have conducted many toxicology studies to demonstrate the safety of the platelet and plasma systems, and we have conducted and plan to conduct toxicology studies for the red blood cell system throughout the product development process. At any time, the FDA and other regulatory authorities may require further toxicology or other studies to further demonstrate our products safety, which could delay or preclude commercialization. In addition, the FDA or foreign regulatory authorities may alter guidance at any time as to what constitutes acceptable clinical trial endpoints or trial design, which may necessitate a redesign of our product or proposed clinical trials and cause us to incur substantial additional expense or time in attempting to gain regulatory approval. Regulatory agencies weigh the potential risks of using our pathogen reduction products against the incremental benefits, which may be difficult or impossible to quantify.

If any additional product candidates receive approval for commercial sale in the United States, or if we obtain approval for expanded label claims for the platelet system or plasma system, the FDA may require one or more post-approval clinical studies as a condition of approval, such as the post-approval clinical study we are required to conduct in connection with the approval of the platelet system, which could involve significant expense and may require us to secure adequate funding to complete. Other regulatory authorities outside of the United States may also require post-marketing studies. Governments or regulatory authorities may impose new regulations or other changes

or we may discover that we are subject to additional regulations that could further delay or preclude regulatory approval and subsequent adoption of our potential products. We cannot predict the adoption, implementation or impact of adverse governmental regulation that might arise from future legislative or administrative action.

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Outside the United States, regulations vary by country, including the requirements for regulatory and marketing approvals or clearance, the time required for regulatory review and the sanctions imposed for violations. In addition to CE mark documentation, countries outside the European Union may require clinical data submissions, registration packages, import licenses or other documentation. Regulatory authorities in Japan, China, Taiwan, South Korea, Vietnam, Thailand, and Singapore and elsewhere, may require, among other requirements, that our products be widely adopted commercially in Europe and the United States, or approved by the FDA, before they are considered for approval or may delay approval decisions until our products are more widely adopted. In addition to the regulatory requirements applicable to us and to our products, there are regulatory requirements in several countries around the world, including the United States, Germany, Canada, Austria, Australia and other countries, applicable to prospective customers of INTERCEPT Blood System products, the blood centers that process and distribute blood and blood products. In those countries, blood centers and other customers are required to obtain approved license supplements from the appropriate regulatory authorities before making available blood products processed with our pathogen reduction systems to hospitals and transfusing physicians. Our customers may lack the resources or capability to obtain such regulatory approvals. For example, in the United States, blood centers will be required to obtain site-specific licenses from CBER prior to engaging in interstate transport of blood components processed using the INTERCEPT Blood System. 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 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.

Red Blood Cell System

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

In 2003, we terminated Phase III clinical trials evaluating a prior generation of the red blood cell system in acute and chronic anemia patients. The trials were terminated due to the detection of antibody reactivity to INTERCEPT-treated red blood cells in two patients in the 2003 chronic anemia trial. Although the antibody reactivity was not associated with any adverse events, we developed process changes designed to diminish the likelihood of antibody reactivity in red blood cells treated with our modified process. In a subsequent Phase I clinical trial that we initiated in the fourth quarter of 2008 to evaluate recovery and survival of treated red blood cells with the modified process, there were no adverse events reported. Based on the results from that trial, we obtained approval for and commenced two Phase III clinical trials in Europe using the modified process in patients with acute and chronic anemia. We recently completed one of these Phase III clinical trials, with the INTERCEPT Blood System for red blood cells meeting its primary endpoint. However, we cannot assure you that the adverse events observed in the terminated 2003 Phase III clinical trials of our earlier red blood cell system will not be observed in the ongoing Phase III or any future clinical trials of our red blood cell system. In addition, although our recently-completed Phase III clinical trial in acute anemia patients using our modified process met its primary endpoint, we cannot assure you that the same or similar results will be observed in our ongoing Phase III or any potential future clinical trials using our modified process.

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The FDA has required that we successfully complete an additional Phase II recovery and survival study, which we completed in December 2014, prior to reaching agreement on any Phase III clinical trial protocol which we would likely need to successfully conduct and complete before the FDA would consider our red blood cell product for approval. We also understand that one or more additional *in vitro* studies will be required to be successfully completed and submitted to the FDA prior to any initiation of a potential Phase III clinical trial. We currently plan to complete our development and CMC activities and planned CE Mark submission, as well as such additional *in vitro* studies and any other prerequisites, before proposing a Phase III clinical trial protocol to the FDA in support of a potential regulatory approval of the red blood cell system in the United States. There can be no assurance that we will be able to successfully satisfy any such prerequisites, nor can there be any assurance that we and the FDA will agree to any trial protocol we propose or that we will otherwise obtain FDA clearance to initiate a potential Phase III clinical trial.

