

CERUS CORP  
Form 10-Q  
November 06, 2015  
Table of Contents

**UNITED STATES**  
**SECURITIES AND EXCHANGE COMMISSION**  
**WASHINGTON, D.C. 20549**

**FORM 10-Q**

(Mark One)

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

**For the quarterly period ended September 30, 2015**

**or**

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

**For the transition period from: \_\_\_\_\_ to \_\_\_\_\_**

**Commission File Number 000-21937**

**CERUS CORPORATION**

**(Exact name of registrant as specified in its charter)**

**Delaware**  
**(State or other jurisdiction of**  
**incorporation or organization)**

**68-0262011**  
**(I.R.S. Employer**  
**Identification No.)**

**2550 Stanwell Dr.**

**Concord, California**  
**(Address of principal executive offices)**  
**(925) 288-6000**

**94520**  
**(Zip Code)**

**(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  NO

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

Edgar Filing: CERUS CORP - Form 10-Q

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

Large accelerated filer  Accelerated filer   
Non-accelerated filer  (Do not check if a smaller reporting company) Smaller reporting company   
Indicate by check mark whether the registrant is a shell company (as defined in Rule 12b-2 of the Exchange Act). YES  NO

As of October 23, 2015, there were 97,138,029 shares of the registrant's common stock outstanding.

**Table of Contents**

**CERUS CORPORATION**  
**QUARTERLY REPORT ON FORM 10-Q**  
**THREE AND NINE MONTHS ENDED SEPTEMBER 30, 2015**  
**TABLE OF CONTENTS**

**PART I FINANCIAL INFORMATION**

Item 1.	<u>Financial Statements</u>	3
	<u>Unaudited Condensed Consolidated Balance Sheets September 30, 2015 and December 31, 2014</u>	3
	<u>Unaudited Condensed Consolidated Statements of Operations Three and nine months ended September 30, 2015 and 2014</u>	4
	<u>Unaudited Condensed Consolidated Statements of Comprehensive Loss Three and nine months ended September 30, 2015 and 2014</u>	5
	<u>Unaudited Condensed Consolidated Statements of Cash Flows Nine months ended September 30, 2015 and 2014</u>	6
	<u>Notes to Unaudited Condensed Consolidated Financial Statements</u>	7
Item 2.	<u>Management's Discussion and Analysis of Financial Condition and Results of Operations</u>	23
Item 3.	<u>Quantitative and Qualitative Disclosures About Market Risk</u>	35
Item 4.	<u>Controls and Procedures</u>	35

**PART II OTHER INFORMATION**

Item 1.	<u>Legal Proceedings</u>	36
Item 1A.	<u>Risk Factors</u>	36
Item 2.	<u>Unregistered Sales of Equity Securities and Use of Proceeds</u>	61
Item 3.	<u>Defaults Upon Senior Securities</u>	61
Item 4.	<u>Mine Safety Disclosures</u>	61
Item 5.	<u>Other Information</u>	61
Item 6.	<u>Exhibits</u>	62

<b><u>SIGNATURES</u></b>	64
--------------------------	----

**Table of Contents****PART I: FINANCIAL INFORMATION****ITEM 1. FINANCIAL STATEMENTS****CERUS CORPORATION****CONDENSED CONSOLIDATED BALANCE SHEETS**

(in thousands)

	<b>September 30, 2015 (Unaudited)</b>	<b>December 31, 2014 <sup>(1)</sup></b>
<b>ASSETS</b>		
Current assets:		
Cash and cash equivalents	\$ 50,795	\$ 22,781
Short-term investments	48,968	28,513
Investment in marketable equity securities	7,684	
Accounts receivable	5,646	5,493
Inventories	12,842	14,956
Prepaid expenses	1,535	1,210
Other current assets	953	1,932
Total current assets	128,423	74,885
Non-current assets:		
Property and equipment, net	3,712	3,781
Goodwill	1,316	1,316
Intangible assets, net	991	1,142
Restricted cash	623	508
Other assets	123	144
Total assets	\$ 135,188	\$ 81,776
<b>LIABILITIES AND STOCKHOLDERS EQUITY</b>		
Current liabilities:		
Accounts payable	\$ 6,813	\$ 9,882
Accrued liabilities	8,108	8,444
Accrued taxes	818	
Deferred revenue - current	306	376
Debt - current	1,449	
Warrant liability	2,424	10,485
Total current liabilities	19,918	29,187
Non-current liabilities:		
Debt - non-current	18,407	9,872

Edgar Filing: CERUS CORP - Form 10-Q

Deferred income taxes	127	115
Other non-current liabilities	1,215	1,081
<b>Total liabilities</b>	<b>39,667</b>	<b>40,255</b>
Commitments and contingencies		
Stockholders' equity:		
Common stock	97	80
Additional paid-in capital	673,653	583,416
Accumulated other comprehensive income (loss)	4,827	(31)
Accumulated deficit	(583,056)	(541,944)
<b>Total stockholders' equity</b>	<b>95,521</b>	<b>41,521</b>
<b>Total liabilities and stockholders' equity</b>	<b>\$ 135,188</b>	<b>\$ 81,776</b>

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

See accompanying Notes to Unaudited Condensed Consolidated Financial Statements.

Table of Contents

**CERUS CORPORATION**  
**CONDENSED CONSOLIDATED STATEMENTS OF OPERATIONS**

**UNAUDITED**

(in thousands, except per share data)

	<b>Three Months Ended September 30,</b>		<b>Nine Months Ended September 30,</b>	
	<b>2015</b>	<b>2014</b>	<b>2015</b>	<b>2014</b>
Revenue	\$ 8,045	\$ 10,362	\$ 24,567	\$ 26,829
Cost of revenue	5,560	5,689	17,302	14,598
Gross profit on revenue	2,485	4,673	7,265	12,231
Operating expenses:				
Research and development	7,689	7,250	18,483	16,614
Selling, general and administrative	10,932	8,724	34,713	27,040
Amortization of intangible assets	50	50	151	151
Total operating expenses	18,671	16,024	53,347	43,805
Loss from operations	(16,186)	(11,351)	(46,082)	(31,574)
Non-operating (expense) income, net:				
Gain from revaluation of warrant liability	1,109	1,738	4,698	14,263
Foreign exchange loss	(10)	(941)	(624)	(945)
Interest expense	(505)	(249)	(1,061)	(333)
Other income, net	7	52	36	106
Total non-operating income, net	601	600	3,049	13,091
Loss before income taxes	(15,585)	(10,751)	(43,033)	(18,483)
Provision (benefit) for income taxes	95	8	(1,921)	90
Net loss	\$ (15,680)	\$ (10,759)	\$ (41,112)	\$ (18,573)
Net loss per share:				
Basic	\$ (0.16)	\$ (0.14)	\$ (0.43)	\$ (0.25)
Diluted	\$ (0.17)	\$ (0.16)	\$ (0.48)	\$ (0.44)
Weighted average shares outstanding used in the calculation of net loss per share:				

Edgar Filing: CERUS CORP - Form 10-Q

Basic	96,864	75,194	95,347	73,407
Diluted	97,605	76,103	96,340	75,437

See accompanying Notes to Unaudited Condensed Consolidated Financial Statements.



