CERUS CORP
Form 10-Q
August 05, 2016

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, 2016

or

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

Commission File Number 000-21937

CERUS CORPORATION

(Exact name of registrant as specified in its charter)

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

(925) 288-6000

(Registrant's telephone number, including area code)

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

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 o

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

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

As of July 28, 2016, there were 102,709,344 shares of the registrant's common stock outstanding.

CERUS CORPORATION

QUARTERLY REPORT ON FORM 10-Q

THREE AND SIX MONTHS ENDED June 30, 2016

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PART I: FINANCIAL INFORMATION

ITEM 1. FINANCIAL STATEMENTS
CERUS CORPORATION

CONDENSED CONSOLIDATED BALANCE SHEETS

(in thousands)

	June 30, 2016 (Unaudited)	December 31, 2015
ASSETS		
Current assets:		
Cash and cash equivalents	$ 7,704	$ 71,018
Short-term investments	76,350	25,698
Investment in marketable equity securities	4,487	11,163
Accounts receivable	5,149	5,794
Inventories	12,111	10,812
Prepaid expenses	1,066	1,166
Other current assets	5,345	4,755
Total current assets	112,212	130,406
Non-current assets:		
Property and equipment, net	3,216	3,549
Goodwill	1,316	1,316
Intangible assets, net	839	940
Restricted cash	575	612
Other assets	2,293	2,579
Total assets	$ 120,451	$ 139,402
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities:		
Accounts payable	$ 7,190	$ 5,217
Accrued liabilities	9,439	9,853
Manufacturing and development obligations - current	2,221	3,282
Debt - current	6,127	2,956
Deferred revenue - current	767	554
Total current liabilities	25,744	21,862
Non-current liabilities:		
Debt - non-current	13,726	16,848
Deferred income taxes	140	122
Manufacturing and development obligations - non-current	4,844	4,542
Other non-current liabilities	1,356	1,263
Total liabilities	45,810	44,637
Commitments and contingencies		
Stockholders' equity:		
Common stock	102	99
Additional paid-in capital	704,402	685,189

Accumulated other comprehensive income	2,978	7,289
Accumulated deficit	(632,841)	(597,812)
Total stockholders' equity	74,641	94,765
Total liabilities and stockholders' equity	$120,451	$139,402

See accompanying Notes to Unaudited Condensed Consolidated Financial Statements.

CERUS CORPORATION

CONDENSED CONSOLIDATED STATEMENTS OF OPERATIONS

UNAUDITED

(in thousands, except per share data)

	Three Months Ended June 30,		Six Months Ended June 30,	
	2016	2015	2016	2015
Revenue	$9,251	$8,830	$16,883	$16,522
Cost of revenue	4,976	7,028	9,239	11,742
Gross profit	4,275	1,802	7,644	4,780
Operating expenses:				
Research and development	8,557	5,213	15,474	10,794
Selling, general and administrative	12,406	12,063	24,153	23,781
Amortization of intangible assets	51	51	101	101
Total operating expenses	21,014	17,327	39,728	34,676
Loss from operations	(16,739)	(15,525)	(32,084)	(29,896)
Non-operating (expense) income, net:				
(Loss) gain from revaluation of warrant liability	-	(2,707)	-	3,589
Foreign exchange gain (loss)	101	499	(16)	(614)
Interest expense	(658)	(301)	(1,313)	(556)
Other income, net	113	27	179	29
Total non-operating (expense) income, net	(444)	(2,482)	(1,150)	2,448
Loss before income taxes	(17,183)	(18,007)	(33,234)	(27,448)
Provision (benefit) for income taxes	983	(2,035)	1,795	(2,016)
Net loss	$(18,166)	$(15,972)	$(35,029)	$(25,432)
Net loss per share:				
Basic	$(0.18)	$(0.17)	$(0.35)	$(0.27)
Diluted	$(0.18)	$(0.17)	$(0.35)	$(0.30)
Weighted average shares outstanding used for calculating net loss per share:				
Basic	101,563	95,728	100,517	94,576
Diluted	101,563	95,728	100,517	95,682

See accompanying Notes to Unaudited Condensed Consolidated Financial Statements.

CERUS CORPORATION

CONDENSED CONSOLIDATED STATEMENTS OF COMPREHENSIVE LOSS

UNAUDITED

(in thousands)

	Three Months Ended June 30,		Six Months Ended June 30,	
	2016	2015	2016	2015
Net loss	$(18,166)	$(15,972)	$(35,029)	$(25,432)
Other comprehensive (loss) income:				
Unrealized (losses) gains on available-for-sale investments, net of taxes of $(205) and $4,552 for the three months ended June 30, 2016 and 2015, respectively, and $(2,263) and $4,552 for the six months ended June 30, 2016 and 2015, respectively	(389)	7,493	(4,311)	7,512
Comprehensive loss	$(18,555)	$(8,479)	$(39,340)	$(17,920)

See accompanying Notes to Unaudited Condensed Consolidated Financial Statements.

CERUS CORPORATION

CONDENSED CONSOLIDATED STATEMENTS OF CASH FLOWS

UNAUDITED

(in thousands)

	Six Months Ended June 30,	
	2016	2015
Operating activities		
Net loss	$(35,029)	$(25,432)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation and amortization	964	835
Stock-based compensation	3,862	3,179
Changes in valuation of warrant liability	-	(3,589)
Non-cash interest expense	603	139
Deferred income taxes	18	7
Non-cash tax expense (benefit) from other unrealized loss on available-for-sale securities	1,702	(2,085)
Changes in operating assets and liabilities:		
Accounts receivable	645	69
Inventories	(1,318)	1,112
Other assets	435	739
Accounts payable	1,902	(4,176)
Accrued liabilities	(458)	(1,538)
Manufacturing and development obligations	(1,082)	-
Deferred revenue	189	256
Net cash used in operating activities	(27,567)	(30,484)
Investing activities		
Capital expenditures	(118)	(325)
Purchases of investments	(70,560)	(69,983)
Proceeds from maturities of investments	19,500	22,444
Restricted cash	37	(114)
Net cash used in investing activities	(51,141)	(47,978)
Financing activities		
Net proceeds from equity incentives and warrants	907	5,472
Net proceeds from public offering	14,547	75,324
Proceeds from loans	-	10,000
Repayment of debt	(60)	(56)
Net cash provided by financing activities	15,394	90,740
Net (decrease) increase in cash and cash equivalents	(63,314)	12,278
Cash and cash equivalents, beginning of period	71,018	22,781
Cash and cash equivalents, end of period	$7,704	$35,059

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 of America, or U.S. ("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, 2016, are not necessarily indicative of the results that may be expected for the year ending December 31, 2016, 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, 2015, which were included in the Company's 2015 Annual Report on Form 10-K, filed with the SEC on March 9, 2016. The accompanying condensed consolidated balance sheet as of December 31, 2015, has been derived from the Company's audited consolidated financial statements as of that date, except as described in the New Accounting Pronouncement section below related to the adoption of Accounting Standards Update ("ASU") No. 2015-03, Interest—Imputation of Interest (Subtopic 835-30): Simplifying the Presentation of Debt Issuance Costs.

Use of Estimates

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

Revenue

The Company recognizes revenue in accordance with Accounting Standards Codification ("ASC") Topic 605-25, "Revenue Recognition – Arrangements with Multiple Deliverables," as applicable. Revenue is recognized when (i) persuasive evidence of the arrangement exists; (ii) delivery has occurred or services have been rendered; (iii) pricing is fixed or determinable; and (iv) collectability is reasonably assured. The Company's main sources of revenues for the three and six months ended June 30, 2016 and 2015 were product revenue from sales of the INTERCEPT Blood System for platelets and plasma ("platelet and plasma systems" or "disposable kits") and UVA illumination devices ("illuminators").

Revenue related to product sales is generally recognized when the Company fulfills its obligations for each element of an agreement. For all sales of the Company's INTERCEPT Blood System products, the Company uses a binding

purchase order or signed sales contract as evidence of an arrangement. The Company sells its platelet and plasma systems directly to blood banks, hospitals, universities, government agencies, as well as to distributors in certain regions. Generally, the Company's contracts with its customers do not provide for open return rights, except within a reasonable time after receipt of goods in the case of defective or non-conforming product. Deliverables and the units of accounting vary according to the provisions of each purchase order or sales contract. For revenue arrangements with multiple elements, the Company determines whether the delivered elements meet the criteria as separate units of accounting. Such criteria require that the deliverable have stand-alone value to the customer and that if a general right of return exists relative to the delivered item, delivery or performance of the undelivered item(s) is considered probable and substantially in the control of the Company. Once the Company determines if the deliverable meets the criteria for a separate unit of accounting, the Company must determine how the consideration should be allocated between the deliverables and how the separate units of accounting should be recognized as revenue. Consideration received is allocated to elements that are identified as discrete units of accounting. Because the Company has no vendor specific objective evidence or third party evidence for its systems 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 systems by considering multiple factors. The Company regularly reviews best estimated selling price.

The Company receives reimbursement under certain U.S. government contracts or grants that support research and development of defined projects. These contracts or grants generally provide for reimbursement of approved costs incurred as defined in the various grants. Funds received are non-refundable. Revenue related to the cost reimbursement provisions under U.S. government contracts or grants are recognized as the qualified direct and indirect costs on the projects are incurred. Costs incurred related to services performed under these contracts are included as a component of research and development expenses in the Company's consolidated statements of operations. The Company's use of estimates in recording accrued liabilities for R&D activities (see "Use of Estimates" above) affects the revenue recorded from development funding and government contracts or grants. Actual results may differ from those estimates under different assumptions or conditions.

Freight costs charged to customers are recorded as a component of revenue. Taxes that the Company invoices to its customers and remits to governments are recorded on a net basis, which excludes such tax from product revenue.

Research and Development Expenses

In accordance with ASC Topic 730, "Accounting for Research and Development Expenses," research and development ("R&D") expenses are charged to expense when incurred, including cost incurred under each grant that has been awarded to the Company by the U.S. government or development contracts. Research and development expenses include salaries and related expenses for scientific and regulatory personnel, payments to consultants, supplies and chemicals used in in-house laboratories, costs of R&D 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 R&D activities (see "Use of Estimates" above) affects the amounts of R&D expenses recorded from development funding and government contracts or grants. 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 include corporate debt, U.S. government agency securities and marketable equity securities of Aduro Biotech, Inc. ("Aduro"), and are designated as available-for-sale and classified as short-term investments or investment in marketable equity securities, 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. The Company views its available-for-sale portfolio as available for use in its current operations. Unrealized gains and losses derived by changes in the estimated fair value of available-for-sale securities were recorded in "Net unrealized (losses) gains on available-for-sale investments, net of taxes" on the Company's unaudited condensed consolidated statements of comprehensive loss. Realized gains (losses) from the sale of available-for-sale investments were recorded in "Other income, net" on the Company's unaudited condensed consolidated statements of operations. The costs of securities sold are based on the specific identification method, if applicable. The Company reported the amortization of any premium and accretion of any discount resulting from the purchase of debt securities as a component of interest income.

The Company also reviews its available-for-sale 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 "Other assets" on the Company's unaudited condensed consolidated balance sheets. The Company also has certain non-U.S. 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, available-for-sale securities and accounts receivable.

Pursuant to the Company's investment policy, substantially all of the Company's cash, cash equivalents and available-for-sale securities are maintained at major financial institutions of high credit standing. The Company monitors the financial credit worthiness of the issuers of its investments and limits the concentration in individual securities and types of investments that exist within its investment portfolio. Generally, all of the Company's investments carry high credit quality ratings, which is in accordance with its investment policy. At June 30, 2016, 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, 2016, the Company does not believe there is significant financial risk from non-performance by the issuers of the Company's cash equivalents and short-term investments.

Concentrations of credit risk with respect to trade receivables exist. 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.

The Company had three customers that accounted for more than 10% of the Company's outstanding trade receivables at June 30, 2016 and December 31, 2015. These customers cumulatively represented approximately 37% and 49% of the Company's outstanding trade receivables at June 30, 2016 and December 31, 2015, respectively. To date, the Company has not experienced collection difficulties from these customers.

Inventories

At June 30, 2016 and December 31, 2015, inventory consisted of work-in-process and finished goods only. Finished goods include INTERCEPT disposable kits, illuminators, and certain replacement parts for the illuminators. Platelet and plasma systems' disposable kits generally have a two-year life from the date of manufacture. Illuminators and replacement parts do not have regulated expiration dates. Work-in-process includes certain components that are manufactured over a protracted length of time before being sold to, and ultimately incorporated and assembled by Fresenius 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, 2016 and December 31, 2015, the Company classified its work-in-process inventory as a current asset on its 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 net realizable 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 consolidated statements of operations. At June 30, 2016 and December 31, 2015, the Company had $1.6 million and $1.8 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 capitalized costs associated with the enterprise resource planning system are being amortized over the estimated useful life of five years.

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 original 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 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 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, based on the present value of future cash flows, 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." 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, 2016 and 2015.

Foreign Currency Remeasurement

The functional currency of the Company’s foreign subsidiary is the U.S. dollar. Monetary assets and liabilities denominated in foreign currencies are remeasured in U.S. dollars using the exchange rates at the balance sheet date. Non-monetary assets and liabilities denominated in foreign currencies are remeasured in U.S. 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 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, and is adjusted for estimated forfeitures. To the extent that stock options contain performance criteria for vesting, stock-based compensation is recognized once the performance criteria are probable of being achieved.

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

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 it accrued for or made payments for interest and penalties. 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 U.S. federal and California tax years through 2015 remain subject to examination by the taxing jurisdictions due to unutilized net operating losses and research credits. The Company continues to carry a full valuation allowance on all of its net deferred tax assets, except for its indefinite lived intangibles.

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, warrants and restricted stock units, which are calculated using the treasury stock method. Diluted net loss per share also gives effect to potential adjustments to the numerator for gains 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, 2016 and 2015, as their inclusion would have been anti-dilutive.

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, 2016 and 2015 (in thousands, except per share amounts):

	Three Months Ended June 30,		Six Months Ended June 30,	
	2016	2015	2016	2015
Numerator for Basic and Diluted:				
Net loss used for basic calculation	$(18,166)	$(15,972)	$(35,029)	$(25,432)
Effect of revaluation of warrant liability	-	-	-	(3,589)
Adjusted net loss used for diluted calculation	$(18,166)	$(15,972)	$(35,029)	$(29,021)
Denominator:				
Basic weighted average number of shares outstanding	101,563	95,728	100,517	94,576
Effect of dilutive potential shares	-	-	-	1,106
Diluted weighted average number of shares outstanding	101,563	95,728	100,517	95,682
Net loss per share:				
Basic	$(0.18)	$(0.17)	$(0.35)	$(0.27)
Diluted	$(0.18)	$(0.17)	$(0.35)	$(0.30)

The table below presents shares underlying stock options, restricted stock units and/or warrants that were 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, 2016 and 2015 (shares in thousands):

	Three Months Ended June 30,		Six Months Ended June 30,	
	2016	2015	2016	2015
Weighted average number of anti-dilutive potential shares:				
Stock options	15,891	14,015	15,331	13,102
Restricted stock units	640	-	428	-
Warrants	-	2,985	-	-
Total	16,531	17,000	15,759	13,102

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 become known and are estimable. The Company has not experienced significant or systemic warranty claims nor is it aware of any existing current warranty claims. Accordingly, the Company had not accrued for any future warranty costs for its products at June 30, 2016 and December 31, 2015.

Fair Value of Financial Instruments

The Company applies the provisions of fair value relating to its financial assets and liabilities. The carrying amounts of accounts receivables, accounts payable, and other accrued liabilities approximate their fair value due to the relative short-term maturities. Based on the borrowing rates currently available to the Company for loans with similar terms, the Company believes the fair value of its debt approximates their carrying amounts. The Company measures and records certain financial assets and liabilities at fair value on a recurring basis, including its available-for-sale securities and warrant liability prior to the expiration and exercise of the warrants in November 2015. The Company classifies instruments within Level 1 if quoted prices are available in active markets for identical assets, which include the Company’s cash accounts and money market funds. The Company classifies instruments in Level 2 if the instruments are valued using observable inputs to quoted market prices, benchmark yields, reported trades, broker/dealer quotes or

alternative pricing sources with reasonable levels of price transparency. These instruments include the Company's corporate debt and U.S. government agency securities holdings. 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. The Company assesses any transfers among fair value measurement levels at the end of each reporting period.

See Notes 2 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 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 August 2015, the FASB issued ASU No. 2015-14, Revenue from Contracts with Customers (Topic 606), Deferral of the Effective Date, which defers by one year the effective date of ASU No. 2014-09 to 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). In March 2016, the FASB issued ASU No. 2016-08, Revenue from Contracts with Customers (Topic 606): Principal versus Agent Considerations (Reporting Revenue Gross versus Net), which clarifies how to identify the unit of accounting for the principal versus agent evaluation and how to apply the control principle to certain types of arrangements. In April 2016, the FASB issued ASU No. 2016-10, Revenue from Contracts with Customers (Topic 606): Identifying Performance Obligations and Licensing, which clarifies the implementation guidance on identifying performance obligations and licensing. In May 2016, the FASB issued ASU No. 2016-12, Revenue from Contracts with Customers (Topic 606): Narrow-Scope Improvements and Practical Expedients, which addresses certain issues on assessing collectability, presentation of sales taxes, noncash consideration, and completed contracts and contract modifications at transition. These ASUs will be effective for the Company in the first quarter of fiscal year 2018, using one of two retrospective application methods. The Company has not selected a transition method and is currently assessing the potential effects of this ASU on the Company's 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. The standard is effective for annual periods beginning after December 15, 2016, and interim periods thereafter, with early application permitted. The adoption of this ASU is not expected to have a material impact on the Company's 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. The Company has adopted this ASU effective January 1, 2016 under the retrospective application method. To conform to the current period presentation, the Company reclassified $32,000 and $36,000, which were previously included in Other current assets and Other assets, respectively, in the Company's condensed consolidated balance sheet as of

December 31, 2015, as a reduction of Debt-current and Debt-non-current, respectively. As a result of the reclassifications, Other current assets and Debt-current decreased by $32,000, and Other assets and Debt- non-current decreased by $36,000, in the Company's condensed consolidated balance sheet as of December 31, 2015.

In January 2016, the FASB issued ASU No. 2016-01, Financial Instruments-Overall (Subtopic 825-10), which requires all equity investments to be measured at fair value with changes in the fair value recognized through net income (other than those accounted for under equity method of accounting or those that result in consolidation of the investee). The amendments also require an entity to present separately in other comprehensive income the portion of the total change in the fair value of a liability resulting from a change in the instrument-specific credit risk when the entity has elected to measure the liability at fair value in accordance with the fair value option for financial instruments. In addition, this ASU eliminates the requirement to disclose the fair value of financial instruments measured at amortized cost for entities that are not public business entities and the requirement to disclose the method(s) and significant assumptions used to estimate the fair value that is required to be disclosed for financial instruments measured at amortized cost on the balance sheet for public business entities. The standard is effective for annual periods beginning after December 15, 2017, and interim periods thereafter, with early application permitted. The Company is currently assessing the future impact of this ASU on the Company's condensed consolidated financial statements.

In February 2016, the FASB issued ASU No. 2016-02, Leases, which, for operating leases, requires a lessee to recognize a right-of-use asset and a lease liability, initially measured at the present value of the lease payments, in its balance sheet. The standard also requires a lessee to recognize a single lease cost, calculated so that the cost of the lease is allocated over the lease term, on a generally straight-line basis. The standard is effective for annual periods beginning after December 15, 2018, and interim periods thereafter, with early application permitted. The Company is currently assessing the future impact of this ASU on its consolidated financial statements and anticipates the new guidance will significantly impact the Company's condensed consolidated financial statements.

In March 2016, the FASB issued ASU No. 2016-09, Compensation-Stock Compensation (Topic 718):Improvements to Employee Share-Based Payment Accounting, which requires entities to record all excess tax benefits and tax deficiencies as income tax expense or benefit in the income statement when awards vest or are settled, and eliminates additional paid-in capital (APIC) pools. The ASU also changes the accounting for an employee's use of shares to satisfy the employer's statutory income tax withholding obligation, and the accounting for forfeitures, and provides two practical expedients for nonpublic entities. The standard is effective for annual periods beginning after December 15, 2016, and interim periods thereafter, with early application permitted. The Company is currently assessing the future impact of this ASU on the Company's condensed consolidated financial statements.