We completed our European Phase III clinical trial of our red blood cell system for acute anemia patients and have another European Phase III clinical trial of our red blood cell system for chronic anemia patients ongoing. Although we plan to undertake additional development and CMC activities to support an anticipated CE Mark submission planned for the second half of 2016, such studies, including any additional studies required by the FDA prior to its review of any proposed U.S. Phase III clinical trial protocol, could prolong development of the red blood cell system, and we do not expect to receive any regulatory approvals of our red blood cell system for a few years, if ever. We understand that while the acute anemia Phase III clinical trial in Europe may be sufficient to receive CE mark approval in Europe, a successful outcome with potentially more safety data in the ongoing Phase III chronic anemia clinical trial may also be required for our red blood cell system to achieve broad market acceptance. In addition, the trials may need to be supplemented by additional, successful Phase III clinical trials for approval in certain countries. If such additional Phase III clinical trials are required, they would likely need to demonstrate equivalency of INTERCEPT-treated red blood cells compared to conventional red blood cells and the significantly lower lifespan for INTERCEPT-treated red blood cells compared to non-treated red blood cells may limit our ability to obtain regulatory approval for the product. A number of trial design issues that could impact efficacy, regulatory approval and market acceptance will need to be resolved prior to the initiation of further clinical trials. As part of our development and CMC activities, we will need to complete a number of *in vitro* studies, finalize development of the final commercial configuration of the red blood cell system and manufacture and validate sufficient quantities of the final red blood cell system prior to receiving any regulatory approvals in Europe and may have to complete additional activities prior to receiving regulatory approvals in the United States. Many of these activities may require capital beyond that which we currently have, and we may be required to obtain additional capital in order to complete the development of and obtain any regulatory approvals for the red blood cell system. If we are unsuccessful in advancing the red blood cell system through clinical trials, resolving process and product design issues or in obtaining subsequent regulatory approvals and acceptable reimbursement rates, we may never realize a return on our research and development expenses incurred to date for the red blood cell system program. Regulatory delays can also materially impact our product development costs. If we continue to experience delays in testing, conducting trials or approvals, our product development costs will increase. Even if we were to successfully complete and receive approval for our red blood cell system, potential customers may object to working with a potent chemical, like S-303, the active compound in the red blood cell system, or may require modifications to automate the process, which would result in additional development costs, any of which could limit any market acceptance of the red blood cell system.

Platelet and Plasma Systems

In 2007, we obtained a CE mark approval (extended in 2012) from European Union regulators for our platelet system and will need to obtain an extension every five years. We or our customers have received approval for the sale and/or use of INTERCEPT-treated platelets in France, Switzerland, Germany and Austria. We or our customers may also be required to conduct additional testing in order to obtain regulatory approval in countries that do not recognize the CE mark as being adequate for commercializing the INTERCEPT Blood System in those countries. The level of

additional product testing varies by country, but could be expensive or take a long time to complete. In addition, regulatory agencies are able to withdraw or suspend previously issued approvals.

In 2006, we obtained a CE mark approval (extended in 2011) from European Union regulators for our plasma system. We or our customers have received approval for the sale and/or use INTERCEPT-treated plasma in France, Switzerland, and Germany. In some countries, including several in Europe, we or our customers may be required to perform additional clinical studies or submit manufacturing and marketing applications in order to obtain regulatory approval. If we or our customers are unable to obtain or maintain regulatory approvals for the use and sale or continued sale and use of INTERCEPT-treated platelets or plasma, market adoption of our products will be negatively affected and our growth prospects would be materially and adversely impacted.