Table of Contents

**CERUS CORPORATION**  
**CONDENSED CONSOLIDATED STATEMENTS OF COMPREHENSIVE LOSS**

**UNAUDITED**

(in thousands)

	<b>Three Months Ended September 30,</b>		<b>Nine Months Ended September 30,</b>	
	<b>2015</b>	<b>2014</b>	<b>2015</b>	<b>2014</b>
Net loss	\$ (15,680)	\$ (10,759)	\$ (41,112)	\$ (18,573)
Other comprehensive (losses) gains:				
Unrealized (losses) gains on available-for-sale investments, net of taxes of (\$1,700) and \$2,852 for the three and nine months ended September 30, 2015	(2,654)	(17)	4,858	(18)
Comprehensive loss	\$ (18,334)	\$ (10,776)	\$ (36,254)	\$ (18,591)

See accompanying Notes to Unaudited Condensed Consolidated Financial Statements.

Table of Contents**CERUS CORPORATION****CONDENSED CONSOLIDATED STATEMENTS OF CASH FLOWS****UNAUDITED****(in thousands)**

	<b>Nine Months Ended September 30,</b>	
	<b>2015</b>	<b>2014</b>
<b>Operating activities</b>		
Net loss	\$ (41,112)	\$ (18,573)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation and amortization	1,229	989
Stock-based compensation	4,912	3,764
Gain from revaluation of warrant liability	(4,698)	(14,263)
Non-cash interest expense	230	65
Deferred income taxes	12	19
Loss on disposal of fixed assets		3
Tax benefit from other unrealized gain on available-for-sale securities	(2,034)	
Changes in operating assets and liabilities:		
Accounts receivable	(153)	(1,241)
Inventories	1,970	(632)
Other assets	802	(2,860)
Accounts payable	(3,085)	(1,555)
Accrued liabilities	(375)	2,728
Deferred revenue	(42)	379
Net cash used in operating activities	(42,344)	(31,177)
<b>Investing activities</b>		
Capital expenditures	(561)	(2,033)
Purchases of investments	(78,261)	(14,807)
Proceeds from maturities of investments	57,444	17,305
Proceeds from sales of certain other assets		50
Restricted cash	(115)	
Net cash (used in) provided by investing activities	(21,493)	515
<b>Financing activities</b>		
Net proceeds from equity incentive plans and warrants	6,609	10,269
Net proceeds from public offering	75,327	6,849
Proceeds from loans, net of discount	10,000	9,848
Repayment of debt	(85)	(3,446)

Net cash provided by financing activities	91,851	23,520
Net increase (decrease) in cash and cash equivalents	28,014	(7,142)
Cash and cash equivalents, beginning of period	22,781	29,485
Cash and cash equivalents, end of period	\$ 50,795	\$ 22,343

See accompanying Notes to Unaudited Condensed Consolidated Financial Statements.

---

**Table of Contents**

**CERUS CORPORATION**

**NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS**

**UNAUDITED**

**Note 1. Summary of Significant Accounting Policies**

**Principles of Consolidation and Basis of Presentation**

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

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

**Use of Estimates**

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

**Reclassifications**

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

**Revenue**

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

Revenue related to sales is generally recognized when the Company fulfills its obligations for each element of an agreement. For all sales of the Company's INTERCEPT Blood System products, the Company uses a binding purchase order and signed sales contract as evidence of an arrangement. The Company sells its platelet and plasma systems directly to blood banks, hospitals, universities and government agencies, as well as to distributors in certain regions. Generally, the Company's contracts with its customers do not provide for open return rights, except within a reasonable time after receipt of goods in the case of defective or non-conforming product. Deliverables and the units of accounting vary according to the provisions of each purchase order or sales contract. For revenue arrangements with multiple elements, the Company determines whether the delivered elements meet the criteria as separate units of accounting. Such criteria require that the deliverable have stand-alone value to the customer and that if a general right of return exists relative to the delivered item, delivery or performance of the undelivered item(s) is considered probable and substantially in the control of the Company. Once the Company determines if the deliverable meets the criteria for a separate unit of accounting, the Company must determine how the consideration should be allocated between the deliverables and how the separate units of

---

**Table of Contents**

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

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

**Research and Development Expenses**

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

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

**Cash Equivalents**

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

**Investments**

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

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

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

### **Restricted Cash**

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

### **Concentration of Credit Risk**

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

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



---

**Table of Contents**

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

The Company had two and one customer that accounted for more than 10% of the Company's outstanding trade receivables at each of September 30, 2015 and December 31, 2014, respectively. These customers cumulatively represented approximately 42% and 36% of the Company's outstanding trade receivables at September 30, 2015 and December 31, 2014, respectively. To date, the Company has not experienced collection difficulties from these customers.

**Inventories**

At September 30, 2015 and December 31, 2014, inventory consisted of work-in-process and finished goods only. Finished goods include INTERCEPT disposable kits, UVA illumination devices ( illuminators ), and certain replacement parts for the illuminators. Platelet and plasma systems disposable kits generally have a two-year shelf life from the date of manufacture. Illuminators and replacement parts do not have regulated expiration dates. Work-in-process includes certain components that are manufactured before being sold to and ultimately incorporated and assembled by Fresenius Kabi Deutschland GmbH or Fresenius, Inc. (with their affiliates, Fresenius ) into the finished INTERCEPT disposable kits. The Company maintains an inventory balance based on its current sales projections, and at each reporting period, the Company evaluates whether its work-in-process inventory would be sold to Fresenius for production of finished units in order to sell to existing and prospective customers within the next twelve-month period. It is not customary for the Company's production cycle for inventory to exceed twelve months. Instead, the Company uses its best judgment to factor in lead times for the production of its work-in-process and finished units to meet the Company's forecasted demands. If actual results differ from those estimates, work-in-process inventory could potentially accumulate for periods exceeding one year. At September 30, 2015 and December 31, 2014, 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 market value. The Company uses significant judgment to analyze and determine if the composition of its inventory is obsolete, slow-moving or unsalable and frequently reviews such determinations. The Company writes-down specifically identified unusable, obsolete, slow-moving, or known unsalable inventory that has no alternative use in the period that it is first recognized by using a number of factors including product expiration dates, open and unfulfilled orders, and sales forecasts. Any write-down of its inventory to net realizable value establishes a new cost basis and will be maintained even if certain circumstances suggest that the inventory is recoverable in subsequent periods. Costs associated with the write-down of inventory are recorded in Cost of revenue on the Company's unaudited condensed consolidated statements of operations. At September 30, 2015 and December 31, 2014, the Company had \$1.3 million and \$0.1 million, respectively, recorded for potential obsolete, expiring or unsalable product.