In June 2016, the FASB issued ASU No. 2016-13, Financial Instruments—Credit Losses (Topic 326): Measurement of Credit Losses on Financial Instruments, which requires measurement and recognition of expected credit losses for financial assets held. The standard is effective for annual periods beginning after December 15, 2019, and interim periods thereafter, with early application permitted. The Company is currently assessing the future impact of this ASU on the Company's condensed consolidated financial statements.

Note 2. Fair Value on Financial Instruments

The Company uses certain assumptions that market participants would use to determine the fair value of an asset or liability 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, 2016, the Company's primary service relies on inputs from multiple industry-recognized pricing sources to determine the price for each investment. Corporate debt and U.S. 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, 2016 (in thousands):

	Balance sheet classification	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	Cash and cash equivalents	$105	$ 105	$ -	$ -
United States government agency securities	Short-term investments	18,982	-	18,982	-
Corporate debt securities	Short-term investments	57,368	-	57,368	-
Marketable equity securities	Marketable equity securities	4,487	4,487	-	-
Total financial assets		$80,942	$ 4,592	$ 76,350	$ -

The fair values of the Company's financial assets and liabilities were determined using the following inputs at December 31, 2015 (in thousands):

	Balance sheet classification	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	Cash and cash equivalents	$59,302	$59,302	$ -	$ -
Corporate debt securities	Short-term investments	25,698	-	25,698	-
Marketable equity securities	Marketable equity securities	11,163	11,163	-	-
Total financial assets		$96,163	$70,465	$ 25,698	$ -

The Company did not have any transfers among fair value measurement levels during the three and six months ended June 30, 2016 or the year ended December 31, 2015. The Company did not have any financial assets or liabilities classified as level 3 financial instruments at June 30, 2016 and December 31, 2015.

Note 3. Available-for-sale Securities

The following is a summary of available-for-sale securities at June 30, 2016 (in thousands):

	June 30, 2016			
	Amortized Cost	Gross Unrealized Gain	Gross Unrealized Loss	Fair Value
Money market funds	$105	$ -	$ -	$105
United States government agency securities	18,974	8	-	18,982
Corporate debt securities	57,323	57	(12)	57,368
Marketable equity securities	-	4,487	-	4,487
Total available-for-sale securities	$76,402	$ 4,552	$ (12)	$80,942

The following is a summary of available-for-sale securities at December 31, 2015 (in thousands):

	December 31, 2015			
	Amortized Cost	Gross Unrealized Gain	Gross Unrealized Loss	Fair Value
Money market funds	$59,302	$ -	$ -	$59,302
Corporate debt securities	25,747	-	(49)	25,698
Marketable equity securities	-	11,163	-	11,163
Total available-for-sale securities	$85,049	$ 11,163	$ (49)	$96,163

Available-for-sale securities at June 30, 2016 and December 31, 2015, consisted of the following by contractual maturity (in thousands):

	June 30, 2016		December 31, 2015	
	Amortized Cost	Fair Value	Amortized Cost	Fair Value
One year or less	$66,291	$66,311	$85,049	$85,000
Marketable equity securities	-	4,487	-	11,163
Greater than one year and less than five years	10,111	10,144	-	-
Total available-for-sale securities	$76,402	$80,942	$85,049	$96,163

The following tables show all available-for-sale marketable securities in an unrealized loss position for which an other-than-temporary impairment has not been recognized and the related gross unrealized losses and fair value, aggregated by investment category and length of time that individual securities have been in a continuous unrealized loss position (in thousands):

	June 30, 2016					
	Less than 12 Months		12 Months or Greater		Total	
	Fair Value	Unrealized Loss	Fair Value	Unrealized Loss	Fair Value	Unrealized Loss
Corporate debt securities	$20,114	$ (12)	$ -	$ -	$20,114	$ (12)
Total available-for-sale securities	$20,114	$ (12)	$ -	$ -	$20,114	$ (12)

	December 31, 2015					
	Less than 12 Months		12 Months or Greater		Total	
	Fair Value	Unrealized Loss	Fair Value	Unrealized Loss	Fair Value	Unrealized Loss
Corporate debt securities	$20,170	$ (46)	$5,528	$ (3)	$25,698	$ (49)
Total available-for-sale securities	$20,170	$ (46)	$5,528	$ (3)	$25,698	$ (49)

As of June 30, 2016, 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. The Company typically invests in highly-rated securities, and its investment policy limits the amount of credit exposure to any one issuer. The policy generally requires investments to be investment grade, with the primary objective of minimizing the potential risk of principal loss. 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, 2016 and 2015, the Company did not recognize any other-than-temporary impairment loss. The Company has no current requirement or intent to sell the securities in an unrealized loss position. The Company expects to recover up to (or beyond) the initial cost of investment for securities held.

The Company did not record any gross realized gains from the sale or maturity of available-for-sale investments during the three and six months ended June 30, 2016 and 2015. The Company did not record any gross realized losses from the sale or maturity of available-for-sale investments during the three and six months ended June 30, 2016 and 2015.

Note 4. Inventories

Inventories at June 30, 2016 and December 31, 2015, consisted of the following (in thousands):

	June 30, 2016	December 31, 2015
Work-in-process	$3,354	$ 3,187
Finished goods	8,757	7,625
Total inventories	$12,111	$ 10,812

Note 5. Goodwill and Intangible Assets, net

Goodwill

During the three and six months ended June 30, 2016, the Company did not dispose of or recognize additional goodwill. The Company expects to perform its annual review of goodwill on August 31, 2016, unless indicators of impairment are identified prior to that date. As of June 30, 2016, 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, 2016 (in thousands):

	June 30, 2016		
	Gross Carrying Amount	Accumulated Amortization	Net Carrying Amount
Acquisition-related intangible assets:			
Reacquired license - INTERCEPT Asia	$2,017	$ (1,178)	$ 839
Total intangible assets	$2,017	$ (1,178)	$ 839

The following is a summary of intangible assets, net at December 31, 2015 (in thousands):

	December 31, 2015		
	Gross Carrying Amount	Accumulated Amortization	Net Carrying Amount
Acquisition-related intangible assets:			
Reacquired license - INTERCEPT Asia	$2,017	$ (1,077)	$ 940
Total intangible assets	$2,017	$ (1,077)	$ 940

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, 2016 and 2015. During the three and six months ended June 30, 2016 and 2015, there were no impairment charges recognized related to the acquired intangible assets.

At June 30, 2016, the expected amortization expense of the intangible assets, net is $0.1 million for the remaining six months of 2016, $0.2 million annually beginning with the year ending December 31, 2017, through the year ending December 31, 2019, and $0.1 million for the year ending December 31, 2020.

Note 6. Marketable Equity Investments

The Company held an investment in preferred shares of Aduro which it had historically accounted for under the cost method of accounting with a net carrying value of zero. 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 (“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 and, as a result became a marketable equity security. Therefore,

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 included in investment in marketable equity securities on the Company's unaudited condensed consolidated balance sheet (Note 2) and will adjust the carrying value of this investment to fair value each quarterly reporting period, with changes in fair value recorded within other comprehensive income (loss), net of tax.

Note 7. Accrued Liabilities

Accrued liabilities at June 30, 2016 and December 31, 2015, consisted of the following (in thousands):

	June 30, 2016	December 31, 2015
Accrued compensation and related costs	$5,074	$ 5,198
Accrued professional services	3,294	2,337
Accrued customer costs	482	987
Accrued insurance premiums	-	438
Other accrued expenses	589	893
Total accrued liabilities	$9,439	$ 9,853

Note 8. Debt

Debt consisted of the following (in thousands):

	June 30, 2016		
	Principal	Unamortized Discount	Total
Loan and Security Agreement	$20,000	$ (147)	$19,853
Less: debt - current	(6,208)	81	(6,127)
Debt - non-current	$13,792	$ (66)	$13,726

	December 31, 2015		
	Principal	Unamortized Discount	Net Carrying Value
Loan and Security Agreement	$20,000	$ (196)	$19,804
Less: debt - current	(3,050)	94	(2,956)
Debt - non-current	$16,950	$ (102)	$16,848

Principal and interest payments on debt at June 30, 2016, are expected to be as follows (in thousands):

Year ended December 31,	Principal	Interest	Total
2016	$3,050	$654	$3,704
2017	6,428	980	7,408
2018	6,892	517	7,409
2019	3,630	1,474	5,104
Total	$20,000	$3,625	$23,625

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. On September 29, 2015, the Term Loan Agreement was amended to extend (i) the period in which the third tranche of $10.0 million ("Term Loan C") can be drawn and (ii) the interest-only period for all advances under the Term Loan Agreement. The Company determined that the amendment to the Term Loan Agreement resulted in a modification. As a result, the Term Loan will continue to be accounted for by using the effective interest method, with a new effective interest rate based on revised cash flows calculated on a prospective basis upon the execution of the amendment to the Term Loan Agreement. As amended, the availability of Term Loan C was subject to the Company achieving consolidated trailing six months' revenue at a specified threshold (the "Revenue Event") no later than June 30, 2016. The Company did not achieve the Revenue Event by June 30, 2016,

and therefore Term Loan C was not available to be drawn. Term Loan A bears an interest rate of 6.95%. Term Loan B bears an interest rate of 7.01%. All of the Term Loans mature on June 1, 2019. The Company was required to make interest only payments through June 2016, followed by thirty-six months of equal principal and interest payments thereafter. 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, 2016. See Note 15 regarding the amendment of the July 28, 2016 Term Loan Agreement to include an additional interest-only period for all advances under the Term Loan Agreement.

Note 9. Commitments and Contingencies

Operating Leases

The Company leases its office facilities, located in Concord, California and Amersfoort, the Netherlands, and certain equipment under non-cancelable operating leases with initial terms in excess of one year that require the Company to pay operating costs, property taxes, insurance and maintenance. The operating leases expire at various dates through 2020, with certain of the leases providing for renewal options, provisions for adjusting future lease payments based on the consumer price index, and the right to terminate the lease

early. The Company's leased facilities qualify as operating leases under ASC Topic 840, "Leases" and as such, are not included on its consolidated balance sheets.

Financed Leasehold Improvements

In 2010, the Company financed $1.1 million of leasehold improvements. The Company pays for the financed leasehold improvements as a component of rent and is required to reimburse its landlord over the remaining life of the respective leases. At June 30, 2016, the Company had an outstanding liability of $0.4 million related to these leasehold improvements, of which $0.1 million was reflected in "Accrued liabilities" and $0.3 million was reflected in "Other non-current liabilities" on the Company's consolidated balance sheets.

Purchase Commitments

The Company is party to agreements with certain suppliers for certain components of the INTERCEPT Blood System. Certain of these agreements require minimum purchase commitments from the Company.

Note 10. Stockholders' Equity

Sales Agreement

On May 5, 2016, the Company entered into Amendment No. 2 to the Controlled Equity Offering^{SM} Sales Agreement, dated August 31, 2012, as previously amended on March 21, 2014, (together, the "Amended Cantor Agreement") with Cantor Fitzgerald & Co. ("Cantor") that provides for the issuance and sale of shares of the Company's common stock over the term of the Amended Cantor Agreement having an aggregate offering price of up to $132.2 million through Cantor. As a result of Amendment No. 2, at May 5, 2016, the Company had $70 million of common stock available to be sold under the Amended Cantor Agreement. 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 six months ended June 30, 2016, 2.4 million shares of the Company's common stock were sold under the Amended Cantor Agreement for net proceeds of $14.5 million. At June 30, 2016, the Company had $70 million of common stock available to be sold under the Amended Cantor Agreement.

Note 11. Stock-Based Compensation

Employee Stock Purchase Plan

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. The Purchase Plan was authorized to issue an aggregate of 1,320,500 shares. 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, 2016, the Company had 1,551,390 shares available for future issuance.

2008 Equity Incentive Plan

The Company also 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. On June 6, 2012 and June 12, 2013, the stockholders approved amendments to the Amended 2008 Plan (collectively the "Amended 2008 Plan") such that the Amended 2008 Plan had reserved for issuance an amount not to exceed 19,540,940 shares. 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. Awards under the Amended 2008 Plan generally have a maximum term of 10 years from the date of the award. The Amended 2008 Plan generally requires options to be granted at 100% of the fair market value of the Company's common stock subject to the option on the date of grant. Options granted by the Company to employees generally vest over four years. Restricted stock units (RSUs) are measured based on the fair market value of the underlying stock on the date of grant and will generally vest over three years. Performance-based stock or cash awards granted under the Amended 2008 Plan are limited to either 500,000 shares of common stock or $1.0 million per recipient per calendar

year. The attainment of any performance-based awards granted shall be conclusively determined by a committee designated by the Company's Board of Directors. At June 30, 2016, no performance-based stock options were outstanding.

At June 30, 2016, the Company had an aggregate of approximately 20.9 million shares of its common stock subject to outstanding options or RSUs, or remaining available for future issuance under the Amended 2008 Plan, of which approximately 15.9 million shares and 0.7 million shares were subject to outstanding options and outstanding RSUs, respectively, and approximately 4.4 million shares were available for future issuance under the Amended 2008 Plan. The Company's policy is to issue new shares of common stock upon the exercise of options or vesting of RSUs.

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, 2015	14,119	$ 4.21
Granted	2,225	5.15
Forfeited	(63)	6.11
Expired	(232)	6.81
Exercised	(196)	2.58
Balances at June 30, 2016	15,853	$ 4.32

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

	Number of Shares Outstanding	Weighted Average Grant Date Fair Value per Share
Balances at December 31, 2015	-	$ -
Granted	687	5.14
Forfeited	(12)	5.06

Vested	-	-
Balances at June 30, 2016	675	$ 5.14

The Company uses the Black-Scholes option pricing model to determine the grant-date fair value of stock options and employee stock purchase plan rights. 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.

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 items 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 effect in continuing operations. During the three and six months ended June 30, 2016, the Company recorded unrealized losses of $0.4 million and $4.3 million, net of taxes, on its investments in available-for-sale securities in other comprehensive income. As a result, the Company recorded tax expense of $1.0 million and $1.8 million for the three and six months ended June, 2016, respectively.

Note 13. Development and License Agreements

Agreements with Fresenius

Fresenius manufactures and supplies the platelet and plasma systems to the Company under a supply agreement. Under the previous agreements with Fresenius, the Company was required to pay royalties on INTERCEPT Blood System product sales at royalty rates

that varied by product. In addition, Fresenius was obligated to sell, and the Company was 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. The pricing was fixed for finished kits with successive decreasing pricing tiers at various annual production volumes. Fresenius was 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.

In October 2015, the Company entered into an Amended and Restated Manufacturing and Supply Agreement (the "2015 Agreement") with Fresenius, which amended and restated its previous agreements. Under the 2015 Agreement, Fresenius continues to be obligated to sell and the Company is obligated to purchase finished disposable kits for the Company's platelet and plasma systems and the Company's red blood cell system product candidate (the "RBC Sets"). The 2015 Agreement permits the Company to purchase platelet and plasma systems and RBC Sets from third parties to the extent necessary to maintain supply qualifications with such third parties or where local or regional manufacturing is needed to obtain product registrations or sales. Pricing terms per unit are initially fixed and decline at specified annual production levels, and are subject to certain adjustments after the initial pricing term. Under the 2015 Agreement, the Company is no longer required to make royalty payments to Fresenius for the sale of products after June 30, 2015. Under the 2015 Agreement, the Company maintains the amounts due from the components sold to Fresenius as a current asset on its accompanying consolidated balance sheets until such time as the Company purchases finished disposable kits using those components.

The 2015 Agreement also requires the Company to make certain payments totaling €8.6 million ("Manufacturing and Development Payments") to Fresenius in 2016 and on December 31 of the earlier of (a) the year of achievement of certain production volumes or (b) 2022. Because these payments represent unconditional payment obligations, the Company recognized its liability for these payments at their net present value at discount rate of 9.72% based on the Company's effective borrowing rate. The Manufacturing and Development Payments liability is accreted through interest expense based on the estimated timing of its ultimate settlement. As of June 30, 2016, the Company had paid $1.2 million (€1.1 million) and accrued $7.0 million (€6.4 million) related to the Manufacturing and Development Payments, of which $2.2 million (€2.0 million) was included in "Manufacturing and development obligations - current", and $4.8 million (€4.4 million) was included in "Manufacturing and development obligations - non-current" on the Company's Consolidated Balance Sheets.

As of December 31, 2015, the Company had accrued $7.8 million (€7.2 million) related to the Manufacturing and Development Payments, of which $3.3 million (€3.0 million) was included in "Manufacturing and development obligations - current", and $4.5 million (€4.2 million) was included in "Manufacturing and development obligations - non-current" on the Company's Consolidated Balance Sheets.

The Manufacturing and Development Payments will be made to support certain projects Fresenius will perform on behalf of the Company related to R&D activities and manufacturing efficiency activities. The Company allocated $4.8 million to R&D activities and $2.4 million to manufacturing efficiency activities based on their market value in October 2015. The prepaid asset related to amounts paid up front for the R&D activities to be conducted by Fresenius on behalf of the Company is expensed over the period which such activities occur. The manufacturing efficiency asset is expensed on a straight line basis over the life of the 2015 Agreement. As of June 30, 2016 and December 31, 2015, the prepaid asset related to amounts paid up front for the R&D activities to be conducted by Fresenius on behalf of the Company was included in "Other current assets" on the Company's Consolidated Balance Sheets at $3.3 million and $4.1 million, respectively. As of June 30, 2016 and December 31, 2015, the manufacturing efficiency asset was included in "Other assets" on the Company's Consolidated Balance Sheets at $2.2 million and $2.4 million, respectively.

The initial term of the 2015 Agreement extends through July 1, 2025 (the "Initial Term") and is automatically renewed thereafter for additional two year terms (each, a "Renewal Term"), subject to termination by either party upon (i) two years written notice prior to the expiration of the Initial Term or (ii) one year written notice prior to the expiration of any Renewal Term. Under the 2015 Agreement, the Company has the right, but not the obligation, to purchase certain assets and assume certain liabilities from Fresenius.

The Company made payments to Fresenius of $3.5 million and $4.7 million relating to the manufacturing of the Company's products during the three months ended June 30, 2016 and 2015, respectively, and $7.0 million and $9.4 million during the six months ended June 30, 2016 and 2015, respectively. At June 30, 2016 and December 31, 2015, the Company owed Fresenius $2.8 million and $2.5 million, respectively, for platelet and plasma system disposable kits manufactured. At June 30, 2016 and December 31, 2015, amounts due from Fresenius were $0.9 million and $0.2 million, respectively.

Agreement with BARDA

In June 2016, the Company entered into an agreement with the Biomedical Advanced Research and Development Authority ("BARDA") to support the Company's clinical development of the INTERCEPT Blood System for red blood cells (the "red blood cell system") for pathogen reduction of red blood cell components.

The five-year agreement with BARDA includes a base period with funding of up to $30.8 million (the "Base Period"), and subsequent option periods (each an "Option Period") that, if exercised by BARDA and completed, would bring the total funding opportunity to

$180.5 million over the five-year contract period. If exercised by BARDA, subsequent options would fund activities related to broader implementation of the platelet and plasma system or the red blood cell system in areas of Zika virus risk, clinical and regulatory development programs in support of the potential licensure of the red blood cell system in the U.S., and development, manufacturing and scale-up activities for the red blood cell system. The Company could be responsible for co-investment of up to $14.5 million. BARDA will make periodic assessments of the Company's progress and the continuation of the agreement is based on the Company's success in completing the required tasks under the Base Period and each Option Period (if and to the extent any Option Periods are exercised by BARDA). BARDA has rights under certain contract clauses to terminate the agreement, including the ability to terminate the agreement for convenience at any time.

Under the contract, the Company is reimbursed and recognizes revenue as allowable direct contract costs are incurred plus allowable indirect costs, based on approved provisional indirect billing rates, which permit recovery of fringe benefits, overhead and general and administrative expenses. The Company did not recognize revenue under the BARDA agreement during the three and six months ended June 30, 2016 and 2015.

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 U.S. are responsible for the R&D 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.