In December 2014, the FDA approved the platelet system for *ex vivo* preparation of pathogen-reduced apheresis platelet components in order to reduce the risk of transfusion-transmitted infection, or TTI, including sepsis, and to potentially reduce the risk of transfusion-associated graft versus host disease, or TA-GVHD. Also in December 2014, the FDA approved the plasma system for *ex vivo* preparation of plasma in order to reduce the risk of TTI when treating patients requiring therapeutic plasma transfusion. We are conducting *in vitro* studies for our platelet system to potentially expand our label claims to include, among others, platelets suspended in 100% plasma, platelets collected from pooled random donors, storage of INTERCEPT-treated platelets for up to seven days rather than five days, and a new processing set for triple dose collections. Failure to obtain any of these label expansion claims may negatively affect market adoption and our growth prospects would be materially and adversely affected.

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As a condition to the FDA approval of the platelet systems, we are required to conduct a post-approval clinical study of the platelet system. If we are unable to complete this study or the results of this study reveal unacceptable safety risks, we could be required to perform additional studies, which may be costly, and even lose U.S. marketing approval of the platelet and/or plasma systems. In addition to these studies, the FDA may also require us to commit to perform other lengthy post-marketing studies, for which we would have to expend significant additional resources, which could have an adverse effect on our operating results, financial condition and stock price. In addition, there is a risk that these studies will show results inconsistent with our previous studies. Should this happen, potential customers may delay or choose not to adopt the INTERCEPT Blood System and existing customers may cease use of the INTERCEPT Blood System.

In addition, we have submitted and received approval from the FDA for an expanded use IDE to conduct a study using INTERCEPT to treat platelet donations in areas of the United States that are currently experiencing outbreaks of the chikungunya and dengue viruses. We also have submitted and received FDA approval for a Phase I clinical study protocol under the IDE to treat plasma derived from convalesced patients that were previously infected with the Ebola virus. The execution and completion of these ongoing studies will continue to result in additional costs, and will require attention and resources from our clinical, regulatory and management teams, which may result in a distraction from our commercialization efforts and other regulatory and clinical programs.

Post-Marketing Approval

We are also required to continue to comply with applicable FDA and other regulatory requirements now that we have obtained approval for the INTERCEPT Blood System for platelets and plasma. These requirements relate to, among other things, labeling, packaging, storage, advertising, promotion, record-keeping and reporting of safety and other information. In addition, our manufacturers and their facilities are required to comply with extensive FDA and foreign regulatory agency requirements, including, in the United States, ensuring that quality control and manufacturing procedures conform to current cGMP and QSR requirements. As such, we and our contract manufacturers are subject to continual review and periodic inspections. Accordingly, we and others with whom we work must continue to expend time, money and effort in all areas of regulatory compliance, including manufacturing, production and quality control. We are also required to report certain adverse events and production problems, if any, to the FDA and foreign regulatory authorities, when applicable, and to comply with requirements concerning advertising and promotion for our products. For example, our promotional materials and training methods must comply with FDA and other applicable laws and regulations, including the prohibition of the promotion of unapproved, or off-label, use. If the FDA determines that our promotional materials or training constitutes promotion of an off-label use, it could request that we modify our training or promotional materials or subject us to regulatory or enforcement actions, including the issuance of an untitled letter, a warning letter, injunction, seizure, civil fine or criminal penalties. It is also possible that other federal, state or foreign enforcement authorities might take action if they consider our promotional or training materials to constitute promotion of an off-label use, which could result in significant fines or penalties under other statutory authorities, such as laws prohibiting false claims for reimbursement. In that event, our reputation could be damaged and adoption of the products could be impaired. Although our policy is to refrain from statements that could be considered off-label promotion of our products, the FDA or another regulatory agency could disagree and conclude that we have engaged in off-label promotion. In addition, the off-label use of our products may increase the risk of product liability claims. Product liability claims are expensive to defend and could divert our management s attention, result in substantial damage awards against us, and harm our reputation.

If a regulatory agency discovers problems with a product, such as adverse events of unanticipated severity or frequency, or problems with the facility or the manufacturing process at the facility where the product is manufactured, or problems with the quality of product manufactured, or disagrees with the promotion, marketing, or labeling of a product, a regulatory agency may impose restrictions on use of that product, including requiring

withdrawal of the product from the market. Our failure to comply with applicable regulatory requirements could result in enforcement action by regulatory agencies, which may include any of the following sanctions:

- adverse publicity, warning letters, fines, injunctions, consent decrees and civil penalties;
- repair, replacement, recall or seizure of our products;
- operating restrictions or partial suspension or total shutdown of production;
- delaying or refusing our requests for approval of new products, new intended uses or modifications to our existing products;
- refusal to grant export or import approval for our products;