**Property and Equipment, net**

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

### **Capitalization of Software Costs**

The Company capitalizes certain significant costs incurred in the acquisition and development of software for internal use, including the costs of the software, materials, and consultants during the application development stage. Costs incurred prior to the application development stage, costs incurred once the application is substantially complete and ready for its intended use, and other costs not qualifying for capitalization, including training and maintenance costs, are charged to expense as incurred. The Company capitalized costs for enhancement of the enterprise resource planning software system and other internal use software of zero and \$1.8 million during the nine months ended September 30, 2015 and 2014, respectively. Capitalized software costs associated with the enterprise resource planning system are being amortized over the estimated useful life of five years.

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

---

**Table of Contents****Goodwill and Intangible Assets, net**

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

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

**Long-lived Assets**

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

**Foreign Currency Remeasurement**

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

### **Stock-Based Compensation**

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

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

## **Table of Contents**

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

## **Warrant Liability**

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

The fair value of outstanding warrants is calculated using the Black-Scholes model and was adjusted accordingly at the end of each reporting period.

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

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

## **Income Taxes**

The Company accounts for income taxes using an asset and liability approach in accordance with ASC Topic 740 *Accounting for Income Taxes*. Under this method, deferred tax assets and liabilities are determined based on differences between the financial reporting and tax bases of assets and liabilities and are measured using the enacted tax rates and laws that will be in effect when the differences are expected to reverse. ASC Topic 740 requires derecognition of tax positions that do not have a greater than 50% likelihood of being recognized upon review by a taxing authority having full knowledge of all relevant information. Use of a valuation allowance as described in ASC Topic 740 is not an appropriate substitute for derecognition of a tax position. The Company recognizes accrued interest and penalties related to unrecognized tax benefits in its income tax expense. To date, the Company has not recognized any interest and penalties in its unaudited condensed consolidated statements of operations, nor has its accrued for or made payments for interest and penalties. The Company continues to carry a full valuation allowance on all of its deferred tax assets. Although the Company believes it more likely than not that a taxing authority would agree with its current tax positions, there can be no assurance that the tax positions the Company has taken will be substantiated by a taxing authority if reviewed. The Company's US federal and California tax years through 2014 remain subject to examination by the taxing jurisdictions due to unutilized net operating losses and research credits.

## **Net Loss Per Share**

Basic net loss per share is computed by dividing net loss by the weighted average number of common shares outstanding for the period. Diluted net loss per share gives effect to all potentially dilutive common shares outstanding

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

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

**Table of Contents**

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

	<b>Three Months Ended September 30,</b>		<b>Nine Months Ended September 30,</b>	
	<b>2015</b>	<b>2014</b>	<b>2015</b>	<b>2014</b>
<b>Numerator for Basic and Diluted:</b>				
Net loss used for basic calculation	\$ (15,680)	\$ (10,759)	\$ (41,112)	\$ (18,573)
Effect of revaluation of warrant liability	(1,109)	(1,738)	(4,698)	(14,263)
Adjusted net loss used for diluted calculation	\$ (16,789)	\$ (12,497)	\$ (45,810)	\$ (32,836)
<b>Denominator:</b>				
Basic weighted average number of shares outstanding	96,864	75,194	95,347	73,407
Effect of dilutive potential shares	741	909	993	2,030
Diluted weighted average number of shares outstanding	97,605	76,103	96,340	75,437
<b>Net loss per share:</b>				
Basic	\$ (0.16)	\$ (0.14)	\$ (0.43)	\$ (0.25)
Diluted	\$ (0.17)	\$ (0.16)	\$ (0.48)	\$ (0.44)

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

	<b>Three Months Ended September 30,</b>		<b>Nine Months Ended September 30,</b>	
	<b>2015</b>	<b>2014</b>	<b>2015</b>	<b>2014</b>
<b>Weighted average number of anti-dilutive potential shares:</b>				
Stock options	7,068	12,032	6,223	11,737

**Guarantee and Indemnification Arrangements**

The Company recognizes the fair value for guarantee and indemnification arrangements issued or modified by the Company. In addition, the Company monitors the conditions that are subject to the guarantees and indemnifications in order to identify if a loss has occurred. If the Company determines it is probable that a loss has occurred, then any such estimable loss would be recognized under those guarantees and indemnifications. Some of the agreements that the Company is a party to contain provisions that indemnify the counter party from damages and costs resulting from claims that the Company's technology infringes the intellectual property rights of a third party or claims that the sale or use of the Company's products have caused personal injury or other damage or loss. The Company has not received any such requests for indemnification under these provisions and has not been required to make material payments pursuant to these provisions.

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

### **Fair Value of Financial Instruments**

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



---

**Table of Contents**

models which vary by asset class. The Company classifies instruments in Level 3 if one or more significant inputs or significant value drivers are unobservable, which include its warrant liability. The Company assesses any transfers among fair value measurement levels at the end of each reporting period.

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

**New Accounting Pronouncements**

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

In August 2014, the FASB issued ASU No. 2014-15, *Presentation of Financial Statements - Going Concern (Subtopic 205-40): Disclosure of Uncertainties about an Entity's Ability to Continue as a Going Concern*, which requires management to evaluate, in connection with preparing financial statements for each annual and interim reporting period, whether there are conditions or events, considered in the aggregate, that raise substantial doubt about an entity's ability to continue as a going concern within one year after the date that the financial statements are issued and provide related disclosures. This ASU will be effective for the Company in fiscal year 2016. Early adoption is permitted. The adoption of this ASU is not expected to have a material impact on the Company's consolidated financial statements.

In April 2015, the FASB issued ASU No. 2015-03, *Interest - Imputation of Interest (Subtopic 835-30): Simplifying the Presentation of Debt Issuance Costs*, which requires debt issuance costs related to a recognized debt liability to be presented in the balance sheet as a direct deduction from the corresponding debt liability rather than as an asset. This ASU will be effective for the Company in fiscal year 2016. Early adoption is permitted. The adoption of this ASU is not expected to have a material impact on the Company's consolidated financial statements.