The Company had the following significant customers that accounted for more than 10% of the Company's total revenue, each of which operates in a country outside of the U.S., during the three and six months ended June 30, 2016 and 2015 (in percentages):

	Three Months Ended June 30,		Six Months Ended June 30,	
	2016	2015	2016	2015
Etablissement Francais du Sang	*	25 %	*	25 %
Rode Kruis Vlaanderen	*	*	10%	*

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

Note 15. Subsequent Event

On July 28, 2016, the Oxford Term Loan Agreement was amended to include an additional interest-only period for all advances under the Term Loan Agreement. As amended, the Company is required to make interest only payments from August 2016 through January 2017 followed by twenty-nine months of equal principal and interest payments thereafter.

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, 2015. Operating results for the three and six months ended June 30, 2016 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, or U.S., 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 U.S., as well as our ability to manage the risks attendant to our international operations;
- 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 amount and availability of funding we may receive under the recently executed agreement with the Biomedical Advanced Research and Development Authority, or BARDA;
- our ability to transition distribution of the INTERCEPT Blood System from third parties to a direct sales model in certain international markets;
- the ability of our products to inactivate the Ebola virus, the Zika 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.

In some cases, you can identify forward-looking statements by terms such as "anticipate," "will," "believe," "estimate," "expec "plan," "may," "should," "could," "would," "project," "predict," "potential," and similar expressions intended to identify such forward-looking statements. Forward-looking statements reflect our current views with respect to future events, are based on assumptions, and are subject to risks and uncertainties. There can be no assurance that 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 extension or additional claims for our products, our ability to obtain reimbursement approval for our products, our ability to complete the development and testing of additional

configurations or redesigns of our products, our need for additional financing and our ability to access funding under the BARDA agreement, 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 red blood cell system's 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, on-going compliance with the requirements of the Sarbanes-Oxley Act of 2002 and other factors discussed below and under the caption "Risk Factors" in Item 1A of this Quarterly Report on Form 10-Q. 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 U.S. Food and Drug Administration, or FDA, for the platelet system and the plasma system. The platelet system is approved in the U.S. 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 U.S. for ex vivo preparation of plasma in order to reduce the risk of TTI when treating patients requiring therapeutic plasma transfusion.

The INTERCEPT Blood System for red blood cells, or the 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 ongoing European Phase III clinical trial of our red blood cell system for chronic anemia patients. Although we plan to complete additional development activities to support an anticipated CE mark submission for the red blood cell system in 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 in the next twelve months, 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, we may need to generate additional safety data from commercial use and/or achieve a successful outcome in the ongoing chronic anemia Phase III clinical trial for our red blood cell system in order 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 activities, we will need to complete a number of in vitro studies prior to receiving any regulatory approvals in Europe and will have to complete additional activities prior to receiving regulatory approvals in the U.S. Successful completion of these activities may require capital beyond that which we currently have or that may be available to us under our agreement with BARDA, 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

experience delays in testing, conducting trials or obtaining approvals, our product development costs will increase.

In June 2016, we entered into a five-year agreement with BARDA, part of the U.S. Department of Health and Human Services' Office of the Assistant Secretary for Preparedness and Response, to receive initial funding of up to $30.8 million with a total funding opportunity of up to $180.5 million to support the development of our red blood cell system, including clinical and regulatory development programs in support of licensure, and development, manufacturing and scale-up activities, as well as activities related to broader implementation of all three INTERCEPT systems in areas of Zika virus risk. Under the contract, BARDA reimburses us as allowable direct contract costs are incurred plus allowable indirect costs. See "BARDA" below for more information.

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, commitments to fund projects with Fresenius, costs to develop different configurations of existing products and new products, including our illuminator, costs associated with planning, enrolling and completing ongoing studies, and

the post-approval studies 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, costs associated with performing the agreed-upon activities under our BARDA agreement, 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 required post-approval studies 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 continued access to funds under our BARDA agreement and the 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 and under our agreement with BARDA, 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 may pursue 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 the volatile global financial markets, general economic uncertainty or other factors, we may need to curtail planned development or commercialization activities. In addition, we may need to obtain additional funds to complete development activities for the red blood cell system necessary for potential regulatory approval in Europe, if costs are higher than anticipated or we encounter delays. We may need to obtain additional funding to conduct additional randomized controlled clinical trials for existing or new products, particularly if we are unable to access the full amount of funding contemplated by our BARDA agreement, and we may choose to defer such activities until we can obtain sufficient additional funding or, at such time, our existing operations provide sufficient cash flow to conduct these trials.

Our commercial activities in the U.S. are currently 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 Commonwealth of Independent States, or 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.

In addition to the product revenues from sales of our platelet and plasma systems, we may recognize revenue from government contracts or grants. We will recognize revenue associated with the BARDA agreement as qualified costs are incurred for reimbursement over the performance period.

Aduro Biotech

We hold an investment in Aduro Biotech Inc., or Aduro, common stock totaling 396,700 shares. Aduro trades on the NASDAQ Global Select Market, under the symbol “ADRO”. As of June 30, 2016, the fair value of Aduro’s common stock was $11.31 per share. We account for the investment in Aduro as an available-for-sale security on our consolidated balance sheet and adjust the carrying value of this investment to fair value each quarterly reporting period with changes in fair value recorded within other comprehensive

income (loss), net of tax. Prior to Aduro's IPO in April 2015, we held the investment in Aduro at zero on our consolidated balance sheet.

Fresenius

Through June 30, 2015, we paid 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 varied by product: 10% of product sales for the platelet system and 3% of product sales for the plasma system. Fresenius 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, which we refer to as the 2013 Agreement. Under the 2013 Agreement, Fresenius was obligated to sell, and we were 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 was purchased from Fresenius, we were able to purchase additional quantities of disposable kits from other third-party manufacturers. The amended terms also provided for fixed pricing for finished kits with successive decreasing pricing tiers at various annual production volumes. In addition, the 2013 Agreement required us to purchase additional specified annual volumes of sets if and when an additional Fresenius manufacturing site was identified and qualified to make INTERCEPT disposable kits, subject to mutual agreement on pricing for disposable kits manufactured at the additional site. Fresenius was also obligated to purchase and maintain specified inventory levels of our proprietary inactivation compounds and compound adsorption devices from us at fixed prices.

In October 2015, we entered into a ten year Amended and Restated Manufacturing and Supply Agreement, or the 2015 Agreement, with Fresenius, which amended and restated the 2013 Agreement. Under the 2015 Agreement, Fresenius continues to be obligated to sell and we are obligated to purchase finished disposable kits for our platelet, plasma and red blood cell systems. The 2015 Agreement permits us to purchase platelet, plasma and red blood cell systems from third parties to the extent necessary to maintain supply qualifications with such third parties or where local or regional manufacturing is needed to obtain product registrations or sales. Pricing terms are initially fixed and decline at specified annual production levels, and are subject to certain adjustments after the initial pricing term.

Under the 2015 Agreement, we are no longer required to make royalty payments to Fresenius for the sale of products after June 30, 2015. Under the 2015 Agreement, we maintain the amounts due from the components sold to Fresenius as a current asset on our accompanying consolidated balance sheets until such time as we purchase finished disposable kits using those components. The 2015 Agreement also requires us to make certain payments totaling €8.6 million, or the Manufacturing and Development Payments, to Fresenius in 2016 and on December 31 of the earlier of (a) the year of achievement of certain production volumes or (b) 2022. Because these payments represent unconditional payment obligations, we recognize our liability for these payments at their net present value. The Manufacturing and Development Payments liability is accreted through interest expense based on the estimated timing of its ultimate settlement. As of June 30, 2016, we had accrued $7.0 million (€6.4 million) related to the Manufacturing and Development Payments.

The Manufacturing and Development Payments will be made to support certain projects Fresenius will perform on our behalf related to research and development, or R&D activities and manufacturing efficiency activities. We allocated $4.8 million to R&D activities and $2.4 million to manufacturing efficiency activities based on their market value in October 2015. The prepaid asset related to amounts paid up front for the R&D activities to be conducted by Fresenius on our behalf is expensed over the period which such activities occur. The manufacturing efficiency asset is expensed on a straight line basis over the life of the 2015 Agreement.

The initial term of the 2015 Agreement extends through July 1, 2025, or the Initial Term, and is automatically renewed thereafter for additional two year terms, or Renewal Terms, subject to termination by either party upon (i) two years written notice prior to the expiration of the Initial Term or (ii) one year written notice prior to the expiration of any Renewal Term. Under the 2015 Agreement, we have the right, but not the obligation, to purchase certain assets and assume certain liabilities from Fresenius.

While we and Fresenius recently entered into the 2015 Agreement, in the event that Fresenius refuses or is unable to continue operating under the 2015 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. Like most regulated manufacturing processes, our ability to produce our products is dependent on our or Fresenius' ability to source components and raw materials which

may at times be in short demand or obsolete. In such cases, we and/or Fresenius may need to source, qualify and obtain approval for replacement materials or components which would likely prove to be disruptive and consume capital resources sooner than we anticipate.

BARDA

In June 2016, we entered into an agreement with BARDA to support our clinical development of the red blood cell system, including access to funding that could potentially support various activities, including funding studies necessary to support a potential PMA submission to the FDA for the red blood cell system, and acceleration of commercial scale up activities to facilitate potential adoption of the red blood cell system by U.S. blood centers.

The five-year agreement with BARDA includes a base period with funding of up to $30.8 million, or the Base Period, and subsequent option periods, or each an Option Period, that, if exercised by BARDA and completed, would bring the total funding opportunity to $180.5 million over the five-year contract period. If exercised by BARDA, each subsequent option would fund activities related to broader implementation of the platelet and plasma system or the red blood cell system in areas of Zika virus risk, clinical and regulatory development programs in support of the potential licensure of the red blood cell system in the U.S., and development, manufacturing and scale-up activities for the red blood cell system. We could be responsible for co-investment of up to $14.5 million. BARDA will make periodic assessments of our progress and the continuation of the agreement is based on our success in completing the required tasks under the Base Period and each Option Period (if and to the extent any Option Periods are exercised by BARDA). BARDA has rights under certain contract clauses to terminate the agreement, including the ability to terminate for convenience at any time.

Under the contract, we will be reimbursed and recognize revenue as qualified direct contract costs are incurred plus allowable indirect costs, based on approved provisional indirect billing rates, which permit recovery of fringe benefits, overhead and general and administrative expenses. We did not recognize revenue under the BARDA agreement during the three and six months ended June 30, 2016 and 2015.

Equity and Debt Agreements

Cantor

On May 5, 2016, we entered into Amendment No. 2 to the Controlled Equity Offering^{SM} Sales Agreement, dated August 31, 2012, as previously amended on March 21, 2014, which together 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 $132.2 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 available under the Securities Act of 1933, as amended. During the six months ended June 30, 2016, 2.4 million shares of our common stock were sold under the Amended Cantor Agreement for aggregate net proceeds of $14.5 million. At June 30, 2016, we had $70 million of common stock available to be sold under the Amended 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 the second tranche, or Term Loan B. On September 29, 2015, the Term Loan Agreement was amended to extend (i)

the period in which the third tranche can be drawn and (ii) the interest-only period for all advances under the Term Loan Agreement. As amended, the availability of the third tranche of $10.0 million, or Term Loan C, was subject to our achievement of consolidated trailing six months' revenue at a specified threshold, or the Revenue Event, no later than June 30, 2016. As we did not achieve consolidated trailing six months' revenue at the specified threshold by June 30, 2016, Term Loan C was not available to be drawn. Term Loan A bears an interest rate of 6.95%, and Term Loan B bears an interest rate of 7.01%. All of the Term Loans mature on June 1, 2019. Following the amendment to Term Loan Agreement, we were required to make interest only payments through June 2016 followed by thirty-six months of equal principal and interest payments thereafter. On July 28, 2016, the Term Loan Agreement was amended to include an additional interest-only period for all advances under the Term Loan Agreement. As amended, we are required to make interest only payments from August 2016 through January 2017 followed by twenty-nine months of equal principal and interest payments thereafter. 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, 2016. 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 2015 Form 10-K with the SEC on March 9, 2016. For a description of our critical accounting policies, please refer to our 2015 Annual Report on Form 10-K.

Results of Operations

Three and Six Months Ended June 30, 2016 and 2015

Revenue

	Three Months Ended June 30,				Six Months Ended June 30,			
(in thousands, except percentages)	2016	2015	Change		2016	2015	Change	
Revenue	$9,251	$8,830	$421	5%	$16,883	$16,522	$361	2%

Revenue increased during the three and six months ended June 30, 2016, compared to the three and six months ended June 30, 2015, primarily as a result of favorable foreign exchange rates during the three months ended June 30, 2016, as compared to the three months ended June 30, 2015, and increased utilization of platelet kits in our European markets during the three and six months ended June 30, 2016.

We anticipate product revenue for INTERCEPT disposable kits 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 and newly accessible geographies. However, deterioration in the Euro relative to the U.S. dollar and continued general declines in the economic climate in Russia and the CIS markets would continue to adversely impact revenue as the majority of our revenues are expected to come from Euro denominated markets. As a result of these and other factors, the historical results may not be indicative of INTERCEPT Blood System revenue in the future.

We did not recognize any revenue from our BARDA agreement during the three and six months ended June 30, 2016 and 2015. We expect to begin recognizing revenue under our BARDA agreement in the third quarter of 2016.

Cost of Revenue

Our cost of revenue consists of the cost of the INTERCEPT Blood System sold, provisions for obsolete, slow-moving and unsaleable product, certain order fulfillment costs, to the extent applicable, costs for idle facilities, and, prior to October 19, 2015, royalties payable to Fresenius for product sales. Inventory is accounted for on a first-in, first-out basis.

(in thousands, except percentages)	Three Months Ended June 30, 2016	2015	Change		Six Months Ended June 30, 2016	2015	Change	
Cost of revenue	$4,976	$7,028	$(2,052)	(29%)	$9,239	$11,742	$(2,503)	(21%)

Cost of revenue decreased during the three and six months ended June 30, 2016, compared to the three and six months ended June 30, 2015. These decreases were primarily the result of the elimination of the royalty to Fresenius in the fourth quarter of 2015 and inventory produced during periods of more favorable foreign currency exchange rates and favorable sales mix of products sold to customers.

Our realized gross margin on product sales was 46% during the three months ended June 30, 2016, up from 20% during the three months ended June 30, 2015. Our realized gross margin on product sales was 45% during the six months ended June 30, 2016, up from 29% during the six months ended June 30, 2015. The increases in gross margins on sales in both periods was primarily due to the favorable foreign exchange impact on cost of revenues which were recorded at foreign exchange rates in effect at the time the inventory was purchased, which was lower than the rates at the time of sale and improved sales mix, and the elimination of the royalty to Fresenius in the fourth quarter of 2015.

Changes in our gross margins are affected by various factors, including the volume of product manufactured and the relative per unit pricing in our agreement with Fresenius Kabi, 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 products are 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, or delays in manufacturing products. In addition, we may face competition which may limit our ability to maintain existing selling prices for our products which in turn would negatively affect our reported gross margins. Our gross margins may be impacted in the future based on all of these and other 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 2015.

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)	2016	2015	Change		2016	2015	Change	
Research and development	$8,557	$5,213	$3,344	64%	$15,474	$10,794	$4,680	43%

Research and development expenses increased during the three and six months ended June 30, 2016, compared to the three and six months ended June 30, 2015, primarily due to increased costs associated with clinical development of our red blood cell system and our pursuit of PMA supplement approvals for the platelet and plasma systems.

We expect to incur additional research and development costs associated with planning, enrolling and completing our required post-approval studies for the platelet system, 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 U.S., completing 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, and costs associated with performing the activities under our BARDA agreement. 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, internal control, legal and facility and infrastructure related expenses, and insurance premiums.

(in thousands, except percentages)	Three Months Ended June 30, 2016	2015	Change		Six Months Ended June 30, 2016	2015	Change	
Selling, general and administrative	$12,406	$12,063	$343	3%	$24,153	$23,781	$372	2%

Selling, general, and administrative expenses increased slightly during the three and six months ended June 30, 2016, compared to the three and six months ended June 30, 2015.

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. and undertake additional activities associated with performing the activities under our BARDA agreement, including incremental back-office support, sales and marketing personnel, as well as medical science liaisons to educate hospitals and physicians on our products and drive hospital demand for INTERCEPT-treated blood components.

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.

(in thousands, except percentages)	Three Months Ended June 30, 2016	2015	Change		Six Months Ended June 30, 2016	2015	Change	
Amortization of intangible assets	$51	$ 51	$ -	0 %	$101	$101	$ -	0 %

Amortization of intangible assets remained flat during the three and six months ended June 30, 2016, compared to the three and six months ended June 30, 2015.

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 Income (Expense), Net

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

(in thousands, except percentages)	Three Months Ended June 30, 2016	2015	Change		Six Months Ended June 30, 2016	2015	Change	
(Loss) gain from revaluation of warrant liability	$-	$(2,707)	$2,707	(100%)	$-	$3,589	$(3,589)	(100%)
Foreign exchange gain (loss)	101	499	(398)	(80 %)	(16)	(614)	598	(97 %)
Interest expense	(658)	(301)	(357)	119 %	(1,313)	(556)	(757)	136 %
Other income, net	113	27	86	319 %	179	29	150	517 %
Total non-operating (expense) income, net	$(444)	$(2,482)	$2,038	(82 %)	$(1,150)	$2,448	$(3,598)	(147%)

Gain from revaluation of Warrant liability

In November 2010, we issued warrants to purchase an aggregate of 3.7 million shares of common stock in connection with an offering of our common stock. In November 2015, all of the outstanding warrants were exercised. The fair value of the outstanding warrants, which was calculated using the Black-Scholes model, was classified as a liability on our unaudited condensed consolidated balance sheets and was adjusted at each reporting period, until such time the instruments were exercised. Upon exercise, the fair value of the warrants was reclassified from liabilities to stockholders' equity. We had no outstanding warrants during the three and six months ended June 30, 2016.

Foreign exchange (loss) gain

We recorded a foreign exchange gain of $0.1 million during the three months ended June 30, 2016, compared to a foreign exchange gain of $0.5 million during the three months ended June 30, 2015, the decrease in foreign exchange gain period over period is primarily attributable to unfavorable foreign currency variations between the Euro and U.S. dollar. Foreign exchange loss decreased during the six months ended June 30, 2016, compared to the six months ended June 30, 2015, primarily attributable to favorable foreign currency variations between the Euro and U.S. dollar during the comparable periods.

Other income, net

Other income, net increased during the three and six months ended June 30, 2016, compared to the three and six months ended June 30, 2015, primarily due to increased interest income from our investments in marketable securities.

Interest expense

Interest expense increased for the three and six months ended June 30, 2016 compared to the three and six months ended June 30, 2015, primarily due a higher effective interest rate and larger outstanding debt balance under our Term Loan Agreement (see discussion under the heading “Debt” below), resulting from the drawdown of Term Loan B of $10.0 million in June 2015.

Provision for Income Taxes

For the three and six months ended June 30, 2016, we recorded a tax expense of $1.0 million and $1.8 million, respectively, which were largely the result of changes in the fair value of our investments, primarily shares of Aduro. The tax expense partially offsets the tax benefit recorded in other comprehensive income which is also associated with the decreased value of our Aduro investment. For both the three and six months ended June 30, 2015, we recorded a tax benefit of $2.0 million, which was associated with the unrealized increase in the fair value of our investment in Aduro.

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 of 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, 2016.

As of June 30, 2016, 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, 2016, we had cash and cash equivalents of $7.7 million, compared to $71.0 million at December 31, 2015. We had $80.8 million of short-term investments and investments in marketable equity securities at June 30, 2016, and $36.9 million at December 31, 2015. We also had total indebtedness under our Term Loan Agreement of approximately $19.9 million at June 30, 2016 and $19.8 million at December 31, 2015. 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, 2016, our investment in marketable equity securities consists of $4.5 million related to our investment in Aduro.

Operating Activities

Net cash used in operating activities was $27.6 million for the six months ended June 30, 2016, compared to $30.5 million during the six months ended June 30, 2015. The decrease in net cash used in operating activities was primarily related to changes in working capital with a net increase in the combined total for our accounts payable and accrued liabilities as a result of the timing of payments during the six months ended June 30, 2016, as compared to the corresponding period in 2015. The decrease in net cash used in operating activities was offset by an increased inventory build during the six months ended June 30, 2016, compared to the corresponding period in 2015 and increased cash spent for development activities for our red blood cell program and selling and administrative expenses related to U.S. commercial launch of our platelet and plasma systems.