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

**Note 2. Fair Value of Financial Instruments**

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

Level 1: Quoted prices in active markets for identical instruments

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

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

Money market funds and equity investments 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 marketable debt securities as of September 30, 2015, the Company's primary service utilizes inputs from multiple industry-recognized pricing sources to determine the price for each investment. Corporate debt and United States government agency securities are systematically priced by this service as of the close of business each business day. If the primary pricing service does not price a specific asset, a secondary pricing service is utilized.

**Table of Contents**

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

	<b>Total</b>	<b>Quoted Prices in Active Markets for Identical Assets (Level 1)</b>	<b>Significant Other Observable Inputs (Level 2)</b>	<b>Significant Unobservable Inputs (Level 3)</b>
Money market funds <sup>(1)</sup>	\$ 42,169	\$ 42,169	\$	\$
Corporate debt securities <sup>(2)</sup>	18,965		18,965	
United States government agency securities <sup>(2)</sup>	30,003		30,003	
Marketable equity securities <sup>(3)</sup>	7,684	7,684		
<b>Total financial assets</b>	<b>\$ 98,821</b>	<b>\$ 49,853</b>	<b>\$ 48,968</b>	<b>\$</b>
Warrant liability <sup>(4)</sup>	\$ 2,424	\$	\$	\$ 2,424
<b>Total financial liabilities</b>	<b>\$ 2,424</b>	<b>\$</b>	<b>\$</b>	<b>\$ 2,424</b>

- (1) Included in cash and cash equivalents on the Company's unaudited condensed consolidated balance sheets.  
(2) Included in short-term investments on the Company's unaudited condensed consolidated balance sheets.  
(3) Included in investment in marketable equity securities on the Company's unaudited condensed consolidated balance sheets.  
(4) Included in current liabilities on the Company's unaudited condensed consolidated balance sheets.

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

	<b>Total</b>	<b>Quoted Prices in Active Markets for Identical Assets (Level 1)</b>	<b>Significant Other Observable Inputs (Level 2)</b>	<b>Significant Unobservable Inputs (Level 3)</b>
Money market funds <sup>(1)</sup>	\$ 3,912	\$ 3,912	\$	\$
Corporate debt securities <sup>(2)</sup>	26,088		26,088	
United States government agency securities <sup>(2)</sup>	3,426		3,426	

Total financial assets	\$ 33,426	\$ 3,912	\$ 29,514	\$
Warrant liability <sup>(3)</sup>	\$ 10,485	\$	\$	\$ 10,485
Total financial liabilities	\$ 10,485	\$	\$	\$ 10,485

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

**Table of Contents**

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

Balance at December 31, 2014	\$ 10,485
Decrease in fair value of warrants	(4,698)
Settlement of warrants exercised	(3,363)
Balance at September 30, 2015	\$ 2,424

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

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

**Note 3. Available-for-sale Securities**

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

	Amortized Cost	September 30, 2015		Fair Value
		Gross Unrealized Gain	Gross Unrealized Loss	
Money market funds	\$ 42,169	\$	\$	\$ 42,169
United States government agency securities	30,000	3		30,003
Corporate debt securities	18,973	3	(11)	18,965
Aduro equity securities		7,684		7,684
<b>Total available-for-sale securities</b>	<b>\$ 91,142</b>	<b>\$ 7,690</b>	<b>\$ (11)</b>	<b>\$ 98,821</b>

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

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

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

	<b>September 30, 2015</b>		<b>December 31, 2014</b>	
	<b>Amortized</b>		<b>Amortized</b>	
	<b>Cost</b>	<b>Fair Value</b>	<b>Cost</b>	<b>Fair Value</b>
One year or less	\$ 91,142	\$ 91,137	\$ 27,752	\$ 27,727
Greater than one year and less than five years			5,705	5,699
<b>Total available-for-sale debt securities</b>	<b>\$ 91,142</b>	<b>\$ 91,137</b>	<b>\$ 33,457</b>	<b>\$ 33,426</b>

As of September 30, 2015, the Company considered the declines in market value of its marketable securities investment portfolio to be temporary in nature and did not consider any of its investments other-than-temporarily impaired. Fair values were determined for each individual security in the investment portfolio. When evaluating an investment for other-than-temporary impairment, the Company reviews factors such as the length of time and extent to which fair value has been below its cost basis, the financial condition of the issuer and any changes thereto, changes in market interest rates, and the Company's intent to sell, or whether it is more likely than not it will be required to sell, the investment before recovery of the investment's cost basis. During the three and nine months ended September 30, 2015 and 2014, the Company did not recognize any other-than-temporary impairment losses.

**Table of Contents**

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

**Note 4. Inventories**

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

	<b>September 30, 2015</b>	<b>December 31, 2014</b>
Work-in-process	\$ 3,859	\$ 2,222
Finished goods	8,983	12,734
<b>Total inventories</b>	<b>\$ 12,842</b>	<b>\$ 14,956</b>

**Note 5. Goodwill and Intangible Assets, net***Goodwill*

During the three and nine months ended September 30, 2015, the Company did not dispose of or recognize additional goodwill. The Company performed its annual review of goodwill on August 31, 2015, and noted no impairment as of that date. As of September 30, 2015, the Company has not identified any indicators of goodwill impairment.

*Intangible Assets, net*

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

	<b>September 30, 2015</b>		
	<b>Gross Carrying Amount</b>	<b>Accumulated Amortization</b>	<b>Net Carrying Amount</b>
Acquisition-related intangible assets:			
Reacquired license - INTERCEPT Asia	\$ 2,017	\$ (1,026)	\$ 991
<b>Total intangible assets</b>	<b>\$ 2,017</b>	<b>\$ (1,026)</b>	<b>\$ 991</b>

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

**December 31, 2014**

	<b>Gross Carrying Amount</b>	<b>Accumulated Amortization</b>	<b>Net Carrying Amount</b>
<b>Acquisition-related intangible assets:</b>			
Reacquired license - INTERCEPT Asia	\$ 2,017	\$ (875)	\$ 1,142
<b>Total intangible assets</b>	<b>\$ 2,017</b>	<b>\$ (875)</b>	<b>\$ 1,142</b>

The Company recognized \$0.05 million and \$0.15 million in amortization expense related to intangible assets for each of the three and nine months ended September 30, 2015 and 2014. During the three and nine months ended September 30, 2015 and 2014, there were no impairment charges recognized related to the acquired intangible assets.