Investing Activities

Net cash used in investing activities was $51.1 million for the six months ended June 30, 2016, compared to $48.0 million during the six months ended June 30, 2015. The change period over period was primarily the result of lower proceeds from maturities of investments in marketable securities during the six months ended June 30, 2016, as

compared to the same period in 2015.

Financing Activities

Net cash provided by financing activities was $15.4 million during the six months ended June 30, 2016, compared to $90.7 million during the six months ended June 30, 2015. The decrease in net cash provided by financing activities was primarily due to the decrease of proceeds received from public offerings. In January 2015, we issued 14.6 million shares of our common stock in an underwritten public offering for approximately $75.3 million. This was further impacted by our drawdown of Term Loan B of $10.0 million in June 2015.

Working Capital

Working capital decreased to $86.5 million at June 30, 2016, from $108.5 million at December 31, 2015, primarily due to the decline of the market value of our investment in Aduro, and lower cash, cash equivalent and short-term investments balances, which was used to support ongoing operations.

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, commitments to fund projects with Fresenius, costs to develop different configurations of existing products and new products, including our illuminator, costs associated with planning, enrolling and completing ongoing studies, and the post-approval studies 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, costs associated with performing the agreed-upon activities under our BARDA agreement, 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 required post-approval studies 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 continued access to funds under our BARDA agreement and the 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 and under our agreement with BARDA, 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 may pursue 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.

While we expect to receive significant funding under our five-year agreement with BARDA, our ability to obtain such funding is subject to various risks and uncertainties, including BARDA’s ability to terminate the agreement for convenience at any time. In addition, access to federal contracts or grants is subject to the authorization of funds and approval of our research plans by various organizations within the federal government, including the U.S. Congress. The general economic environment, coupled with tight federal budgets, has led to a general decline in the amount available for government funding. If BARDA were to eliminate, reduce or delay funding under our agreement, this would have a significant negative impact on the programs associated with such funding and could have a significant negative impact on our revenues and cash flows. In addition, if we are unable to reach agreement with the FDA on a license enabling Phase III clinical trial design for our red blood cell system, our agreement with BARDA will be severely limited in scope or could be terminated altogether, and our ability to complete the development activities required for licensure in the U.S. may require additional capital beyond which we currently have. If alternative sources

of funding are not available, we may be forced to suspend or terminate development activities related to the red blood cell system in the U.S.

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. We may need to curtail planned development or commercialization activities. In addition, we may need to obtain additional funds to complete development activities for the red blood cell system necessary for potential regulatory approval in Europe, if costs are higher than anticipated or we encounter delays. If we are unable to access any portion of the funding available under the BARDA agreement, we may need to obtain additional funding to conduct additional randomized controlled clinical trials for existing or new products, particularly if we are unable to access the full amount of funding contemplated by our BARDA agreement, and we may choose to defer such activities until we can obtain sufficient additional funding or, at such time, our existing operations provide sufficient cash flow to conduct these trials.

Commitments and Off-Balance Sheet Arrangements

Off-balance sheet arrangements

We did not have any off-balance sheet arrangements as of June 30, 2016.

Contractual Commitments

The following summarizes our contractual commitments at June 30, 2016:

(in thousands)	Total	Less than 1 year	1 - 3 years	4 - 5 years	After 5 years
Minimum purchase requirements	$6,895	$6,183	$356	$356	$ -
Manufacturing and development obligations	8,329	2,221	6,108	-	-
Debt	23,625	7,408	16,217	-	-
Operating leases	3,112	1,165	1,637	310	-
Other commitments	1,156	809	287	60	-
Total contractual obligations	$43,117	$17,786	$24,605	$726	$ -

Minimum purchase requirements

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

Manufacturing and development obligations

On October 19, 2015, we entered into the 2015 Agreement with Fresenius. The 2015 Agreement calls for remaining payments of $2.2 million (€2.0 million) to be made in 2016, and a payment of $6.1 million (€5.5 million) on December 31 of the year in which certain production volumes are achieved, or December 31, 2022, whichever occurs first. We expect to achieve, and the table above assumes that we achieve, the production threshold in 2018.

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 2020, 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. Our leased facilities qualify as operating leases under ASC Topic 840, “Leases” and as such, are not included on our unaudited condensed consolidated balance sheets.

Other commitments

Our other commitments primarily consist of obligations for landlord financed leasehold improvements, which are in addition to the operating leases we have for office and laboratory space and consulting fees. 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. At June 30, 2016, we had an outstanding liability of $0.4 million related to these leasehold

improvements. Also included in other commitments are consulting fees of $0.6 million to be paid in 2016 and 2017.

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. On September 29, 2015, the Term Loan Agreement was amended to extend the period in which the third tranche could have been drawn and the interest-only period for all advances under the Term Loan Agreement. As amended, the third tranche of $10.0 million, Term Loan C, was subject to our achievement of the Revenue Event no later than June 30, 2016. We did not achieve the Revenue Event by June 30, 2016 and therefore Term Loan C was not available to be drawn. Term Loan A bears an interest rate of 6.95%., and Term Loan B bears an interest rate of 7.01%. All of the Term Loans mature on June 1, 2019. Following the amendment, we were required to make interest only payments through June 2016 followed by thirty-six months of equal principal and interest payments thereafter. 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. The Term Loan Agreement contains certain nonfinancial covenants, with which we were in compliance at June 30, 2016. 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.

On July 28, 2016, the Term Loan Agreement was amended to include an additional interest-only period for all advances under the Term Loan Agreement. As amended, we are required to make interest only payments from August 2016 through January 2017 followed by twenty-nine months of equal principal and interest payments thereafter.

Financial Instruments

Our investment policy is to manage our marketable securities portfolio to preserve principal and liquidity while maximizing the return on the investment portfolio to assist us in funding our operations. We currently invest our cash and cash equivalents in money market funds and interest-bearing accounts with financial institutions. Our money market funds are classified as Level 1 in the fair value hierarchy, in which quoted prices are available in active markets, as the maturity of money market funds are relatively short and the carrying amount is a reasonable estimate of fair value. Our marketable equity securities consist of our investment in Aduro and are classified as Level 1 in the fair value hierarchy, as quoted price in active markets is readily available. 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, 2016 or the year ended December 31, 2015. 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

See “New Accounting Pronouncements” section in Note 1, “Summary of Significant Accounting Policies” in the Notes to our unaudited condensed consolidated financial statements.

ITEM 3. QUANTITATIVE AND QUALITATIVE DISCLOSURES ABOUT MARKET RISK

During the six months ended June 30, 2016, 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, 2015.

ITEM 4. CONTROLS AND PROCEDURES

Evaluation of Disclosure Controls and Procedures

Our principal executive officer and principal financial officer are responsible for establishing and maintaining “disclosure controls and procedures” (as defined in Rules 13a-15(e) and 15d-15(e), promulgated under the Securities Exchange Act of 1934, as amended) for our company. Based on their evaluation of our disclosure controls and procedures as of the end of the period covered by this Quarterly Report on Form 10-Q, our principal executive officer and principal financial officer have concluded that our disclosure controls and procedures were effective as of June 30, 2016.

Changes in Internal Control over Financial Reporting

There were no changes in our internal control over financial reporting which occurred during our fiscal quarter ended June 30, 2016, that have 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. Accordingly, our disclosure controls and procedures are designed to provide reasonable assurance, not absolute assurance, that the objectives of our disclosure control system are met and, as set forth above, our principal executive officer and principal financial officer have concluded, that based on their evaluation as of the end of the period covered by this Quarterly Report on Form 10-Q, our disclosure controls and procedures were effective to provide reasonable assurance that the objective of our disclosure control system were met.

PART II: OTHER INFORMATION

ITEM 1. LEGAL PROCEEDINGS
None.

ITEM 1A. RISK FACTORS
Risk Factors

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

We depend substantially upon the commercial success of the INTERCEPT Blood System for platelets and plasma in the United States, or U.S., and our inability to successfully commercialize the INTERCEPT Blood System in the U.S. would have a material adverse effect 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 U.S. market. As a result, our business is substantially dependent on our ability to successfully commercialize the INTERCEPT Blood System in the U.S. in a timely manner. In December 2014, we received U.S. regulatory approval of the INTERCEPT Blood System for platelets and plasma, with certain restrictions regarding usage and although the INTERCEPT Blood System is now commercially available in the U.S., we have no prior experience commercializing any products in the U.S. and we may be unable to commercialize the INTERCEPT Blood System in the U.S. successfully or in a timely manner, or at all. Based on our experience in foreign jurisdictions, potential customers in the U.S. may first choose to validate our technology or conduct experience studies of the INTERCEPT Blood System, among other activities, 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. Until those licenses are obtained, U.S. blood centers will be limited to sales to hospital customers within the state in which the INTERCEPT-treated platelets or plasma are processed. 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 further delay customer adoption in the U.S. If we are not successful in achieving market adoption of the INTERCEPT Blood System in the U.S., 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 U.S. 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, support and maintain 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;
- 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 U.S. 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;

- 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;
- the amount available for reimbursement pursuant to codes we have obtained 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 U.S. is dependent on our ability to operate without infringing on the intellectual property rights of others. For example, we are aware of a U.S. 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 U.S.

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 U.S., 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, or the perception of 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 customers that attempt to optimize collection practices in order to produce the highest volume of transfusable units with those collections may view adoption of INTERCEPT as detrimental to their processing yield and therefore revenue potential. 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, efficacy or other factors.

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 been shown to be effective in reducing 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. Should INTERCEPT-treated components contain detectable levels of pathogens after treatment, the efficacy of INTERCEPT may be called into question, whether or not any remaining pathogens are the result of INTERCEPT's efficacy or other factors. Such uncertainties may limit the market adoption of our products.

We have been operating 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 a 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. In addition, strains of infectious agents in living donors may be different from those strains commercially available or for which we have tested and for which we have received approval of the inactivation claims for our products. To the extent that actual results in human patients differ, commercially available or tested strains prove to be different, 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 studies 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, and hospitals may need to amend their product labels and inventory management systems before being able to move forward with INTERCEPT. This may require coordination between hospital suppliers and 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 data management application software for their operations before they would consider adopting INTERCEPT. Such software development efforts may be costly or we may be unsuccessful in developing a data management application that would be broadly accepted. Developing, maintaining and supporting software can be time consuming, costly and may require resources and skill sets that we do not possess. Failure to do so may limit market adoption in geographies where we commercialize the INTERCEPT Blood System, including the U.S.

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 economic legislation in certain 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 in the U.S. for in-patient treatment, 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 specific reimbursement. In the U.S., we only recently obtained HCPCS reimbursement codes for INTERCEPT treated platelets and plasma in the outpatient setting. 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, including under the new HCPCS codes, 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. Moreover, the market for pathogen reduction systems in the U.S. is highly concentrated and dominated by a small number of blood collection organizations. In the U.S., the American Red Cross represents the largest single portion of the blood collection market. While we entered into a multi-year commercial agreement with the American Red Cross in February 2016, we cannot guarantee the volume or timing of commercial purchases that the American Red Cross may make, if any, under our agreement. Conversely, given the large relative size of the American Red Cross, should they deploy the technology rapidly, our resources may be inadequate to fulfill the American Red Cross's and other customers' demands, which could result in a loss of revenues or customer contracts, or both. 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 December 2015, we entered into a new two-year framework agreement with the Établissement Français du Sang, or the EFS, to supply platelet and plasma disposable kits. The structure of this contract differs from our previous contract with EFS and requires that a subsequent contract be entered into to define prices and volumes. In March 2016, we entered into a subsequent contract with EFS for a period of one year at certain defined prices. We cannot provide any assurance that the terms, including the pricing or committed volumes, if any, of any additional subsequent contract will be equivalent or superior to the terms under our current subsequent contract. If the final commercial terms of any subsequent contract are less favorable than the terms under our existing contract, our financial results may be adversely impacted.

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 are currently under development but 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 cost of product sold, research and development and selling, general and administrative expenses have resulted in substantial losses since our inception. The platelet and plasma systems have been approved in the U.S. only since December 2014 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 blood safety interventions or 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 U.S., we expect to incur additional R&D costs associated with new product development, enhancements to existing products, planning, enrolling and completing our required post-approval studies, 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 U.S., and completing 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. These costs could be substantial and could extend the period during which we expect to operate at a loss, particularly if we experience any difficulties or delays in completing the activities.

In certain countries, governments have issued regulations relating to the pricing and profitability of medical products and medical product companies. Healthcare reform in the U.S. has also placed downward pressure on the pricing of medical products that could have a negative impact on 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 economy and credit and financial markets, including the sovereign debt crisis in certain countries in Europe, disruptions due to political instability or terrorist attacks, economies and currencies largely effected by declining commodity prices 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, or the announcement of the withdrawal of, one or more member countries from the European Union, or E.U., following the United Kingdom's, or U.K.'s, referendum in which voters approved an exit from the E.U., 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.

Additionally, a meaningful amount of our revenue has come from sales to our distributor in Russia and other CIS countries. Low worldwide oil prices and the current political conflict stemming from tensions in the Ukraine have significantly devalued the Russian Ruble and other CIS currencies and may continue to have a negative impact on the Russian and other CIS countries' economies, particularly if sanctions continue to be levied against Russia or are strengthened from those currently in place from either the E.U., U.S. or both. While our agreement with our Russian and other CIS distributors 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 or other CIS currencies may further weaken or remain weak, and our business in Russia and other CIS countries may be negatively impacted further. Similarly, low worldwide oil prices and current political conflicts may negatively impact potential future sales of our products in the Middle East and other oil producing exporters.

In addition, terrorist attacks and civil unrests in some of the countries where we do business, and the resulting need for enhanced security measures may impact our ability to deliver services, threaten the safety of our employees, and increase our costs of operations.

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 U.S. 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 labels from the FDA limit our current approvals to certain platelet collection platforms and a particular storage solution for the particular collection platform. For instance, our FDA approved claims permit apheresis collection of platelets on the Fresenius-Kabi Amicus device while stored in an additive solution or for apheresis collection of platelets collected on the Terumo Trima device and stored in 100% plasma. We may be required to provide the FDA with data for each permutation for which blood banking treatment practices exist which may be time consuming, costly and limit the potential size of the U.S. market that can use our products. In addition, in order to generate data that would be satisfactory to the FDA, we will need to test our products with different blood center production configurations producing otherwise saleable platelet products for the blood center. As such, we will generally need to purchase platelet components which are expensive and may be limited during periods of low platelet availability. Any such inability to procure platelets and generate data sufficient for label claim expansion may negatively impact our business opportunities.

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, delays in the conduct of the clinical trial by personnel at the clinical site or due to our inability to actively and timely monitor clinical trial sites because of travel restrictions, political instability or terrorist activity or concerns over employee safety. For example, our chronic anemia trial is currently enrolling patients in Turkey. We will not be able to monitor and manage the trial on site in Turkey until travel restrictions are lifted, if ever. 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 regulatory approval and 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 U.S., 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 or in vitro 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 and the additional post-approval study that we are required to conduct on recovery and survival of platelets suspended in 100% plasma in connection with the recent expanded label claim that we received for the platelet system. Each of these studies and any additional studies that the FDA may require could involve significant expense and may require us to secure adequate funding to complete. Other regulatory authorities outside of the U.S. 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.

Outside the U.S., 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 E.U. may require clinical data submissions, registration packages, import licenses or other documentation. Regulatory authorities in Japan, China, Taiwan, South Korea, Vietnam, Thailand, Singapore and elsewhere may require, among other requirements, that our products be widely adopted commercially in Europe and the U.S., 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 U.S., 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 U.S., blood centers are 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. Final development of the red blood cell system may never occur and failure can occur any time during the process. Any failure or delay in completing the development 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, growth prospects and potential future market adoption of any of our products, including the red blood cell system. 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 or the results of routine use if we are able to commercialize 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 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, inefficient use of our resources and could distract personnel from other activities. 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 U.S. 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, respectively. We successfully completed the acute anemia Phase III clinical trial, 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 chronic anemia 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 chronic anemia or any potential future clinical trials using our modified process.

We will need to successfully conduct and complete a license enabling Phase III clinical trial in the U.S. before the FDA will 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. There can be no assurance that we will be able to successfully satisfy any such in vitro studies, 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. In addition, if we are unable to reach agreement with the FDA on a license enabling Phase III clinical trial design for our red blood cell system, our agreement with BARDA will be severely limited in scope or could be terminated altogether.

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 complete development activities to support an anticipated CE mark submission planned for the second half of 2016, such activities, 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 cannot predict when we would receive regulatory approval of our red blood cell system, if ever. We understand that while the acute anemia Phase III clinical trial in Europe may be sufficient to receive CE mark approval in the E.U., we may need to generate additional safety data from commercial use and/or achieve a successful outcome in the ongoing chronic anemia Phase III clinical trial for our red blood cell system in order to achieve broad market acceptance. Failure to enroll sufficient patients and generate a body of data in chronic patients in a clinical or commercial setting may delay regulatory approval, commercialization or market adoption. 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. In addition, if we are unable to secure the full amount of funding contemplated by the BARDA agreement for any reason, our ability to complete the development activities required for licensure in the U.S. may require additional capital beyond 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 alternative sources of funding are not available, we may be forced to suspend or terminate development activities related to the red blood cell system in the U.S. 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 R&D expenses incurred to date for the red blood cell system program. Regulatory delays can also materially impact our product development costs. If we experience delays in testing, conducting trials or approvals, our product development costs will increase, which costs may not be reimbursable to us under the BARDA agreement. Even if we were to successfully complete and receive approval for our red blood cell system, potential blood center customers may object to working with a potent chemical, like amustaline, 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. If the red blood cell system were to face such objections from potential customers, we may choose to pay

for capital assets, specialized equipment or personnel for the blood center, which would have a negative impact on any potential contribution margin from red blood cell system sales.

Platelet and Plasma Systems

In 2007, we obtained a CE mark approval (extended in 2012) from E.U. 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 within the Europe 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 due to changes in regulatory law, our inability to maintain compliance with regulations or other factors.

In 2006, we obtained a CE mark approval (extended in 2011) from E.U. regulators for our plasma system and are in the process of filing a renewal for the approval in accordance with the five year renewal schedule. We or our customers have received approval for

the sale and/or use INTERCEPT-treated plasma within Europe 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 have conducted and are conducting additional in vitro studies for our platelet system to potentially expand our label claims to include, among others, 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.

As a condition to the initial FDA approval of the platelet system, we are required to conduct a post-approval clinical study of the platelet system. Successful enrollment and completion of this study requires that we develop sufficient INTERCEPT production capabilities with U.S. blood center customers. Delays in delivering INTERCEPT systems to blood centers that can supply INTERCEPT-treated platelets to hospitals involved in the study may lead to increased costs to us and may jeopardize our ability to complete the study in a timeframe acceptable to the FDA. In addition, we must identify and contract with hospitals that have the desire and ability to participate and contribute to the study in a timely manner and who are willing to purchase INTERCEPT-treated platelets from our blood center customers. If we are unable to complete this study, in a timely manner or at all, 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 system. Further, we are required to conduct a post-approval recovery and survival clinical study in connection with the label expansion approval for the use of the platelet system to treat platelets suspended in 100% plasma. Successful enrollment and completion of this additional study will also require that we identify and contract with hospitals that have the desire and ability to participate and contribute to the study in a timely manner and who are willing to purchase INTERCEPT-treated platelets from our blood center customers. If we are unable to complete this study, in a timely manner or at all, 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 system. 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.

The execution and completion our ongoing IDE 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 U.S., ensuring that quality control and manufacturing procedures conform to cGMP and current 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.

Should a regulatory agency question a reported adverse event, we may not be able to rule out product failure as the cause, whether or not product failure is the cause of the reported adverse event. If a regulatory agency suspects or 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;
- withdrawing marketing approvals that have already been granted, resulting in prohibitions on sales of our products; and
- criminal prosecution.

Any of these actions, in combination or alone, could prevent us from selling our products and harm our business. In addition, any government investigation of alleged violations of law could require us to expend significant time and resources in response and could generate negative publicity. Any failure to comply with ongoing or changing regulatory requirements may significantly and adversely affect our ability to successfully commercialize and generate additional revenues from our platelet and plasma systems or any future products. If regulatory sanctions are applied or if regulatory approval is withdrawn, the value of our company and our operating results will be adversely affected. Additionally, if we are unable to continue to generate revenues from the sale of our platelet and plasma systems, our potential for achieving operating profitability will be diminished and the need for additional capital to fund our operations will be increased.