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

#### **Note 6. 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



**Table of Contents**

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

	<b>September 30, 2015</b>	<b>December 31, 2014</b>
Accrued compensation and related costs	\$ 4,046	\$ 3,951
Accrued professional services	2,277	2,123
Accrued inventory costs	92	870
Accrued customer costs and deposits	413	385
Accrued insurance premiums	583	264
Other accrued expenses	697	851
<b>Total accrued liabilities</b>	<b>\$ 8,108</b>	<b>\$ 8,444</b>

**Note 8. Debt**

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

	<b>September 30, 2015</b>		
	<b>Unamortized</b>		
	<b>Principal</b>	<b>Discount</b>	<b>Total</b>
Loan and Security Agreement	\$ 20,000	\$ (144)	\$ 19,856
Less: debt - current	(1,512)	63	(1,449)
<b>Debt - non-current</b>	<b>\$ 18,488</b>	<b>\$ (81)</b>	<b>\$ 18,407</b>

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

	<b>December 31, 2014</b>		
	<b>Unamortized</b>		
	<b>Principal</b>	<b>Discount</b>	<b>Total</b>
Loan and Security Agreement	\$ 10,000	\$ (128)	\$ 9,872
Less: debt - current			

Debt - non-current	\$ 10,000	\$ (128)	\$ 9,872
--------------------	-----------	----------	----------

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

Year ended December 31,	Principal	Interest	Total
2015	\$	\$ 349	\$ 349
2016	3,050	1,352	4,402
2017	6,428	980	7,408
2018	6,892	517	7,409
2019	3,630	1,474	5,104
Total	\$ 20,000	\$ 4,672	\$ 24,672

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

---

**Table of Contents***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 the period in which the third tranche can be drawn and the interest-only period for all advances under the Term Loan Agreement. The Company determined that the Term Loan Agreement Amendment 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 third tranche of \$10.0 million ( Term Loan C ) would be available, subject to the Company achieving consolidated trailing six months revenue at a specified threshold (the Revenue Event ), from the date of the achievement of the Revenue Event, to the earlier of (i) June 30, 2016, and (ii) 60 days after the Revenue Event is achieved. Term Loan A bears an interest rate of 6.95%. Term Loan B bears an interest rate of 7.01%. Term Loan C will bear an interest rate calculated at the greater of 6.95% or 6.72% plus the three month U.S. London Interbank Offered Rate, or LIBOR in effect three business days prior to the funding date. All of the Term Loans mature on June 1, 2019. The Company is required to make interest only payments through June 2016 followed by thirty-six months of equal principal and interest payments thereafter; however, if the Revenue Event is achieved no later than May 31, 2016, then the interest-only period may be extended through December 31, 2016, and the amortization period will be reduced to thirty months. The Company is also required to make a final payment equal to 7% of the principal amounts of the Term Loans drawn, payable on the earlier to occur of maturity or prepayment. The costs associated with the final payment are recognized as interest expense over the life of the Term Loans. The Company may prepay at any time the Term Loans subject to declining prepayment fees over the term of the Term Loan Agreement. The Company pledged all current and future assets, excluding its intellectual property and 35% of the Company's investment in its subsidiary, Cerus Europe B.V., as security for borrowings under the Term Loan Agreement. The Term Loan Agreement contains certain nonfinancial covenants, with which the Company was in compliance at September 30, 2015.

**Note 9. Commitments and Contingencies***Operating Leases*

The Company leases its office facilities, located in Concord, California and Amersfoort, the Netherlands, and certain equipment under non-cancelable operating leases with initial terms in excess of one year that require the Company to pay operating costs, property taxes, insurance and maintenance. The operating leases expire at various dates through 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. In June 2013, the Company entered into a new lease for additional space in Concord. The lease initially had a two-year term with four two-year options for the Company to renew, the first of which the Company exercised in March 2015 and obligates the Company to make rent payments for the remaining three months of 2015 of less than \$0.1 million and \$0.2 million and \$0.1 million in 2016 and 2017, respectively. The Company's leased facilities qualify as operating leases under ASC Topic 840, *Leases* and as such, are not included on its unaudited condensed consolidated balance sheets.

*Financed Leasehold Improvements*

In 2010, the Company financed \$1.1 million of leasehold improvements at one of its facilities in Concord, California. The Company pays for the financed leasehold improvements as a component of rent and is required to reimburse its landlord over the remaining life of the lease. If the Company exercises its right to early terminate the Concord,

California lease under which such improvements were made, which may occur at any time hereafter, the Company would be required to repay for any remaining portion of the landlord financed leasehold improvements at such time. At September 30, 2015, the Company had an outstanding liability of \$0.5 million related to these leasehold improvements, of which \$0.1 million was reflected in Accrued liabilities and \$0.4 million was reflected in Other non-current liabilities on the Company's unaudited condensed consolidated balance sheets.

*Purchase Commitments*

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

**Note 10. Stockholders' Equity**

*Public Offering of Common Stock*

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

**Table of Contents***Common Stock and Associated Warrant Liability*

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

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

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

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

	<b>September 30, 2015</b>	<b>December 31, 2014</b>
2010 Warrants	\$ 2,424	\$ 10,485

The fair value of the Company's 2010 Warrants was based on an option valuation model using the following assumptions at September 30, 2015 and December 31, 2014:

	<b>September 30, 2015</b>	<b>December 31, 2014</b>
<b>2010 Warrants:</b>		
Expected term (in years)	0.11	0.86
Estimated volatility	61%	55%
Risk-free interest rate	0.02%	0.25%
Expected dividend yield	0%	0%

The Company recorded non-cash gains of \$1.1 million and \$1.7 million during the three months ended September 30, 2015 and September 30, 2014, respectively, and non-cash gains of \$4.7 million and \$14.3 million during the nine months ended September 30, 2015 and 2014, respectively, in *Gain from revaluation of warrant liability* on its unaudited condensed consolidated statements of operations due to the changes in fair value of the warrants.

Significant changes to the Company's market price for its common stock will impact the implied and/or historical volatility used to calculate the fair value the 2010 Warrants. Any significant increases in the Company's stock price will likely create an increase in the fair value of warrant liability. Similarly, any significant decreases in the Company's stock price will likely create a decrease in the fair value of warrant liability. During the three months and nine months ended September 30, 2015, 175,000 and 1,544,123 shares of common stock were issued, respectively, in connection with the exercise of outstanding 2010 Warrants. As of September 30, 2015, 2010 Warrants to purchase approximately

1.8 million shares of common stock were outstanding.

### *Sales Agreement*

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

### **Note 11. Stock-Based Compensation**

The Company maintains an equity compensation plan to provide long-term incentives for employees, contractors, and members of its Board of Directors. The Company currently grants equity awards from one plan, the 2008 Equity Incentive Plan (the 2008 Plan ).

**Table of Contents**

The 2008 Plan allows for the issuance of non-statutory and incentive stock options, restricted stock, restricted stock units, stock appreciation rights, other stock-related awards, and performance awards which may be settled in cash, stock, or other property. The Company continues to have equity awards outstanding under its previous stock plans: 1998 Non-Officer Stock Option Plan and 1999 Equity Incentive Plan (collectively, the Prior Plans). Equity awards issued under the Prior Plans continue to adhere to the terms of those respective stock plans and no further options may be granted under those previous plans. However, at June 2, 2008, any shares that remained available for future grants under the Prior Plans became available for issuance under the 2008 Plan. On June 10, 2015, the Company's stockholders approved an amendment and restatement of the 2008 Plan that increased the aggregate number of shares of common stock authorized for issuance under the 2008 Plan by 5,000,000 shares. At September 30, 2015, the Company had an aggregate of approximately 21.7 million shares of its common stock reserved for issuance under the Amended 2008 Plan and the Prior Plans, of which approximately 14.5 million shares were subject to outstanding options and other stock-based awards, and approximately 7.2 million shares were available for future issuance under the Amended 2008 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. 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 September 30, 2015, the Company had 1.7 million shares of its common stock available for future issuance under the Purchase Plan.

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

	<b>Number of Options Outstanding</b>	<b>Weighted Average Exercise Price per Share</b>
Balances at December 31, 2014	11,323	\$ 4.13
Granted	3,628	4.57
Forfeited	(155)	4.73
Expired	(41)	6.57
Exercised	(308)	2.91
Balances at September 30, 2015	14,447	4.25

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.

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

	<b>Three Months Ended</b>		<b>Nine Months</b>	
	<b>September 30,</b>		<b>Ended</b>	
	<b>2015</b>	<b>2014</b>	<b>September 30,</b>	<b>2014</b>
Stock-based compensation expense by caption:				
Research and development	\$ 332	\$ 281	\$ 954	\$ 740
Selling, general and administrative	1,402	1,197	3,958	3,024
Total stock-based compensation expense	\$ 1,734	\$ 1,478	\$ 4,912	\$ 3,764



---

**Table of Contents****Note 12. Income Taxes**

Intraperiod tax allocation rules require the Company to allocate the provision for income taxes between continuing operations and other categories of earnings, such as other comprehensive income. In periods in which the Company has a year-to-date pre-tax loss from continuing operations and pre-tax income in other categories of earnings, such as other comprehensive income, the Company must allocate the tax provision to the other categories of earnings. The Company then records a related tax benefit in continuing operations. During the three months ended September 30, 2015, the Company recorded unrealized losses of \$2.7 million, net of taxes, on its investments in available-for-sale securities in other comprehensive income. During the nine months ended September 30, 2015, the Company recorded unrealized gains of \$4.9 million, net of taxes, on investments in available-for-sale securities in other comprehensive income. As a result, for the three months ended September 30, 2015, the Company recorded tax expense of \$0.1 million and tax benefits of \$1.9 million for the nine months ended September 30, 2015.

**Note 13. Development and License Agreements****Agreements with Fresenius**

The Company had an agreement with Fresenius that required the Company to pay royalties on future INTERCEPT Blood System product sales at royalty rates that vary by product: 10% of product sales for the platelet system and 3% of product sales for the plasma system. During the three months ended September 30, 2015 and 2014, the Company made royalty payments to Fresenius of \$0.7 million and \$0.6 million, respectively. During each of the nine months ended September 30, 2015 and 2014, the Company made royalty payments to Fresenius of \$1.9 million. At both September 30, 2015 and December 31, 2014, accrued royalties due to Fresenius were \$0.7 million.

Through December 31, 2013, the Company and Fresenius operated under a supply agreement (the Original Supply Agreement ) for the manufacture of the Company's platelet and plasma systems. Under the Original Supply Agreement, the Company paid Fresenius a set price per kit, which was established annually, plus a fixed surcharge per kit. In addition, volume driven manufacturing overhead was to be paid or refunded if actual manufacturing volumes were lower or higher than the estimated production volumes.

In November 2013, the Company amended the Original Supply Agreement with Fresenius, with the new terms effective January 1, 2014 (the 2013 Amendment ). Under the 2013 Amendment, Fresenius 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. Once the specified annual volume of disposable kits was purchased from Fresenius, the Company was able to purchase additional quantities of disposable kits from other third-party manufacturers. The 2013 Amendment also provided for fixed pricing for finished kits with successive decreasing pricing tiers at various annual production volumes. In addition, the 2013 Amendment required the Company to purchase additional specified annual volumes of sets per annum 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 the Company's proprietary inactivation compounds and adsorption media from the Company at fixed prices. During the three and nine months ended September 30, 2015, the Company sold \$0.5 million and \$1.5 million, respectively, of such components to Fresenius. During the three and nine months ended September 30, 2014, respectively, the Company sold \$2.2 million and \$6.0 million of such components to Fresenius. The Company maintains the amounts due from the components sold to Fresenius as a current asset on its accompanying unaudited condensed consolidated balance sheets until such time as the Company purchases finished disposable kits using those components. In October 2015, the Company entered into an Amended and Restated Manufacturing and Supply Agreement with Fresenius, which amends and restates the 2013 Amendment and Original

Supply Agreement (see Note 15).

The Company made payments to Fresenius of \$3.0 million and \$4.3 million relating to the manufacturing of the Company's products during the three months ended September 30, 2015 and 2014, respectively, and \$12.5 million and \$13.9 million during the nine months ended September 30, 2015 and 2014, respectively. At September 30, 2015 and December 31, 2014, accrued amounts due to Fresenius were \$1.8 million and \$5.1 million, respectively, for INTERCEPT disposable kits manufactured. At September 30, 2015 and December 31, 2014, amounts due from Fresenius were \$0.4 million and \$1.3 million, respectively.

**Note 14. Segment, Customer and Geographic Information**

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

The Company's operations outside of the U.S. include a wholly-owned subsidiary headquartered in Europe. The Company's operations in the United States of America are responsible for the research and development and global and domestic commercialization of the INTERCEPT Blood System, while operations in Europe are responsible for the commercialization efforts of

**Table of Contents**

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 customer that accounted for more than 10% of the Company's total product revenue, which operates in a country outside of the United States of America, during the three and nine months ended September 30, 2015 and 2014 (in percentages):

	Three Months Ended		Nine Months Ended	
	September 30, 2015	September 30, 2014	September 30, 2015	September 30, 2014
Etablissement Francais du Sang	27%	30%	26%	26%

**Note 15. Subsequent Event****Agreement with Fresenius**

In October 2015, the Company entered into an Amended and Restated Manufacturing and Supply Agreement (the 2015 Agreement) with Fresenius, which amends and restates the 2013 Amendment and Original Supply Agreement. 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 INTERCEPT Blood System for Red Blood Cells (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 are initially fixed, and are subject to certain adjustments, including for market pricing, changes in the relevant producer price index (as published by the U.S. Bureau of Labor Statistics), cost increase or decrease in raw materials and other components and other relevant factors.