In addition, the regulations to which we are subject are complex and have tended to become more stringent over time. Regulatory changes could result in restrictions on our ability to carry on or expand our operations, higher than anticipated costs or lower than anticipated sales.

A significant portion of the funding for the development of the red blood cell system is expected to come from our BARDA agreement, and if BARDA were to eliminate, reduce or delay funding from our contract, this could have a significant, negative impact on our revenues and cash flows, and we may be forced to suspend or terminate our U.S. red blood cell development program or obtain alternative sources of funding.

We anticipate that a significant portion of the funding for the development of the red blood cell system will come from our agreement with BARDA. In this regard, in June 2016, we announced that we had entered into an agreement with BARDA that is worth up to approximately $180.5 million to support the development of the red blood cell system. However, our agreement with BARDA only reimburses certain specified development and clinical activities that have been previously authorized by BARDA pursuant to the base period of the agreement and the potential exercise of subsequent option periods. To date, BARDA has committed only approximately $30.8 million under the base period of the agreement. Accordingly, our ability to receive any of the additional $149.7 million in funding provided for under the BARDA agreement is dependent on BARDA exercising subsequent options under the agreement, which it may do or not do at its sole discretion. In addition, BARDA is entitled to terminate our BARDA

agreement for convenience at any time, in whole or in part, and is not required to provide continued funding beyond amounts currently obligated under the agreement. Moreover, the continuation of our BARDA agreement depends in large part on our ability to meet development milestones previously agreed to with BARDA and on our compliance with certain operating procedures and protocols. BARDA may suspend or terminate the agreement should we fail to achieve key milestones, or fail to comply with the operating procedures and processes approved by BARDA and its audit agency. There can be no assurance that we will be able to achieve these milestones or continue to comply with these procedures and protocols. There can also be no assurance that our BARDA agreement will not be terminated, that our BARDA agreement will be extended through the exercise of subsequent option periods, that any such extensions would be on terms favorable to us, or that we will otherwise obtain the funding that we anticipate to obtain under our agreement with BARDA. Moreover, changes in government budgets and agendas may result in a decreased and deprioritized emphasis on supporting the development of pathogen reduction technology. If our BARDA agreement is terminated or suspended, if there is any reduction or

delay in funding under our BARDA agreement, or if BARDA determines not to exercise some or all of the options provided for under the agreement, our revenues and cash flows could be significantly and negatively impacted and we may be forced to seek alternative sources of funding, which may not be available on non-dilutive terms, terms favorable to us or at all. If alternative sources of funding are not available, we may be forced to suspend or terminate development activities related to the red blood cell system in the U.S.

In addition, under the BARDA agreement, BARDA will regularly review our development efforts and clinical activities. Under certain circumstances, BARDA may advise us to delay certain activities and invest additional time and resources before proceeding. If we follow such BARDA advice, overall red blood cell program delays and costs associated with additional resources for which we had not planned may result. Also, the costs associated with following such advice may or may not be reimbursed by BARDA under our agreement. Finally, we may decide not to follow the advice provided by BARDA and instead pursue activities that we believe are in the best interests of our red blood cell program and Cerus, even if BARDA would not reimburse us under our agreement.

Unfavorable provisions in government contracts, including in our contract with BARDA, may harm our business, financial condition and operating results.

U.S. government contracts typically contain unfavorable provisions and are subject to audit and modification by the government at its sole discretion, which will subject us to additional risks. For example, under our agreement with BARDA, the U.S. government has the power to unilaterally:

- audit and object to any BARDA agreement-related costs and fees on grounds that they are not allowable under the Federal Acquisition Regulation, or FAR, and require us to reimburse all such costs and fees;
- suspend or prevent us for a set period of time from receiving new contracts or grants or extending our existing agreement based on violations or suspected violations of laws or regulations;
- claim nonexclusive, nontransferable rights to product manufactured and intellectual property developed under the BARDA agreement and may, under certain circumstances, such as circumstances involving public health and safety, license such inventions to third parties without our consent;
- cancel, terminate or suspend our BARDA agreement based on violations or suspected violations of laws or regulations;
- terminate our BARDA agreement in whole or in part for the convenience of the government for any reason or no reason, including if funds become unavailable to the U.S. Department of Health and Human Services' Office of the Assistant Secretary for Preparedness and Response;
- reduce the scope and value of our BARDA agreement;
- decline to exercise an option to continue the BARDA agreement;
- direct the course of the development of the red blood cell system in a manner not chosen by us;
- require us to perform the option periods provided for under the BARDA agreement even if doing so may cause us to forego or delay the pursuit of other red blood cell program opportunities with greater commercial potential;
- take actions that result in a longer development timeline than expected;
- limit the government's financial liability to amounts appropriated by the U.S. Congress on a fiscal-year basis, thereby leaving some uncertainty about the future availability of funding for the red blood cell program even after it has been funded for an initial period; and
- change certain terms and conditions in our BARDA agreement.

Generally, government contracts, including our agreement with BARDA, contain provisions permitting unilateral termination or modification, in whole or in part, at the U.S. government's convenience. Termination-for-convenience provisions generally enable us to recover only our costs incurred or committed (plus a portion of the agreed fee) and settlement expenses on the work completed prior to termination. Except for the amount of services received by the government, termination-for-default provisions do not permit recovery of fees. In addition, in the event of termination or upon expiration of our BARDA agreement, the U.S. government may dispute wind-down and termination costs and

may question prior expenses under the contract and deny payment of those expenses. Should we choose to challenge the U.S. government for denying certain payments under our BARDA agreement, such a challenge could subject us to substantial additional expenses that we may or may not recover. Further, if our BARDA agreement is terminated for convenience, or if we default by failing to perform in accordance with the contract schedule and terms, a significant negative impact on our cash flows and operations could result.

In addition, government contracts normally contain additional requirements that may increase our costs of doing business and expose us to liability for failure to comply with these terms and conditions. These requirements include, for example:

- specialized accounting systems unique to government contracts;
- mandatory financial audits and potential liability for price adjustments or recoupment of government funds after such funds have been spent;
- public disclosures of certain contract information, which may enable competitors to gain insights into our research program;
- mandatory internal control systems and policies; and
- mandatory socioeconomic compliance requirements, including labor standards, non-discrimination and affirmative action programs and environmental compliance requirements.

If we fail to maintain compliance with these requirements, we may be subject to potential liability and to the termination of our BARDA agreement.

Furthermore, we will enter into agreements and subcontracts with third parties, including suppliers, consultants and other third-party contractors, in order to satisfy our contractual obligations under our BARDA agreement. Negotiating and entering into such arrangements can be time-consuming and we may not be able to reach agreement with such third parties. Any such agreement must also be compliant with the terms of our BARDA agreement. Any delay or inability to enter into such arrangements or entering into such arrangements in a manner that is non-compliant with the terms of our contract, may result in violations of our BARDA agreement.

As a result of the unfavorable provisions in our BARDA agreement, we must undertake significant compliance activities. The diversion of resources from our development and commercial programs to these compliance activities, as well as the exercise by the U.S. government of any rights under these provisions, could materially harm our business.

Laws and regulations affecting government contracts, including our BARDA agreement, make it more costly and difficult for us to successfully conduct our business. Failure to comply with these laws and regulations could result in significant civil and criminal penalties and adversely affect our business.

We must comply with numerous laws and regulations relating to the administration and performance of our BARDA agreement. Among the most significant government contracting regulations are:

- the FAR and agency-specific regulations supplemental to the FAR, which comprehensively regulate the procurement, formation, administration and performance of government contracts;
- the business ethics and public integrity obligations, which govern conflicts of interest and the hiring of former government employees, restrict the granting of gratuities and funding of lobbying activities and incorporate other requirements such as the Anti-Kickback Statute, the Procurement Integrity Act, the False Claims Act and the U.S. Foreign Corrupt Practices Act;
- export and import control laws and regulations; and
- laws, regulations and executive orders restricting the exportation of certain products and technical data.

In addition, as a U.S. government contractor, we are required to comply with applicable laws, regulations and standards relating to our accounting practices and are subject to periodic audits and reviews. As part of any such audit or review, the U.S. government may review the adequacy of, and our compliance with, our internal control systems and policies, including those relating to our purchasing, property, estimating, compensation and management information systems. Based on the results of its audits, the U.S. government may adjust our BARDA agreement-related costs and fees, including allocated indirect costs. This adjustment could impact the amount of revenues reported on a historic basis and could impact our cash flows under the contract prospectively. In addition, in the event BARDA determines that certain costs and fees were unallowable or determines that the allocated indirect cost rate was higher than the actual indirect cost rate, BARDA would be entitled to recoup any overpayment from us

as a result. In addition, if an audit or review uncovers any improper or illegal activity, we may be subject to civil and criminal penalties and administrative sanctions, including termination of our BARDA agreement, forfeiture of profits, suspension of payments, fines and suspension or prohibition from doing business with the U.S. government. We could also suffer serious harm to our reputation if allegations of impropriety were made against us, which could cause our stock price to decline. In addition, under U.S. government purchasing regulations, some of our costs may not be reimbursable or allowed under our contracts. Further, as a U.S. government contractor, we are subject to an increased risk of investigations, criminal prosecution, civil fraud, whistleblower lawsuits and other legal actions and liabilities as compared to private sector commercial companies.

If we or our third-party suppliers fail to comply with the FDA's good manufacturing practice regulations, it could impair our ability to market our products in a cost-effective and timely manner.

In order to be used in clinical studies or sold in the U.S., our products are required to be manufactured in FDA-approved facilities. If any of our suppliers fail to comply with FDA's cGMP regulations or otherwise fail to maintain FDA approval, we may be required to identify an alternate supplier for our products or components. Our products are complex and difficult to manufacture. Finding alternate facilities and obtaining FDA approval for the manufacture of the INTERCEPT Blood System at such facilities would be costly and time-consuming and would negatively impact our ability to generate revenue from the sale of our platelet or plasma system in the U.S. and achieve operating profitability.

We and our third-party suppliers are also required to comply with the FDA-mandated cGMP and QSR requirements, which cover the methods and documentation of the design, testing, production, control, quality assurance, labeling, packaging, sterilization, storage and shipping of our products. The FDA audits compliance with cGMP and QSR requirements through periodic announced and unannounced inspections of manufacturing and other facilities. The FDA may conduct inspections or audits at any time. If we or our suppliers fail to adhere to cGMP and QSR requirements, have significant non-compliance issues or fail to timely and adequately respond to any adverse inspectional observations or product safety issues, or if any corrective action plan that we or our suppliers propose in response to observed deficiencies is not sufficient, the FDA could take enforcement action against us, which could delay production of our products and may include:

- untitled letters, warning letters, fines, injunctions, consent decrees and civil penalties;
- unanticipated expenditures to address or defend such actions;
- customer notifications or repair, replacement, refunds, recall, detention or seizure of our products;
- operating restrictions or partial suspension or total shutdown of production;
- refusing or delaying our requests for premarket approval of new products or modified products;
- withdrawing marketing approvals that have already been granted;
- refusal to grant export or import approval for our products; or
- criminal prosecution.

Any of the foregoing actions could have a material adverse effect on our reputation, business, financial condition and operating results. Furthermore, our key suppliers may not continue to be in compliance with all applicable regulatory requirements, which could result in our failure to produce our products on a timely basis and in the required quantities, if at all. In addition, before any additional products would be considered for marketing approval in the U.S. or elsewhere, our suppliers will have to pass an audit by the FDA or other regulatory agencies. We are dependent on our suppliers' cooperation and ability to pass such audits. Such audits and any audit remediation may be costly. Failure to pass such audits by any of our suppliers would affect our ability to obtain licensure in the U.S. or elsewhere.

If we modify our FDA-approved products, we may need to seek additional approvals, which, if not granted, would prevent us from selling our modified products.

Any modifications to the platelet and plasma systems that could significantly affect their safety or effectiveness, including significant design and manufacturing changes, or that would constitute a major change in their intended use, manufacture, design, components, or technology requires approval of a new PMA or PMA supplement. However, certain changes to a PMA-approved device do not require submission and approval of a new PMA or PMA supplement and may only require notice to FDA in a PMA Annual Report. The FDA requires every supplier to make this determination in the first instance, but the FDA may review any supplier's decision. The FDA may not agree with our decisions regarding whether new clearances or approvals are necessary. Our products could be subject to recall if the FDA determines, for any reason, that our products are not safe or effective or that appropriate regulatory submissions were not made. If new regulatory approvals are required, this could delay or preclude our ability to market the modified system. For example, due to the obsolescence of certain parts, we have redesigned the illuminators used in the platelet and plasma systems, and we will need to receive approval of this redesign from the

FDA. In addition, in order to address the entire market in the U.S., we will need to obtain approval for additional configurations of the platelet system, including triple dose collections and random donor platelets. Our approved labels from the FDA limit our current approvals to certain platelet collection platforms and a particular storage solution for the particular collection platform. For instance, our approved claims permit apheresis collection of platelets on the Fresenius-Kabi Amicus device while stored in an additive solution or for apheresis collection of platelets collected on the Terumo Trima device and stored in 100% plasma. We may be required to provide the FDA with data for each permutation for which blood banking treatment practices exist which may be time consuming, costly and limit the potential size of the U.S. market that can use our products. We have conducted and are conducting additional in vitro studies for our platelet system to potentially expand our label claims to include, among others, 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. Our failure to obtain FDA and foreign regulatory approvals of new platelet and plasma product configurations could significantly limit revenues from sales of the platelet and plasma systems. In any event, delays in receipt or failure to receive approvals, the loss of previously received approvals, or the failure to comply with any other existing or future regulatory requirements, could reduce our sales and negatively impact our profitability potential and future growth prospects. In addition, if the FDA or other regulatory or accrediting body were to mandate safety interventions, including the option of pathogen reduction technology, when we had not received approval for all operational configurations, the market to which we could sell our products may be limited until we obtain such approvals, if ever, or may be permanently impaired if competing options are more broadly available.

We operate a complex global commercial organization, with limited experience in many countries, including the U.S. We have limited resources and experience complying with regulatory, legal, tax and political complexities as we expand into new and increasingly broad geographies.

We are responsible for worldwide sales, marketing, distribution, maintenance and regulatory support of the INTERCEPT Blood System. If we fail in our efforts to develop or maintain such internal competencies or establish acceptable relationships with third parties to support us in these areas on a timely basis, our ability to commercialize the INTERCEPT Blood System may be irreparably harmed.

We have a wholly-owned subsidiary, headquartered in the Netherlands, dedicated primarily to selling and marketing the platelet and plasma systems in Europe, the CIS and the Middle East. Our commercial activities for the U.S., Latin and South America and Asia are based out of our headquarters in Concord, California with certain support from our European headquarters in the Netherlands, with certain individuals servicing Latin and South America and Asia, domiciled outside of the U.S. Our commercial organization focused on the U.S. market has limited resources and is relatively inexperienced, and as a result, has limited to no experience selling and marketing our platelet and plasma systems. Given the large relative size of the American Red Cross, should they deploy INTERCEPT rapidly under our commercial agreement, our resources may be inadequate to fulfill the American Red Cross's and other customers' demands, which could result in a loss of revenues or customer contracts, or both. We will need to maintain and may need to increase our competence and size in a number of functions, including sales, marketing, regulatory, inventory and logistics, customer service, credit and collections, risk management, and quality assurance systems in order to successfully support our commercialization activities in all of the jurisdictions we currently sell and market, or anticipate selling and marketing, our products. Many of these competencies require compliance with U.S., E.U., South American, Asian and local standards and practices, including regulatory, legal and tax requirements, with some of which we have limited experience. In this regard, should we obtain regulatory approval in an increased number of geographies, we will need to ensure that we maintain a sufficient number of personnel or develop new business processes to ensure ongoing compliance with the multitude of regulatory requirements in those territories. Hiring, training and retaining new personnel is costly, time consuming and distracting to existing employees and management. We have limited experience operating on a global scale and we may be unsuccessful complying with the variety and complexity of laws and regulations in a timely manner, if at all. In addition, in some cases, the cost of obtaining approval and maintaining compliance with certain regulations and laws may exceed the revenue that we recognize from such a territory, which would adversely affect our results of operations and could adversely affect our financial condition.

Further, on June 23, 2016, the U.K. held a referendum in which voters approved an exit from the E.U., commonly referred to as "Brexit". As a result of the Brexit referendum, it is expected that the British government will begin negotiating the terms of the U.K.'s withdrawal from the E.U. A withdrawal could, among other outcomes, disrupt the free movement of goods, services and people between the U.K. and the E.U., undermine bilateral cooperation in key policy areas and significantly disrupt trade between the U.K. and the E.U. We may also face new regulatory costs and challenges as result of Brexit that could have a material adverse effect on our operations. In addition, Brexit could lead to legal uncertainty and potentially divergent national laws and regulations as the U.K. determines which E.U. laws to replace or replicate. Altered regulations could add time and expense to the process by which our product candidates

receive regulatory approval in the E.U. Given the lack of comparable precedent, it is unclear what financial, regulatory, trade and legal implications the withdrawal of the U.K. from the E.U. will have and how such withdrawal will affect us.

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

We have entered into distribution agreements, generally on a geographically exclusive basis, with distributors in certain regions. We rely on these distributors to obtain and maintain any necessary in-country regulatory approvals, as well as market and sell the INTERCEPT Blood System, provide customer and technical product support, maintain inventories, and adhere to our quality system in all material respects, among other activities. Generally, our distribution agreements require distributors to purchase minimum quantities in a given year over the term of the agreement. Failure by our distributors to meet these minimum purchase obligations may impact our financial results. In addition, failure by our distributors to provide an accurate forecast impacts our ability to predict the timing of revenue and our ability to accurately forecast our product supply needs. While our contracts generally require distributors to exercise diligence, these distributors may fail to commercialize the INTERCEPT Blood System in their respective territories. For

example, our distributors may fail to sell product inventory they have purchased from us to end customers or may sell competing products ahead of or in conjunction with INTERCEPT. In addition, initial purchases of illuminators or INTERCEPT disposable kits by these third parties may not lead to follow-on purchases of platelet and plasma systems' disposable kits. Agreements with our distributors typically require the distributor to maintain quality standards that are compliant with standards generally accepted for medical devices. We may be unable to ensure that our distributors are compliant with such standards. Further, we have limited visibility into the identity and requirements of blood banking customers these distributors may have. Accordingly, we may be unable to ensure our distributors properly maintain illuminators sold or provide quality technical services to the blood banking customers to which they sell. In addition, although our agreements with our distributors generally require compliance with local anti-corruption laws, the U.S. Foreign Corrupt Practices Act, and other local and international regulations, we have limited ability to control the actions of our distributors to ensure they are in compliance. Noncompliance by a distributor could expose us to civil or criminal liability, fines and/or prohibitions on selling our products in certain countries.

Currently, a fairly concentrated number of distributors make up a significant portion of our revenue and we may have little recourse, short of termination, in the event that a distributor fails to execute according to our expectations and contractual provisions. In 2013 and 2014, we experienced weaker than expected growth due to declining performance by certain of our distributors. Periodically, we transition certain territories to new distribution partners or our direct sales force where we believe we can improve performance relative to the distributor. Because new distribution partners or our direct sales force may have limited experience marketing and selling our products in certain territories, or at all, we cannot be certain that they will perform better than the predecessor distributor. In certain cases, our distributors hold the regulatory approval to sell INTERCEPT for their particular geography. Termination, loss of exclusivity or transitioning from these distributors would require us to negotiate a transfer of the applicable regulatory approvals to us or new distributors which may be difficult to do in a timely manner, or at all. We expect that our product revenues will be adversely impacted with the loss or transition of one or more of these distributors. If we chose to terminate additional distributor agreements, we would either need to reach agreement with, qualify, train and supply a replacement distributor or supply and service end-user customer accounts in those territories ourselves. Although our distribution agreements generally provide that the distributor will promptly and efficiently transfer its existing customer agreements to us, there can be no assurance that this will happen in a timely manner or at all. In addition, terminated distributors may own illuminators placed at customer sites and may require us to repurchase those devices or require end-user customers to purchase new devices from us. These factors may be disruptive for our customers and our reputation may be damaged as a result. Our distribution partners may have more established relationships with potential end user customers than a new distributor or we may have in particular territory, which could adversely impact our ability to successfully commercialize our products in these territories. In addition, it may take longer for us to be paid if payment timing and terms in these new arrangements are less favorable to us than those in our existing distributor arrangements. As we service end-user accounts directly rather than through distributors, we incur additional expense, our working capital is negatively impacted due to longer periods from cash collection from direct sales customers when compared to the timing of cash collection from our former distribution partners and we may be exposed to additional complexity including local statutory and tax compliance. Current or transitioning distributors may irreparably harm relationships with local existing and prospective customers and our standing with the blood banking community in general. In the event that we are unable to find alternative distributors or mobilize our own sales efforts in the territories in which a particular distributor operates, customer supply, our reputation and our operating results may be adversely affected. In addition, in territories where new distributors are responsible for servicing end-user accounts, there will be a period of transition in order to properly qualify and train these new distributors, which may disrupt the operations of our customers and adversely impact our reputation and operating results.

Our products are a novel technology in the U.S. and blood centers and clinicians have little to no experience with pathogen reduction systems. Further, we have no prior experience commercializing products in the U.S. We may be unable to develop and maintain an effective and qualified U.S. based commercial organization or educate blood centers, clinicians and hospital personnel. As a result, we may not be able to successfully educate the market on the value of pathogen reduction or commercialize our platelet and plasma systems in the U.S.

Our ability to generate significant revenue from our platelet and plasma systems depends in part on our ability to achieve market acceptance of, and to otherwise effectively market, our platelet and plasma systems in the U.S. Even if we are able to achieve market acceptance in the U.S. or newly commercialized markets, we have provided and may continue to provide adoption incentives which may negatively impact our reported sales. As a company, we have no prior experience in commercializing any products in the U.S. and we will need to attract, retain, train and support sales, marketing and scientific affairs personnel and other commercial talent. For example, we will need to retain our medical science liaisons team, or MSLs, to help educate hospitals and physicians on our products, clinical trial history and publications. MSLs are highly educated and trained professionals and the hiring and employment market for MSLs is highly competitive. As such, we will need to commit significant additional management and other resources in order to maintain and expand our MSL team and sales and marketing functions. We may be unable to develop and maintain adequate MSL, sales and marketing capabilities for the U.S. market and we also may not be able to devote sufficient resources to the advertising, promotion and sales efforts for the platelet and plasma systems in the U.S. We will also have to compete with other life sciences and medical device companies to recruit, hire, train and retain the MSL, sales and marketing personnel that we anticipate we will need in the future. For these and other reasons, we may be unable to develop and maintain an effective and qualified U.S.-based commercial

organization in a cost-effective manner or realize a positive return on our investment. If we are unable to develop and maintain an effective and qualified U.S.-based commercial organization in a timely manner or at all, we may fail to realize the full sales potential of our platelet and plasma systems in the U.S.

Our manufacturing supply chain exposes us to significant risks.

We do not own our own manufacturing facilities, but rather manufacture our products using a number of third party suppliers, many of whom are our sole suppliers for the particular product or component that we procure. We rely on various contracts and our relationships with these suppliers to ensure that the sourced products are manufactured in sufficient quantities, timely, to our exact specifications and at prices we agree upon with the supplier. The price that we pay to some of our suppliers is dependent on the volume of products or components that we order. If we are unable to meet the volume tiers that afford the most favorable pricing, our margins will decrease.

In October 2015, we amended and restated our manufacturing and supply agreement with Fresenius. Under the amended agreement, Fresenius is obligated to sell, and we are obligated to purchase finished disposable kits for the platelet, plasma and red blood cell kits from Fresenius with certain exceptions permitted. The initial term of the amended agreement extends through July 1, 2025, and is automatically renewed thereafter for additional two year renewal terms, subject to termination by either party upon (i) two years written notice prior to the expiration of the initial term or (ii) one year written notice prior to the expiration of any renewal term. We and Fresenius each have normal and customary termination rights, including termination for material breach. Fresenius is our sole supplier for the manufacture of these products. Fresenius may fail to manufacture an adequate supply of INTERCEPT disposable kits which would harm our business. Disruptions to our supply chain as a result of any potential ensuing protests, strikes or other work-stoppages would be detrimental to our business and operating results. While we and Fresenius recently entered into the amended agreement, 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.

We also have contracts with other third-party suppliers, including Ash Stevens for the manufacture of amotosalen, our proprietary compound for reducing pathogens that is used in our platelet and plasma systems; Purolite, and separately, Porex, for the manufacture of components of the compound adsorption devices used in our platelet and plasma systems; and NOVA for the manufacture of illuminators and certain components of the INTERCEPT Blood System. These independent suppliers are currently our sole qualified suppliers for such components and products.

Our manufacturing and supply agreement with Ash Stevens currently extends through December 31, 2017, and is automatically renewable thereafter for periods of two years each, but may be terminated by Ash Stevens provided that Ash Stevens notifies us in writing at least two years in advance. Although we are not subject to minimum annual purchase requirements under the manufacturing and supply agreement with Ash Stevens, we may be required to pay a maintenance fee of up to $50,000 a year if specified quantities of amotosalen are not purchased in any year. We have incurred these maintenance fees in the past and may incur these maintenance fees in future periods.

Our supply agreement with Porex was amended in December 2014 and now expires on December 31, 2016. Porex is our sole supplier for certain components of the compound adsorption devices. We are subject to certain minimum annual purchase requirements under our agreement with Porex and are required to compensate Porex if we do not meet such minimum annual purchase requirements. Although we are actively seeking to develop alternative manufacturers and components, commercially viable alternatives are likely at least a year away. Any new agreement or amendment to the existing Porex agreement may contain terms that are unfavorable to us relative to existing terms or we may not reach agreement with Porex at all which would impact our ability to produce and supply qualified components. We entered into an amended and restated supply agreement with Purolite, which supplies other components of the compound adsorption devices, in April 2014. The amended supply agreement expires in April 2021 and will automatically renew for an additional year unless either party has provided notice not to renew at least two years prior to the expiration. Under the terms of the amended agreement, pricing is volume based and is subject to

annual, prospective adjustments based on a Producer Price Index subject to an annual cap. Our agreement with NOVA, which manufacturers our illuminators, currently extends through September 2016 and is automatically renewable for one year terms, but may be terminated by NOVA on at least twelve months' prior written notice. We have not been notified by NOVA of their intention to terminate the agreement.

Facilities at which the INTERCEPT Blood System or its components are manufactured may cease operations for planned or unplanned reasons or may unilaterally change the formulations of certain commercially available reagents that we use, causing at least temporary interruptions in supply. Even a temporary failure to supply adequate numbers of INTERCEPT Blood System components may cause an irreparable loss of customer goodwill. Although we are actively evaluating alternate suppliers for certain components, we do not have qualified suppliers beyond those on which we currently rely, and we understand that Fresenius relies substantially on sole suppliers of certain materials for our products. In addition, suppliers that our contract manufacturers source components and raw materials from may cease production of or providing those components to our contract manufacturers. For example, we understand

that certain plastics used to make INTERCEPT disposable kits will only be available for a finite period of time. As a result, we and our manufacturers have identified alternate plastics but will need to qualify and validate those plastics before we can utilize them in commercial manufacturing. Identification and qualification of alternate suppliers will be time consuming and costly. If we conclude that supply of the INTERCEPT Blood System or components from Fresenius and others is uncertain, we may choose to build and maintain inventories of raw materials, work-in-process components, or finished goods, which would consume capital resources faster than we anticipate and may cause our supply chain to be less efficient.

Currently NOVA is manufacturing illuminators to meet customer demand and maintain our own inventory levels. Subject to obsolescence, we may be required to identify and qualify replacement components for illuminators and in doing so, we may be required to conduct additional studies, which could include clinical trials to demonstrate equivalency or validate any required design or component changes. We and our customers rely on the availability of spare parts to ensure that customer platelet and plasma production is not interrupted. If we are not able to supply spare parts for the maintenance of customer illuminators, our ability to keep existing customers or sign up new customers may be negatively impacted. Due to the obsolescence of certain parts, which are in limited supply, we have redesigned the illuminators used in the platelet and plasma systems, and we will need to receive approval of this redesign from the FDA. Our failure to obtain FDA and foreign regulatory approvals of a new illuminator could constrain our ability to penetrate the U.S. market and may otherwise significantly limit revenues from sales of the platelet and plasma systems. In any event, delays in receipt or failure to receive these approvals could reduce our sales and negatively impact our profitability potential and future growth prospects. In addition, our illuminators contain embedded proprietary software that runs on software code we have developed and that we own. Changes to certain components due to obsolescence, illuminator redesign or market demand, may require us to modify the existing software code or to develop new illuminator software. Our ability to develop new illuminator software, correct coding flaws and generally maintain the software code is reliant on third-party contractors who, in some cases, have sole knowledge of the software code. Our ability to develop and maintain the illuminator software may be impaired if we are not able to continue contracting with those key third-party contracted developers or if we are unable to source alternate employees or consultants to do so. Software development is inherently risky and may be time consuming and costly.

In the event that alternate manufacturers are identified and qualified, we will need to transfer know-how relevant to the manufacture of the INTERCEPT Blood System to such alternate manufacturers; however, certain of our supplier's materials, manufacturing processes and methods are proprietary to them, which will impair our ability to establish alternate sources of supply, even if we are required to do so as a condition of regulatory approval. We may be unable to establish alternate suppliers without having to redesign certain elements of the platelet and plasma systems. Such redesign may be costly, time consuming and require further regulatory review and approvals. We may be unable to identify, select, and qualify such manufacturers or those third parties able to provide support for development and testing activities on a timely basis or enter into contracts with them on reasonable terms, if at all. Moreover, the inclusion of components manufactured by new suppliers could require us to seek new or updated approvals from regulatory authorities, which could result in delays in product delivery. We may not receive any such required regulatory approvals. We cannot assure you that any amendments to existing manufacturing agreements or any new manufacturing agreements that we may enter into will contain terms more favorable to us than those that we currently have with our manufacturers. Many of the existing agreements we have with suppliers contain provisions that we have been operating under for an extended period of time, including pricing. Should we enter into agreements or amend agreements with any manufacturer with less favorable terms, including pricing, our results of operations may be impacted, our recourse against such manufacturers may be limited, and the quality of our products may be impacted.

Raw materials, components or finished product may not meet specifications or may be subject to other nonconformities. In several instances over the past two years, nonconformities in certain component lots have caused delays in manufacturing of INTERCEPT disposable kits. Non-conformities can increase our expenses and reduce gross margins. Should non-conformities occur in the future, we may be unable to manufacture products to meet customer demand, which would result in lost sales and could cause irreparable damage to our customer relationships. Later discovery of problems with a product, manufacturer or facility may result in additional restrictions on the

product, manufacturer or facility, including withdrawal of the product from the market. We are subject to risks and costs of product recall, which include not only potential out-of-pocket costs, but also potential interruption to our supply chain. In such an event, our customer relations could be harmed and we would incur unforeseen losses.

In the event of a failure by Fresenius or other manufacturers to perform their obligations to supply components of the INTERCEPT Blood System to us, damages recoverable by us may be insufficient to compensate us for the full loss of business opportunity. Many of our supply agreements contain limitations on incidental and consequential damages that we may recover. A supplier's potential liability in the event of non-performance may not be sufficient to compel the supplier to continue to act in conformity with our agreements. Our product supply chain requires us to purchase certain components in minimum quantities and may result in a production cycle of more than one year. Significant disruptions to any of the steps in our supply chain process may result in longer productions cycles which could lead to inefficient use of cash or may impair our ability to supply customers with product.

We may encounter unforeseen manufacturing difficulties which, at a minimum, may lead to higher than anticipated costs, scrap rates, or delays in manufacturing products. In addition, we may not receive timely or accurate demand information from distributors or may

not accurately forecast demand ourselves for the INTERCEPT Blood System. Further, certain customers require, and potential future customers may require, product with a minimum shelf life. As a result, we may need to manufacture sufficient product to meet that forecasted demand. As a result, we may carry excess work-in-process or finished goods inventory, which would consume capital resources and may become obsolete, or our inventory may be inadequate to meet customer demand. We have entered into certain public tenders, some which call for us to maintain certain minimum levels of inventory. If our suppliers fail to produce components or our finished products satisfactorily, timely, at acceptable costs, and in sufficient quantities, we may incur delays, shortfalls and additional expenses, or non-compliance with certain public tenders which may in turn result in permanent harm to our customer relations or loss of customers. Conversely, we may choose to overstock inventory in order to mitigate any unforeseen potential disruption to manufacturing which could consume our cash resources faster than we anticipate and may cause our supply chain to be less efficient. Our platelet and plasma systems' disposable kits have a two-year shelf life from the date of manufacture. We and our distributors may be unable to ship product to customers prior to the expiration of the product shelf life, a risk that is heightened if we elect to increase our inventory levels in order to mitigate supply disruptions. Certain customers may require product with a minimum shelf life remaining prior to shipment. If customers requiring minimum shelf-lives order smaller quantities or do not purchase product as we anticipate, or at all, we may have elevated inventory levels with relatively short shelf-lives which may lead to increased write-offs and inefficient use of our cash. Should we chose not to fulfill smaller orders with minimum shelf lives, our product sales may be harmed. We will need to destroy or consume outdated inventory in product demonstration activities, which may in turn lead to elevated product demonstration costs and/or reduced gross margins.

Shortage of key components of and accessories to the INTERCEPT Blood System, such as plastics, saline or other reagents may impact operational costs of our customers and may increase the prices at which we sell our products, resulting in slower than anticipated growth or negative future financial performance.

The manufacture, supply and availability of key components of, and accessories to, our products are dependent upon a limited number of third parties and the commercial adoption and success of our products is dependent upon the continued availability of these components or accessories. For example, our customers rely on continued availability of third-party supplied plastics, saline and reagents for processing, storing and manufacturing blood components. If the blood product industry experiences shortages of these components or accessories, the availability and use of our products may be impaired. Additionally, the current international shortage of saline has adversely impacted our ability to source the optimal fill weight of saline vials for use in our chronic anemia study of the red blood cell system. As a result, we were required to purchase saline vials with higher than preferred fill weights at a higher cost.

With respect to the manufacture of our products, our third party manufacturers source plastic for the manufacture of the INTERCEPT processing sets from a limited number of suppliers and we do not have guaranteed supply contracts with all of the raw material suppliers for our products, which magnifies the risk of shortage and decreases our manufacturers' ability to negotiate pricing with their suppliers. Any shortage of plastics or other components or accessories and the inability to control costs associated with those raw materials could increase our costs to manufacture our products. Further, if any supplier to our third party manufacturers is unwilling or unable to provide high quality raw materials in required quantities and at acceptable prices, our manufacturers may be unable to find alternative sources or may fail to find alternative suppliers at commercially acceptable prices, on satisfactory terms, in a timely manner, or at all. If any of these events were to occur, our product quality, competitive position, reputation and business could suffer, we could experience cancellations of customer orders, refusal by customers to accept deliveries or a reduction in our prices and margins to the detriment of our financial performance and results of operations.

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

We are subject to a number of laws that affect our sales, marketing and other promotional activities by limiting the kinds of financial arrangements we may have with hospitals, physicians, healthcare providers or other potential

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

In addition, there are numerous U.S. federal and state healthcare regulatory laws, including, but not limited to, anti-kickback laws, false claims laws, privacy laws, and transparency laws. Our relationships with healthcare providers and entities, including but not limited to, hospitals, physicians, healthcare providers and our customers are or will be subject to scrutiny under these laws. Violations of these laws can subject us to penalties, including, but not limited to, administrative, civil and criminal penalties, damages, fines, disgorgement, imprisonment, exclusion from participation in federal and state healthcare programs, including the Medicare and Medicaid programs, and the curtailment of our operations. Healthcare fraud and abuse regulations are complex, and even minor

irregularities can potentially give rise to claims that a statute or prohibition has been violated. The laws that may affect our ability to operate include, but are not limited to:

- the federal Anti-Kickback Statute, which prohibits, among other things, persons and entities from knowingly and willfully soliciting, receiving, offering, or paying remuneration, directly or indirectly, in cash or in kind, in exchange for or to induce either the referral of an individual for, or the purchase, lease, order or recommendation of, any good, facility, item or service for which payment may be made, in whole or in part, under federal healthcare programs such as Medicare and Medicaid;
- federal false claims laws that prohibit, among other things, knowingly presenting, or causing to be presented, claims for payment from Medicare, Medicaid or other third-party payors that are false or fraudulent, and which may apply to entities that provide coding and billing advice to customers;
- the civil monetary penalties statute, which imposes penalties against any person or entity who, among other things, is determined to have presented or caused to be presented, a claim to a federal healthcare program that the person knows, or should know, is for an item or service that was not provided as claimed or is false or fraudulent;
- the federal Health Insurance Portability and Accountability Act of 1996, as amended, or HIPAA, which created federal criminal laws that prohibit executing a scheme to defraud any healthcare benefit program or making false statements relating to healthcare matters;
- HIPAA, as amended by the Health Information Technology for Economic and Clinical Health Act of 2009, or HITECH, and their respective implementing regulations, which impose requirements on certain covered healthcare providers, health plans and healthcare clearinghouses as well as their business associates that perform services for them that involve individually identifiable health information, relating to the privacy, security and transmission of individually identifiable health information without appropriate authorization, including mandatory contractual terms as well as directly applicable privacy and security standards and requirements;
- the Federal Trade Commission Act and similar laws regulating advertisement and consumer protections; and
- foreign or U.S. state law equivalents of each of the above federal laws, such as anti-kickback and false claims laws which may apply to items or services reimbursed by any third-party payor, including commercial insurers; U.S. state laws that require device companies to comply with the industry's voluntary compliance guidelines and the relevant compliance guidance promulgated by the U.S. federal government or otherwise restrict payments that may be made to healthcare providers; U.S. state laws that require device manufacturers to report information related to payments and other transfers of value to physicians and other healthcare providers or marketing expenditures; and U.S. state laws governing the privacy and security of certain health information, many of which differ from each other in significant ways and often are not preempted by HIPAA, thus complicating compliance efforts.

We are also subject to foreign laws and regulations covering data privacy and the protection of health-related and other personal information. In this regard, E.U. member states and other foreign jurisdictions, including Switzerland, have adopted data protection laws and regulations which impose significant compliance obligations. For example, the E.U. Data Protection Directive, as implemented into national laws by the E.U. member states, imposes strict obligations and restrictions on the ability to collect, analyze and transfer personal data, including health data from clinical trials and adverse event reporting. The E.U. Data Protection Directive prohibits the transfer of personal data to countries outside of the European Economic Area, or EEA, such as the U.S., which are not considered by the European Commission, or EC, to provide an adequate level of data protection. Switzerland has adopted similar restrictions. Although there are legal mechanisms to allow for the transfer of personal data from the EEA and Switzerland to the U.S., a recent judgment of the European Court of Justice that invalidated the EC decision on the U.S. safe harbor has increased uncertainty around the adequacy of these legal mechanisms. This means that it will no longer be possible to transfer personal data from the E.U. to entities in the U.S. that rely on safe harbor certification as a legal basis for the transfer of such data. In addition, data protection authorities from the different E.U. member states may interpret the E.U. Data Protection Directive and national laws differently, and guidance on implementation and compliance practices are often updated or otherwise revised, which adds to the complexity of processing personal data in the E.U. If we fail to comply with applicable data privacy laws, or if the legal mechanisms we rely upon to allow for the transfer of personal data from the EEA or Switzerland to the U.S. (or other countries not considered by the EC to provide an adequate level of data protection) are not considered adequate, we could be subject to government enforcement actions and significant penalties against us, and our business could be adversely impacted if our ability to

transfer personal data outside of the EEA or Switzerland is restricted, which could adversely impact our operating results. Further, a proposal for an E.U. Data Protection Regulation, intended to replace the current E.U. Data Protection Directive, is currently under consideration. The proposed E.U. Data Protection Regulation, if adopted, is expected to introduce new data protection requirements and substantial fines for breaches of the data protection rules. When the draft E.U. Data Protection Regulation is adopted, it may increase our responsibility and liability in relation to personal data that we process, and we may be required to put in place additional mechanisms to ensure compliance with the new E.U. data protection rules.