The 2015 Agreement also contemplates that the Company and Fresenius will jointly fund certain specified initiatives focused on the implementation of automation, installation of new equipment, capacity expansion and cost reduction. The Company is also required to make certain milestone payments, subject to achievement of certain contractually defined events. Fresenius has also agreed to identify and qualify a second manufacturing facility if production volumes under the 2015 Agreement exceed certain specified thresholds. In addition, under the 2015 Agreement, the Company is no longer required to make royalty payments to Fresenius (see Note 13) for the sale of products after June 30, 2015. The initial term of the 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.

---

**Table of Contents**

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

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

*This Quarterly Report on Form 10-Q contains forward-looking statements within the meaning of Section 27A of the Securities Act of 1933, as amended, and Section 21E of the Securities and Exchange Act of 1934, as amended, that involve risks and uncertainties. The forward-looking statements are contained principally in this Item 2,*

*Management's Discussion and Analysis of Financial Condition and Results of Operations and in Item 1A, Risk Factors. These statements relate to future events or to our future operating or financial performance and involve known and unknown risks, uncertainties and other factors that may cause our actual results, performance or achievements to be materially different from any future results, performances or achievements expressed or implied by the forward-looking statements. Examples of forward-looking statements include, but are not limited to, statements about:*

*future sales of and our ability to effectively commercialize and achieve market acceptance of the INTERCEPT Blood System, including our ability to comply with applicable United States and foreign laws, regulations and regulatory requirements;*

*our ability to manage the growth of our business and attendant cost increases, including in connection with the commercialization of the INTERCEPT Blood System in the United States, as well as our ability to manage the risks attendant to our international operations;*

*the timing or likelihood of regulatory submissions and approvals and other regulatory actions or interactions;*

*our ability to obtain and maintain regulatory approvals of the INTERCEPT Blood System;*

*our ability to obtain adequate clinical and commercial supplies of the INTERCEPT Blood System from our sole source suppliers;*

*the initiation, scope, rate of progress, results and timing of our ongoing and proposed preclinical and clinical trials of the INTERCEPT Blood System;*

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

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

*our ability to protect our intellectual property and operate our business without infringing upon the intellectual property rights of others;*

*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.*

---

**Table of Contents**

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

**Overview**

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

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

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

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

---

**Table of Contents**

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

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

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



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

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

Although we have begun the combined commercial launch of the plasma and platelet systems in the United States and have announced the first customer contracts for the sale of the INTERCEPT Blood System for platelets and plasma, we do not expect to

---

**Table of Contents**

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

***Aduro Biotech***

We held an investment in preferred shares of Aduro which we 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, our preferred shares in Aduro converted to 396,700 shares of common stock. The initial public offering price was \$17.00 per share. As of September 30, 2015, the fair value of Aduro's common stock was \$19.37 per share. As a result of the initial public offering, we no longer account for the investment in Aduro under the cost basis of accounting but reflect the investment as an available-for-sale security on our consolidated balance sheet. We 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.

***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 has assumed Fenwal's rights and obligations under those agreements, including our manufacturing and supply agreement. In this report, references to Fresenius include references to its predecessors-in-interest, Fenwal and Baxter.

In November 2013, we amended our manufacturing and supply agreement, or 2013 Agreement, with Fresenius with the new terms effective January 1, 2014. 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 an Amended and Restated Manufacturing and Supply Agreement, or the 2015 Agreement, with Fresenius, which amends and restates the 2013 Amendment. Under the 2015 Agreement, Fresenius continues to be obligated to sell and we are obligated to purchase finished disposable kits for our platelet and plasma systems, and the INTERCEPT Blood System for Red Blood Cells, or RBC Sets. The 2015 Agreement permits us to purchase platelet and plasma 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 are subject to certain adjustments, including for market pricing, changes in the relevant producer price index (as published by the U.S. Bureau of Labor Statistics), cost increase or decrease in raw materials and other components and other relevant factors.

The 2015 Agreement also contemplates that we and Fresenius will jointly fund certain specified initiatives focused on the implementation of automation, installation of new equipment, capacity expansion and cost reduction. We are also required to make certain milestone payments, subject to achievement of certain contractually defined events. Fresenius has also agreed to identify and qualify a second manufacturing facility if production volumes under the 2015 Agreement exceed certain specified thresholds. In addition, under the 2015 Agreement, we are no longer required to make royalty payments to Fresenius (see Note 13) for the sale of products after June 30, 2015. The initial term of the 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. The Company and Fresenius each have customary termination rights, including termination for material breach.

---

**Table of Contents**

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.

**Equity and Debt Agreements***Cantor*

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

*Debt Agreement*

On June 30, 2014, we entered into a five year loan and security agreement with Oxford Finance, or the Term Loan Agreement, to borrow up to \$30.0 million in term loans in three equal tranches, or the Term Loans. On June 30, 2014, we received \$10.0 million from the first tranche, or Term Loan A. On June 15, 2015, we received \$10.0 million from Term Loan B. On September 29, 2015, the Term Loan Agreement was amended to extend the period in which the third tranche can be drawn and the interest-only period for all advances under the Term Loan Agreement. As amended, the third tranche of \$10.0 million, or Term Loan C, would be available, subject to our achievement of consolidated trailing six months revenue at a specified threshold, or the Revenue Event, from the date on which the Revenue Event is achieved, to the earlier of (i) June 30, 2016, and (ii) 60 days after the Revenue Event is achieved. Term Loan A bears an interest rate of 6.95%, and Term Loan B bears an interest rate of 7.01%. Term Loan C will bear an interest rate calculated at the greater of 6.95% or 6.72% plus the three month U.S. London Interbank Offered Rate, or LIBOR in effect three business days prior to the applicable funding date. All of the Term Loans mature on June 1, 2019. Following the Amendment to Term Loan Agreement, we are required to make interest only payments through June 2016 followed by thirty-six months of equal principal and interest payments thereafter; however, if the Revenue Event is achieved no later than May 31, 2016, then the interest-only period may be extended through December 31, 2016, and the amortization period will be reduced to thirty months. We are also required to make a final payment equal to 7% of the principal amounts of the Term Loans drawn payable on the earlier to occur of maturity or prepayment. We pledged all current and future assets, excluding our intellectual property and 35% of our investment in our subsidiary, Cerus Europe B.V., as security for borrowings under the Term Loan Agreement. The Term Loan Agreement contains certain nonfinancial covenants, with which we were in compliance at September 30, 2015. For additional discussion on the Term Loan Agreement, see *Commitments and Off-Balance Sheet Arrangements Debt*.