We are also subject to the U.S. Foreign Corrupt Practices Act and anti-corruption laws, and similar laws with a significant anti-corruption intent in foreign countries. In general, there is a worldwide trend to strengthen anticorruption laws and their enforcement. Any violation of these laws by us or our agents or distributors could create a substantial liability for us, subject our officers and directors to personal liability and also cause a loss of reputation in the market. We currently operate in many countries where the public sector is perceived as being more or highly corrupt. Our strategic business plans include expanding our business in regions and countries that are rated as higher risk for corruption activity, such as China, India and Russia. Becoming familiar with and implementing the infrastructure necessary to comply with laws, rules and regulations applicable to new business activities and mitigate and protect against corruption risks could be quite costly. In addition, failure by us or our agents or distributors to comply with these laws, rules and regulations could delay our expansion into high-growth markets, could damage market perception of our business and could adversely affect our existing business operations. Increased business in higher risk countries could also subject us and our officers and directors to increased scrutiny and increased liability.

Further, the Patient Protection and Affordable Care Act, as amended by the Health Care and Education Reconciliation Act of 2010, or, collectively, the Affordable Care Act, among other things, amends the intent requirements of the federal Anti-Kickback Statute and certain criminal statutes governing healthcare fraud. A person or entity can now be found guilty of violating the statute without actual knowledge of the statute or specific intent to violate it. In addition, the Affordable Care Act provides that the government may assert that a claim including items or services resulting from a violation of the federal Anti-Kickback Statute constitutes a false or fraudulent claim for purposes of the federal False Claims Act. Moreover, while we do not submit claims and our customers make the ultimate decision on how to submit claims, from time-to-time, we may provide reimbursement guidance to our customers. If a government authority were to conclude that we provided improper advice to our customers or encouraged the submission of false claims for reimbursement, we could face action against us by government authorities. Any violations of these laws, or any action against us for violation of these laws, even if we successfully defend against it, could result in a material adverse effect on our reputation, business, results of operations and financial condition.

Because of the breadth of these laws and the narrowness of the statutory exceptions and regulatory safe harbors available under such laws, it is possible that some of our business activities, including our relationships with healthcare providers and entities, including, but not limited to, hospitals, physicians, healthcare providers and our distributors, and certain sales and marketing practices, including the provision of certain items and services to our customers, could be subject to challenge under one or more of such laws.

To enforce compliance with the healthcare regulatory laws, federal and state enforcement bodies have recently increased their scrutiny of interactions between healthcare companies and healthcare providers, which has led to a number of investigations, prosecutions, convictions and settlements in the healthcare industry. Responding to investigations can be time-and resource-consuming and can divert management’s attention from the business. Additionally, as a result of these investigations, healthcare providers and entities may have to agree to additional onerous compliance and reporting requirements as part of a consent decree or corporate integrity agreement. Any such investigation or settlement could increase our costs or otherwise have an adverse effect on our business.

In addition, there has been a recent trend of increased U.S. federal and state regulation of payments and transfers of value provided to healthcare professionals or entities. Section 6002 of the Affordable Care Act known as the Physician Payment Sunshine Act that imposes new annual reporting requirements on device manufacturers for payments and other transfers of value provided by them, directly or indirectly, to physicians and teaching hospitals, as well as ownership and investment interests held by physicians and their family members. A manufacturer’s failure to submit timely, accurately and completely the required information for all payments, transfers of value or ownership or investment interests may result in civil monetary penalties of up to an aggregate of $150,000 per year, and up to an aggregate of $1.0 million per year for “knowing failures.” Manufacturers must submit reports by the 90th day of each subsequent calendar year. Due to the difficulty in complying with the Physician Payment Sunshine Act, we cannot assure you that we will successfully report all payments and transfers of value provided by us, and any failure to comply could result in significant fines and penalties. Some states, such as California and Connecticut, also mandate

implementation of commercial compliance programs, and other states, such as Massachusetts and Vermont, impose restrictions on device manufacturer marketing practices and tracking and reporting of gifts, compensation and other remuneration to healthcare professionals and entities. The shifting commercial compliance environment and the need to build and maintain robust and expandable systems to comply with different compliance and reporting requirements in multiple jurisdictions increase the possibility that we may fail to comply fully with one or more of these requirements.

Although compliance programs can mitigate the risk of investigation and prosecution for violations of these laws, the risks cannot be entirely eliminated. Any action against us for violation of these laws, even if we successfully defend against it, could cause us to incur significant legal expenses and divert our management's attention from the operation of our business.

Most of these laws apply to not only the actions taken by us, but also actions taken by our distributors or other third party agents. We have limited knowledge and control over the business practices of our distributors and agents, and we may face regulatory action against us as a result of their actions which could have a material adverse effect on our reputation, business, results of operations and financial condition.

In addition, the scope and enforcement of these laws is uncertain and subject to rapid change in the current environment of healthcare reform, especially in light of the lack of applicable precedent and regulations. U.S. federal or state regulatory authorities might challenge our current or future activities under these laws. Any such challenge could have a material adverse effect on our reputation, business, results of operations and financial condition. Any U.S. federal or state or foreign regulatory review of us, regardless of the outcome, would be costly and time-consuming. Additionally, we cannot predict the impact of any changes in these laws, whether or not retroactive. Compliance with these and other changing regulations will increase our costs and may require increasing management attention.

Legislative or regulatory healthcare reforms may make it more difficult and costly for us to obtain regulatory approval of our products and to produce, market and distribute our products after approval is obtained.

Regulatory guidance and regulations are often revised or reinterpreted by the regulatory agencies in ways that may significantly affect our business and our products. Any new regulations or revisions or reinterpretations of existing regulations may impose additional costs or lengthen review times of our products. Delays in receipt of, or failure to receive, regulatory approvals for our new products or product configurations would have a material adverse effect on our business, results of operations and financial condition.

Federal and state governments in the U.S. have recently enacted legislation to overhaul the nation’s healthcare system. While the goal of healthcare reform is to expand coverage to more individuals, it also involves increased government price controls, additional regulatory mandates and other measures designed to constrain medical costs. The Affordable Care Act significantly impacts the medical device industry. Among other things, the Affordable Care Act:

- imposes an annual excise tax of 2.3% on eligible entities that manufacture or import medical devices offered for sale in the U.S.;
- establishes a new Patient-Centered Outcomes Research Institute to oversee and identify priorities in comparative clinical effectiveness research in an effort to coordinate and develop such research;
- implements payment system reforms including a national pilot program on payment bundling to encourage hospitals, physicians and other providers to improve the coordination, quality and efficiency of certain healthcare services through bundled payment models; and
- creates an independent payment advisory board that will submit recommendations to reduce Medicare spending if projected Medicare spending exceeds a specified growth rate.

In addition, other legislative changes have been proposed and adopted since the Affordable Care Act was enacted. On August 2, 2011, President Obama signed into law the Budget Control Act of 2011, which, among other things, created the Joint Select Committee on Deficit Reduction to recommend to Congress proposals in spending reductions. The Joint Select Committee did not achieve a targeted deficit reduction of at least $1.2 trillion for the years 2013 through 2021, triggering the legislation’s automatic reduction to several government programs. This includes reductions to Medicare payments to providers of 2% per fiscal year, which went into effect in April 2013 and will stay in effect through 2024, unless additional congressional action is taken. On January 2, 2013, President Obama signed into law the American Taxpayer Relief Act of 2012 which, among other things, further reduced Medicare payments to several providers, including hospitals, and increased the statute of limitations period for the government to recover overpayments to providers from three to five years. We expect that additional U.S federal and state and foreign healthcare reform measures will be adopted in the future, any of which could limit the amounts that governments will pay for healthcare products and services, which could result in reduced demand for our products or additional pricing pressure.

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

The equipment and materials used to collect platelets vary by manufacturer and by geographic region. Platelets may be collected from a single donor by apheresis using an automated collection machine. Apheresis devices currently

used in the U.S. and European markets differ, among other characteristics, in their ability to collect platelets in reduced volumes of plasma. Platelet collection device manufacturers may need to modify device collection parameters or software before a prospective customer could use INTERCEPT. Failure to comply by these manufacturers may limit the potential market for our products. Platelet concentrates may also be prepared from whole blood by pooling together platelets from multiple donors. There are two commonly used methods for preparing whole blood platelets: the buffy coat method, which is used extensively in Europe, and the pooled random donor method, which is used in the U.S. Our platelet system is designed to work with platelets collected and stored in storage solutions, called InterSol and SSP+, and for platelets suspended in 100% plasma. Fresenius is the exclusive manufacturer of InterSol and MacoPharma of SSP+, both widely-used platelet additive solutions. Many of our customers and prospective customers use InterSol or SSP+ in connection with INTERCEPT treatment. Similarly, many of our customers combine multiple plasma components from whole blood donations before treating the combined product with INTERCEPT. Grifols makes such a product (Plasmix). Customers' ability to use our INTERCEPT

products may be impaired should manufacturers of those products, including those sold by Grifols, not provide access to the products allowing for the combination of multiple components. Should Fresenius, MacoPharma, or Grifols fail to obtain or maintain regulatory approval for InterSol, SSP+, or Plasmix, respectively, or if any should decide to cease distribution of those respective products to customers and prospective customers, our ability to sell the INTERCEPT Blood System may be impaired.

In order to address the entire market in the U.S., Japan, and potentially elsewhere, we will need to develop and test additional configurations of the platelet system. For example, in the U.S., we understand a significant number of platelet concentrates are derived from larger volumes collected from apheresis donors split into three therapeutic transfusable doses. Future configurations of the platelet system will be needed to treat platelet donations with such processing parameters. We estimate that the majority of platelets used in the U.S. are collected by apheresis, though a significant minority is prepared from pooled random donor platelets derived from whole blood collections. In addition, many blood centers may view pooled random donor platelets treated with INTERCEPT as an economically optimal approach. In the U.S., our platelet system is currently only approved for apheresis collections and for use with platelets suspended in a storage solution or in 100% plasma. In order to gain regulatory approvals for a pathogen reduction system compatible with triple dose collections, and random donor platelets, we will need to perform additional product development and testing, including additional clinical trials. We have conducted and are conducting additional in vitro studies for our platelet system to potentially expand our label claims to include, among others, 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. Our approved labels from the FDA limit our current approvals to certain platelet collection platforms and a particular storage solution for the particular collection platform. For instance, our approved claims permit apheresis collection of platelets on the Fresenius-Kabi Amicus device while stored in an additive solution or for apheresis collection of platelets collected on the Terumo Trima device and stored in 100% plasma. We may be required to provide the FDA with data for each permutation for which blood banking treatment practices exist which may be time consuming, costly and limit the potential size of the U.S. market that can use our products. Our failure to obtain FDA and foreign regulatory approvals of any new configurations could significantly limit revenues from sales of the platelet system. In addition, given that there is some loss of platelets using our product, blood centers may need to increase collection volumes in order to use our product and maintain an adequate concentration for a triple therapeutic dose. In any event, delays in receipt or failure to receive approval could reduce our sales and negatively impact our profitability potential and future growth prospects. Similarly, to achieve market acceptance in certain geographies, we may be required to design, develop and test new product configurations for the platelet and plasma systems. In addition, if the FDA or other regulatory or accrediting body were to mandate safety interventions, including the option of pathogen reduction technology, when we had not received approval for all operational configurations, the market to which we could sell our products may be limited until we obtain such approvals, if ever, or may be permanently impaired if competing options are more broadly available. In addition, we will need to continue to generate acceptable data in order to conform with the evolving collection practices such as automated whole-blood collection. If we are unable to conform to evolving collection practices our ability to address those portions of the market may be compromised. These development activities will increase our costs significantly and may not be successful. We may need to demonstrate the safety and efficacy of our platelet system using a variety of configurations before our platelet system would be approved for such configurations. Delays in obtaining any future approvals would adversely affect our ability to introduce new or enhanced products in a timely manner, which in turn would harm our revenue and potential future profitability.

If our competitors develop products superior to ours, market their products more effectively than we market our products, or receive regulatory approval before our products, our commercial opportunities could be reduced or eliminated.

We expect our products will continue to encounter significant competition. The INTERCEPT Blood System products compete with other approaches to blood safety currently in use and may compete with future products that may be developed by others. Our success will depend in part on our ability to respond quickly to customer and prospective customer needs, successfully receive and maintain regulatory approvals, and adapt to medical and technological

changes brought about by the development and introduction of new products. Competitors' products or technologies may make our products obsolete or non-competitive before we are able to generate any significant revenue. In addition, competitors or potential competitors may have substantially greater financial and other resources than we have. They may also have greater experience in preclinical testing, human clinical trials and other regulatory approval procedures. If competitors' products experience significant problems, customers and potential customers may question the safety and efficacy of all pathogen reduction technologies, including the INTERCEPT Blood System. Such questions and concerns may impair our ability to market and sell the INTERCEPT Blood System.

Several companies have, or are developing, technologies that are, or in the future may be, the basis for products that will directly compete with or reduce the market for our pathogen reduction systems. A number of companies are specifically focusing on alternative strategies for pathogen reduction in platelets and plasma.

These alternative strategies may be more effective in reducing certain types of pathogens from blood products, including certain non-lipid-enveloped viruses, such as hepatitis A and E viruses, which our products have not demonstrated an ability to inactivate, or human parvovirus B-19, which is also a non-lipid-enveloped virus, for which our products have not demonstrated a high level of inactivation. While studies have demonstrated that our products can effectively inactivate a broad spectrum of pathogens in blood

components, market adoption of our products may be reduced if customers determine that competitors' products inactivate a broader range of pathogens that are of particular interest to the transfusion medicine community. In addition, customers and prospective customers may believe that our competitors' products are safer, more cost effective or easier to implement and incorporate into existing blood processing procedures than INTERCEPT Blood System products. In Europe, several companies, including Grifols S.A., Octapharma AG, MacoPharma International and Kedrion Biopharma, are developing or selling commercial pathogen reduction systems or services to treat fresh frozen plasma. Terumo BCT, a subsidiary of Terumo Corporation, has developed a pathogen reduction system for blood products and has been issued CE marks for its system for both platelets and plasma. We further understand that Terumo BCT developed a pathogen reduction system for whole blood and has recently completed a clinical trial of its whole blood system in Ghana, receiving a class II CE mark. Terumo's products may offer competitive advantages over our INTERCEPT Blood System. Terumo Corporation is a large Japanese-based, multinational corporation with more mature products and relationships than we have. Our ability to commercialize our products in certain markets, particularly in Japan, may be negatively affected by Terumo's resources and their pre-existing relationships with regulators and customers. Should Terumo BCT's product be approved for use and commercialized in Japan, our products would likely directly compete with their products and we believe we would likely either need to establish operations in Japan or partner with a local Japanese company.

Octapharma AG received FDA approval in January 2013 to sell treated fresh frozen plasma for certain indications and is currently commercially available. Should Octapharma enter into exclusive agreements with key customers, our plasma system may encounter market resistance and we will have a more limited market into which we can sell.

In addition, we understand that Octapharma received approval to sell fresh frozen plasma in France. Octapharma's entry into the French market may pose a competitive threat to other pathogen reduced plasmas, including INTERCEPT and may in turn limit the potential market available to us in France.

Other companies developing competing products may also offer and sell other blood-banking products and services. As a result, competitors may have pre-existing long-term relationships with customers and may be able to offer synergies for both pathogen reduction and non-pathogen reduction products that we are unable to offer. Regulatory agencies may mandate use of competing products which would limit our ability to sell our products in those markets.

New methods of testing whole blood for specific pathogens have been approved by the FDA and in Europe, as have tests for bacteria in platelets. Other companies are marketing rapid, point-of-care bacterial tests, and developing synthetic blood product substitutes and products to stimulate the growth of platelets. Development and commercialization of any of these or other related technologies could limit the potential market for our products as would a mandate of any competing technology other than INTERCEPT.

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

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

determine whether any residual amount of a pathogen remains in the blood component treated by our products and there is no way to exclude that such residual amount would be enough to cause disease in the transfused patient or was a result of a potential defect or lack of efficacy of our products. For ethical reasons, we cannot conduct human testing to determine whether an individual who receives a transfusion of a blood component containing a pathogen that was inactivated using the INTERCEPT Blood System might show positive results if tested for an antibody against that pathogen. While we believe, based on the clinical experience of our scientists, that the level of inactivated pathogens would likely be too small to induce a detectable antibody response in diagnostic tests, we cannot exclude that a transfused patient might show positive results if tested for an antibody against that pathogen. We could be subject to a claim from a patient that tests positive, even though that patient did not contract a disease. In addition, should personnel at clinical study sites or ultimately, potential customers, be harmed by amustaline, or believe they have been or could be harmed by amustaline, our insurance coverage may be insufficient to provide coverage for any related potential liabilities. Amustaline is considered a potent chemical and is the active compound of our red blood cell system.

We maintain product liability insurance, but do not know whether the insurance will provide adequate coverage against potential liabilities. If we cannot successfully defend ourselves against product liability claims, we may incur substantial liabilities or be required to limit commercialization of our products.

Our research and development activities involve the controlled use of hazardous materials, including certain hazardous chemicals, radioactive materials and infectious pathogens, such as HIV and hepatitis viruses. Although we believe that our safety procedures for handling and disposing of hazardous materials are adequate and comply with regulatory requirements, we cannot eliminate the risk of accidental contamination or injury. If an accident occurs, we could be held liable for any damages that result.

A recall of our products, either voluntarily or at the direction of the FDA or another governmental authority, or the discovery of serious safety issues with our products that leads to corrective actions, could have a significant adverse impact on us.

The FDA and similar foreign governmental authorities have the authority to require the recall of commercialized products in the event of material deficiencies or defects in design or manufacture of a product or in the event that a product poses an unacceptable risk to health. The FDA's authority to require a recall must be based on an FDA finding that there is reasonable probability that the device would cause serious injury or death. Manufacturers may also, under their own initiative, recall a product if any material deficiency in a device is found or withdraw a product to improve device performance or for other reasons. The FDA requires that certain classifications of recalls be reported to the FDA within ten working days after the recall is initiated. A government-mandated or voluntary recall by us or one of our distributors could occur as a result of an unacceptable risk to health, component failures, malfunctions, manufacturing errors, design or labeling defects or other deficiencies and issues. Regulatory agencies in other countries have similar authority to recall devices because of material deficiencies or defects in design or manufacture that could endanger health. Any recall would divert management attention and financial resources and could cause the price of our stock to decline, expose us to product liability or other claims and harm our reputation with customers. Such events could impair our ability to supply our products in a cost-effective and timely manner in order to meet our customers' demands. Companies are required to maintain certain records of recalls, even if they are not reportable to the FDA or similar foreign governmental authorities. We may initiate voluntary recalls involving our products in the future that we determine do not require notification of the FDA or foreign governmental authorities. If the FDA or foreign governmental authorities disagree with our determinations, they could require us to report those actions as recalls. A future recall announcement could harm our reputation with customers and negatively affect our sales. In addition, the FDA or a foreign governmental authority could take enforcement action for failing to report the recalls when they were conducted.

In addition, under the FDA's medical device reporting regulations, we are required to report to the FDA any incident in which our products may have caused or contributed to a death or serious injury or in which our product malfunctioned and, if the malfunction were to recur, would likely cause or contribute to death or serious injury. Repeated product malfunctions may result in a voluntary or involuntary product recall. We are also required to follow detailed recordkeeping requirements for all firm-initiated medical device corrections and removals, and to report such corrective and removal actions to FDA if they are carried out in response to a risk to health and have not otherwise been reported under the medical device reporting regulations. If we do not adequately address problems associated with our devices, we may face additional regulatory enforcement action, including FDA warning letters, product seizure, injunctions, administrative penalties, or civil or criminal fines. We may also be required to bear other costs or take other actions that may have a negative impact on our sales as well as face significant adverse publicity or regulatory consequences, which could harm our business, including our ability to market our products in the future.

Any adverse event involving our products, whether in the U.S. or abroad could result in future voluntary corrective actions, such as recalls or customer notifications, or agency action, such as inspection, mandatory recall or other enforcement action. Any corrective action, whether voluntary or involuntary, as well as defending ourselves in a lawsuit, will require the dedication of our time and capital, distract management from operating our business and may

harm our reputation and financial results.

If we fail to obtain the capital necessary to fund our future operations or if we are unable to generate positive cash flows from our operations, we will need to curtail planned development or sales and commercialization activities.

Our near-term capital requirements are dependent on various factors, including operating costs and working capital investments associated with commercializing the INTERCEPT Blood System, including in connection with the continuing U.S. commercial launch of our platelet and plasma systems, commitments to fund projects with Fresenius, costs to develop different configurations of existing products and new products, including our illuminator, costs associated with planning, enrolling and completing ongoing studies, and the post-approval studies 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, costs associated with performing the agreed-upon activities under our BARDA agreement, 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 required post-approval studies 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 continued access to funds under our BARDA agreement and the 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 and under our agreement with BARDA, 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 may pursue 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.

While we expect to receive significant funding under our five-year agreement with BARDA, our ability to obtain the funding we expect to receive under the agreement is subject to various risks and uncertainties, including with respect to BARDA’s ability to terminate the agreement for convenience at any time. In addition, access to federal contracts or grants is subject to the authorization of funds and approval of our research plans by various organizations within the federal government, including the U.S. Congress. The general economic environment, coupled with tight federal budgets, has led to a general decline in the amount available for government funding. If BARDA were to eliminate, reduce or delay funding under our agreement, this would have a significant negative impact on the programs associated with such funding and could have a significant negative impact on our revenues and cash flows. In addition, if we are unable to reach agreement with the FDA on a license enabling Phase III clinical trial design for our red blood cell system, our agreement with BARDA will be severely limited in scope or could be terminated altogether, and our ability to complete the development activities required for licensure in the U.S. may require additional capital beyond which we currently have. If alternative sources of funding are not available, we may be forced to suspend or terminate development activities related to the red blood cell system in the U.S.

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 the volatile global financial markets, general economic uncertainty or other factors, we may need to curtail planned development or commercialization activities. In addition, we may need to obtain additional funds to complete development activities for the red blood cell system necessary for potential regulatory approval in Europe, if costs are higher than anticipated or we encounter delays. We may need to obtain additional funding to conduct additional randomized controlled clinical trials for existing or new products, particularly if we are unable to access the full amount of funding contemplated by our BARDA agreement, and we may choose to defer such activities until we can obtain sufficient additional funding or, at such time, our existing operations provide sufficient cash flow to conduct these trials.

Covenants in our loan and security agreement restrict our business and operations in many ways and if we do not effectively manage our covenants, our financial conditions and results of operations could be adversely affected. In addition, our operations may not provide sufficient cash to meet the repayment obligations of our debt incurred under the loan and security agreement.

Our loan and security agreement with Oxford Finance provided for up to $30.0 million in term loans due on June 1, 2019, of which $20.0 million in term loans became available and has been borrowed to date. Our ability to access the final $10.0 million under the loan and security agreement was subject to our ability to achieve a certain revenue threshold no later than June 30, 2016, which condition we did not achieve. All of our current and future assets, except for intellectual property and 35% of our investment in our subsidiary, Cerus Europe B.V., are secured for our borrowings under the loan and security agreement. The loan and security agreement requires that we comply with certain covenants applicable to us and our subsidiary, including among other things, covenants restricting dispositions, changes in business, management, ownership or business locations, mergers or acquisitions, indebtedness, encumbrances, distributions, investments, transactions with affiliates and subordinated debt, any of which could restrict our business and operations, particularly our ability to respond to changes in our business or to take specified actions to take advantage of certain business opportunities that may be presented to us. Our failure to comply with any of the covenants could result in a default under the loan and security agreement, which could permit the lenders to declare all or part of any outstanding borrowings to be

immediately due and payable, or to refuse to permit additional borrowings under the loan and security agreement. If we are unable to repay those amounts, the lenders under the loan and security agreement could proceed against the collateral granted to them to secure that debt, which would seriously harm our business. In addition, should we be unable to comply with these covenants or if we default on any portion of our outstanding borrowings, the lenders can also impose a 5% penalty and restrict access to additional borrowings under the loan and security agreement.

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

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

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

We are highly dependent upon our executive management team and other critical personnel, including our specialized research and development, regulatory and operations personnel, many of whom have been employed with us for many years and have a significant amount of institutional knowledge about us and our products. We do not carry “key person” insurance. If one or more members of our executive management team or other key personnel were to retire or resign, our ability to achieve development, regulatory or operational milestones for commercialization of our products could be adversely affected if we are unable to replace them with employees of comparable knowledge and experience. For example, our President of Cerus Europe B.V. and we have entered into a separation agreement. While we have identified and hired an interim general manager as a replacement, we cannot be certain that the new general manager will be able to learn our business timely or at all or successfully maintain or grow our commercial business in Europe, the Middle East or African markets. In addition, we may not be able to retain or recruit other qualified individuals, and our efforts at knowledge transfer could be inadequate. If knowledge transfer, recruiting and retention efforts are inadequate, significant amounts of internal historical knowledge and expertise could become unavailable to us.

We also rely on our ability to attract, retain and motivate skilled and highly qualified personnel in order to grow our company. Competition for qualified personnel in the medical device and pharmaceutical industry is very intense. If we are unable to attract, retain and motivate quality individuals, our business, financial condition, ability to perform under our BARDA agreement, or results of operations and growth prospects could be adversely affected. Even if we are able to identify and hire qualified personnel commensurate with our growth objectives and opportunities, the process of integrating new employees is time consuming, costly and distracting to existing employees and management. Such disruptions may have an adverse impact on our operations, our ability to service existing markets and customers, or our ability to comply with regulations and laws.

All of the employees of our subsidiary, Cerus Europe B.V., are employed outside the U.S., including in France, where labor and employment laws are relatively stringent and, in many cases, grant significant job protection to certain employees, including rights on termination of employment. In addition, one of our manufacturing partners that we are dependent on is located in France and may have employees that are members of unions or represented by a works council as required by law. These more stringent labor and employment laws to the extent that they are applicable, coupled with the requirement to consult with the relevant unions or works' councils, could increase our operational costs with respect to our own employees and could result in passed through operational costs by our manufacturing partner. If the increased operational costs become significant, our business, financial condition and results of operations could be adversely impacted.

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

Our business is increasingly dependent on complex and interdependent information technology systems, including internet-based systems, databases and programs, to support our business processes as well as internal and external communications. These computer systems are potentially vulnerable to breakdown, malicious intrusion and computer viruses which may result in the impairment of

production and key business processes or loss of data or information. Additionally, our systems are potentially vulnerable to data security breaches—whether by employees or others—which may expose sensitive data to unauthorized persons. Such data security breaches could lead to the loss of trade secrets or other intellectual property, or could lead to the public exposure of personal information (including sensitive personal information) of our employees, clinical trial patients, distributors, customers and others. Such disruptions and breaches of security could have a material adverse effect on our business, financial condition and results of operations.

In addition, our enterprise resource planning system, or ERP System, is extremely complex and impacts a significant number of our business processes. Should we experience unforeseen difficulties with our ERP System, we may experience disruptions to our operations, increased costs in troubleshooting and resolving the issues, and erosion in confidence from customers and employees, any of which could have a material adverse effect on our business and operations.

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

Our ability to use our federal and state net operating loss, or NOL, carryforwards to offset potential future taxable income and related income taxes that would otherwise be due is dependent upon our generation of future taxable income before the expiration dates of the NOL carryforwards, and we cannot predict with certainty when, or whether, we will generate sufficient taxable income to use all of our NOL carryforwards. In addition, utilization of NOL carryforwards to offset potential future taxable income and related income taxes that would otherwise be due is subject to annual limitations under the “ownership change” provisions of Sections 382 of the Internal Revenue Code of 1986, as amended, or the Code, and similar state provisions, which may result in the expiration of NOL carryforwards before future utilization. In general, under the Code, if a corporation undergoes an “ownership change,” generally defined as a greater than 50% change (by value) in its equity ownership over a three-year period, the corporation’s ability to use its pre-change NOL carryforwards and other pre-change tax attributes (such as research and development credit carryforwards) to offset its post-change taxable income or taxes may be limited. Our equity offerings and other changes in our stock ownership, some of which are outside of our control, may have resulted or could in the future result in an ownership change. Although we have completed studies to provide reasonable assurance that an ownership change limitation would not apply, we cannot be certain that a taxing authority would reach the same conclusion. If, after a review or audit, an ownership change limitation were to apply, utilization of our domestic NOL and tax credit carryforwards could be limited in future periods and a portion of the carryforwards could expire before being available to reduce future income tax liabilities.

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

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

- obtain patents;
- protect trade secrets;
- operate without infringing upon the proprietary rights of others; and
- prevent others from infringing on our proprietary rights.

We cannot be certain that our patents or patents that we license from others will be enforceable and afford protection against competitors. Our patents or patent applications, if issued, may be challenged, invalidated or circumvented. Our patent rights may not provide us with proprietary protection or competitive advantages against competitors with similar technologies. Others may independently develop technologies similar to ours or independently duplicate our technologies. For example, we are aware of a U.S. patent issued to a third-party that covers methods to remove psoralen compounds from blood products. We have reviewed the patent and believe there exist substantial questions

concerning its validity. We cannot be certain, however, that a court would hold the patent to be invalid or not infringed by our platelet or plasma systems. 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. Our patents expire at various dates between now and 2031. Recent patent applications will, if granted, result in patents with later expiration dates. In addition, we have a license from Fresenius to U.S. and foreign patents relating to the INTERCEPT Blood System, which expire at various dates between 2018 and 2024. Due to the extensive time required for development, testing and regulatory review of our potential products, our patents may expire or remain in existence for only a short period following commercialization. This would reduce or eliminate any advantage of the patents.

We cannot be certain that we were the first to make the inventions covered by each of our issued patents or pending patent applications or that we were the first to file patent applications for such inventions. We may need to license the right to use third-party patents and intellectual property to continue development and commercialization of our products, including in connection with our planned commercialization of the platelet and plasma systems in the U.S. We may not be able to acquire such required licenses on acceptable terms, if at all. If we do not obtain such licenses, we may need to design around other parties' patents, or we may not be able to proceed with the development, manufacture or sale of our products.

Our patents do not cover all of the countries in which we are selling, and planning to sell, our products. We will not be able to prevent potential competitors from using our technology in countries where we do not have patent coverage. Further, the laws of some foreign countries may not protect intellectual property rights to the same extent as the laws of the U.S., including the CIS countries, China and India, jurisdictions where we are currently expanding our commercialization efforts through distributors. In certain countries, compulsory licensing laws exist that may be used to compel a patent owner to grant licenses to third parties, for reasons such as non-use of the patented subject matter within a certain period of time after patent grant or commercializing in a manner that is cost-prohibitive in the country. In those countries, we may have limited remedies if our patents are infringed or if we are compelled to grant a license for INTERCEPT to a third party, which could materially diminish the value of such patents. This could adversely impact our potential revenue opportunities.

We may face litigation requiring us to defend against claims of infringement, assert claims of infringement, enforce our patents, protect our trade secrets or know-how or determine the scope and validity of others' proprietary rights. Patent litigation is costly. In addition, we may require interference proceedings before the U.S. Patent and Trademark Office to determine the priority of inventions relating to our patent applications. Litigation or interference proceedings could be expensive and time consuming, and we could be unsuccessful in our efforts to enforce our intellectual property rights. We may rely, in certain circumstances, on trade secrets to protect our technology. However, trade secrets are difficult to protect. We protect our proprietary technology and processes, in part, by confidentiality agreements with employees, consultants and contractors. These agreements may be breached and we may not have adequate remedies for any breach or our trade secrets may otherwise become known or be independently discovered by competitors. To the extent that our employees, consultants or contractors use intellectual property owned by others, disputes also may arise as to the rights in related or resulting know-how and inventions.

As our international operations grow, we may be subject to adverse fluctuations in exchange rates between the U.S. dollar and foreign currencies.

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

Product sales of the INTERCEPT Blood System sold outside of the U.S. are typically invoiced to customers in Euros. In addition, we purchase finished INTERCEPT disposable kits for our platelet and plasma systems and incur certain operating expenses in Euros and other foreign currencies. Our exposure to foreign exchange rate volatility is a direct result of our product sales, cash collection and cash payments for expenses to support our international operations. Foreign exchange rate fluctuations are recorded as a component of other income, net on our consolidated statements of operations. Significant fluctuations in the volatility of foreign currencies relative to the U.S. dollar may materially affect our results of operations. For example, the announcement of Brexit caused severe volatility in global currency exchange rate fluctuations that resulted in the strengthening of the U.S. dollar against foreign currencies in which we transact business, and should this foreign exchange volatility continue, it could cause volatility in our results of operations. In addition, in a period where the U.S. dollar is strengthening/weakening as compared to Euros and other currencies we transact in, our revenues and expenses denominated in Euros or other foreign currencies are translated into U.S. dollars at a lower/higher value than they would be in an otherwise constant currency exchange rate

environment.

Currently we do not have a formal hedging program to mitigate the effects of foreign currency volatility. As our commercial operations grow globally, our operations are exposed to more currencies and as a result our exposure to foreign exchange risk will grow.

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

Our shares of common stock are currently quoted on the Nasdaq Global Market under the symbol “CERS.” The market for our common stock has been limited due to low trading volume and the small number of brokerage firms acting as market makers. Active trading markets generally result in lower price volatility and more efficient execution of buy and sell orders. The absence of an active trading market increases price volatility and reduces the liquidity of our common stock. As long as this condition continues, the sale of a significant number of shares of common stock at any particular time could be difficult to achieve at the market prices prevailing

immediately before such shares are offered, which may limit our ability to effectively raise money. In addition, due to the limitations of our market and the volatility in the market price of our stock, investors may face difficulties in selling shares at attractive prices when they want to sell. As a result of this lack of trading activity, the quoted price for our common stock is not necessarily a reliable indicator of its fair market value.

We are obligated to develop and maintain proper and effective internal control over financial reporting. In the future, we may not complete our analysis of our internal control over financial reporting in a timely manner, or these internal controls may not be determined to be effective, which may adversely affect investor confidence in our company and, as a result, the value of our common stock.

We are required, pursuant to Section 404 of the Sarbanes-Oxley Act, to furnish a report by management on, among other things, the effectiveness of our internal control over financial reporting. This assessment includes disclosure of any material weakness identified by our management in our internal control over financial reporting, as well as a statement that our independent registered public accounting firm has issued an attestation report on the effectiveness of our internal control over financial reporting.

Complying with Section 404 requires a rigorous compliance program as well as adequate time and resources. As a result of expanding our commercialization efforts, developing, improving and expanding our core information technology systems as well as implementing new systems to support our sales, supply chain activities and reporting capabilities, all of which require significant management time and support, we may not be able to complete our internal control evaluation, testing and any required remediation in a timely fashion. Additionally, if we identify one or more material weaknesses in our internal control over financial reporting, we will not be unable to assert that our internal controls are effective. For example, our management concluded that our internal control over financial reporting was ineffective as of December 31, 2014, because material weaknesses existed in our internal control over financial reporting related to the valuation of our inventory and cost of product revenue and the timeliness and accuracy of recording adjustments to certain accrued liabilities as reported on our consolidated balance sheets and statements of operations. Although we have been able to successfully remediate those internal control deficiencies, to the extent we identify future weaknesses or deficiencies, there could be material misstatements in our consolidated financial statements and we could fail to meet our financial reporting obligations. As a result, our ability to obtain additional financing, or obtain additional financing on favorable terms, could be materially and adversely affected which, in turn, could materially and adversely affect our business, our financial condition and the value of our common stock. If we are unable to assert that our internal control over financial reporting is effective in the future, or if our independent registered public accounting firm is unable to express an opinion or expresses an adverse opinion on the effectiveness of our internal controls in the future, investor confidence in the accuracy and completeness of our financial reports could be further eroded, which would have a material adverse effect on the price of our common stock.

Provisions of our charter documents, our stockholder rights plan, our compensatory arrangements and Delaware law could make it more difficult for a third party to acquire us, even if the offer may be considered beneficial by our stockholders.

Provisions of the Delaware General Corporation Law could discourage potential acquisition proposals and could delay, deter or prevent a change in control. The anti-takeover provisions of the Delaware General Corporation Law impose various impediments to the ability of a third party to acquire control of us, even if a change in control would be beneficial to our existing stockholders. In addition, Section 203 of the Delaware General Corporation Law, unless its application has been waived, provides certain default anti-takeover protections in connection with transactions between us and an “interested stockholder”. Generally, Section 203 prohibits stockholders who, alone or together with their affiliates and associates, own more than 15% of the subject company from engaging in certain business combinations for a period of three years following the date that the stockholder became an interested stockholder of such subject company without approval of the board or the vote of two-thirds of the shares held by the independent stockholders. Our board of directors has also adopted a stockholder rights plan, or “poison pill,” which would

significantly dilute the ownership of a hostile acquirer. Additionally, provisions of our amended and restated certificate of incorporation and bylaws could deter, delay or prevent a third party from acquiring us, even if doing so would benefit our stockholders, including without limitation, the authority of the board of directors to issue, without stockholder approval, preferred stock with such terms as the board of directors may determine. In addition, our executive employment agreements, change of control severance benefit plan and equity incentive plans and agreements thereunder provide for certain severance benefits in connection with a change of control of us, including single-trigger equity vesting acceleration benefits with respect to outstanding stock options, which could increase the costs to a third party acquirer and/or deter such third party from acquiring us.

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

None.

ITEM 3. DEFAULTS UPON SENIOR SECURITIES

None.

ITEM 4. MINE SAFETY DISCLOSURES
Not applicable.

ITEM 5. OTHER INFORMATION
None.

ITEM 6. EXHIBITS

Exhibit Number	Description of Exhibit
3.1 (1)	Amended and Restated Certificate of Incorporation of Cerus Corporation.
3.2 (1)	Certificate of Amendment to the Amended and Restated Certificate of Incorporation of Cerus Corporation.
3.3 (6)	Certificate of Amendment to the Amended and Restated Certificate of Incorporation of Cerus Corporation.
3.4 (1)	Certificate of Designation of Series C Junior Participating Preferred Stock of Cerus Corporation.
3.5 (2)	Amended and Restated Bylaws of Cerus Corporation.
4.1 (3)	Specimen Stock Certificate.
4.2 (4)	Rights Agreement, dated as of November 3, 1999, as amended as of August 6, 2001, between Cerus Corporation and Wells Fargo Bank, N.A. (formerly known as Norwest Bank Minnesota, N.A.).
4.3 (5)	Amendment to Rights Agreement, dated as of October 28, 2009, between Cerus Corporation and Wells Fargo Bank, N.A. (which includes the form of Rights Certificate as Exhibit B thereto).
31.1	Certification of the Principal Executive Officer of Cerus Corporation pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.
31.2	Certification of the Principal Financial Officer of Cerus Corporation pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.
32.1 (7)	Certification of the Principal Executive Officer and Principal Financial Officer pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.
101.INS	XBRL Instance Document.
101.SCH	XBRL Taxonomy Extension Schema Document.
101.CAL	XBRL Taxonomy Extension Calculation Linkbase Document.
101.DEF	XBRL Taxonomy Extension Definition Linkbase Document.
101.LAB	XBRL Taxonomy Extension Label Linkbase Document.
101.PRE	XBRL Taxonomy Extension Presentation Linkbase Document.

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

(2) Incorporated by reference to the like-described exhibit to the Registrant's Current Report on Form 8-K (File No. 000-21937), filed with the SEC on June 19, 2008.
(3) Incorporated by reference to the like-described exhibit to the Registrant's Registration Statement on Form S-1 (File No. 333-11341) and amendments thereto.
(4) Incorporated by reference to the like-described exhibit to the Registrant's Quarterly Report on Form 10-Q (File No. 000-21937), for the quarter ended June 30, 2009.
(5) Incorporated by reference to the like-described exhibit to the Registrant's Current Report on Form 8-K (File No. 000-21937), filed with the SEC on October 30, 2009.
(6) Incorporated by reference to the like-described exhibit to the Registrant's Quarterly Report on Form 10-Q (File No. 000-21937), for the quarter ended June 30, 2014.
(7) This certification accompanies the Form 10-Q to which it relates, is not deemed filed with the Securities and Exchange Commission, and is not incorporated by reference into any filing of the Registrant under the Securities Act of 1933, as amended, or the Securities Exchange Act of 1934, as amended (whether made before or after the date of the Form 10-Q), irrespective of any general incorporation language contained in such filing.

SIGNATURES

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

CERUS CORPORATION

Date: August 5, 2016 /s/ Kevin D. Green
Kevin D. Green
Vice President, Finance and Chief Financial Officer

(on behalf of registrant and as Principal Financial Officer)

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