**Critical Accounting Policies and Management Estimates**

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

**Table of Contents****Results of Operations*****Three and Nine Months Ended September 30, 2015 and 2014******Revenue***

<b>(in thousands, except percentages)</b>	<b>Three Months Ended September 30,</b>			<b>Nine Months Ended September 30,</b>		
	<b>2015</b>	<b>2014</b>	<b>Change</b>	<b>2015</b>	<b>2014</b>	<b>Change</b>
Revenue	\$ 8,045	\$ 10,362	\$ (2,317) (22)%	\$ 24,567	\$ 26,829	\$ (2,262) (8)%

Revenue decreased during the three and nine months ended September 30, 2015, compared to the three and nine months ended September 30, 2014, primarily as a result of the deterioration in the Euro relative to the U.S. dollar of approximately 16% and 18% for three and nine months ended September 30, 2015, respectively, compared to the corresponding prior periods since most of our revenue has been invoiced and transacted in Euro and we report revenues in U.S. dollars. Lower unit sales volume of our disposable platelet system kits also contributed to the decrease in revenues during the three months ended September 30, 2015, primarily due to the timing of fulfilled orders during the three months ended September 30, 2015, and sales declines in CIS territories. The decrease in revenue during the nine months ended September 30, 2015, was partially offset by higher unit sales volume of our disposable platelet system kits.

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

***Cost of Revenue***

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

<b>(in thousands, except percentages)</b>	<b>Three Months Ended September 30,</b>			<b>Nine Months Ended September 30,</b>		
	<b>2015</b>	<b>2014</b>	<b>Change</b>	<b>2015</b>	<b>2014</b>	<b>Change</b>
Cost of revenue	\$ 5,560	\$ 5,689	\$ (129) (2)%	\$ 17,302	\$ 14,598	\$ 2,704 19%

Cost of revenue slightly decreased during the three months ended September 30, 2015 compared to the three months ended September 30, 2014. The decrease was primarily the result of lower unit sales volume and inventory produced during periods of more favorable foreign currency exchange rates, partially offset by increased obsolescence and manufacturing charges in the current period. Cost of revenue increased during the nine months ended September 30, 2015, compared to the nine months ended September 30, 2014. The increase was primarily the result of higher unit

sales volume and increased obsolescence and manufacturing charges in the current period, partially offset by inventory produced during periods of more favorable foreign currency exchange rates.

Our gross margin on product sales was 31% during the three months ended September 30, 2015, down from 45% during the three months ended September 30, 2014. Our gross margin on product sales was 30% during the nine months ended September 30, 2015, down from 46% during the nine months ended September 30, 2014. The decrease in gross margins on sales was primarily due to the deterioration in the Euro relative to the U.S. dollar on current period revenues, partially offset by the impact on cost of revenues which were recorded at foreign exchange rates in effect at the time the inventory was purchased. In addition, period charges for outdated product resulted in the overall decreases in gross margins for three and nine months ended September 30, 2015, relative to the corresponding prior periods.

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

**Table of Contents**

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

**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.

(in thousands, except percentages)	Three Months Ended			Nine Months Ended				
	September 30,			September 30,				
	2015	2014	Change	2015	2014	Change		
Research and development	\$ 7,689	\$ 7,250	\$ 439	6%	\$ 18,483	\$ 16,614	\$ 1,869	11%

Research and development expenses increased during the three and nine months ended September 30, 2015, compared to the three and nine months ended September 30, 2014, primarily due to increased costs associated with pursuing potential label claim extensions for the platelet systems in the U.S., conducting our IDE studies in 2015 and development activities for our red blood cell program.

We expect to incur additional research and development costs associated with planning, enrolling and completing our required post-approval study and the ongoing studies under our IDEs, pursuing potential regulatory approvals in other geographies where we do not currently sell our platelet and plasma systems, planning and conducting in vitro studies and clinical development of our red blood cell system in Europe and the United States, and completing chemistry, manufacturing and control, or CMC, activities to support a potential CE Mark submission for our red blood cell system in Europe, which is planned for the second half of 2016. Due to the inherent uncertainties and risks associated with developing biomedical products, including, but not limited to, intense and changing government regulation, uncertainty of future preclinical studies and clinical trial results and uncertainty associated with manufacturing, it is not possible to reasonably estimate the costs to complete these research and development projects. We face numerous risks and uncertainties associated with the successful completion of our research and development projects, which risks and uncertainties are discussed in further detail under Item 1A *Risk Factors* in Part II of this Quarterly Report on Form 10-Q.

***Selling, General, and Administrative Expenses***

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

Three Months Ended	Nine Months
September 30,	Ended



September 30,

(in thousands, except percentages)

	2015	2014	Change		2015	2014	Change	
Selling, general and administrative	\$ 10,932	\$ 8,724	\$ 2,208	25%	\$ 34,713	\$ 27,040	\$ 7,673	28%

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

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

#### *Amortization of Intangible Assets*

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

**Table of Contents**

(in thousands, except percentages)	Three Months Ended September 30,			Nine Months Ended September 30,		
	2015	2014	Change	2015	2014	Change
Amortization of intangible assets	\$ 50	\$ 50	\$ 0%	\$ 151	\$ 151	\$ 0%

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

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

**Non-Operating (Expense) Income, Net**

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

(in thousands, except percentages)	Three Months Ended September 30,				Nine Months Ended September 30,			
	2015	2014	Change		2015	2014	Change	
Gain from revaluation of warrant liability	\$ 1,109	\$ 1,738	\$ (629)	(36)%	\$ 4,698	\$ 14,263	\$ (9,565)	(67)%
Foreign exchange loss	(10)	(941)	931	(99)%	(624)	(945)	321	(34)%
Interest expense	(505)	(249)	(256)	103%	(1,061)	(333)	(728)	219%
Other income, net	7	52	(45)	(87)%	36	106	(70)	(66)%
Total non-operating income, net	\$ 601	\$ 600	\$ 1	0%	\$ 3,049	\$ 13,091	\$ (10,042)	(77)%

**Gain from revaluation of Warrant liability**

In August 2009 and November 2010, we issued warrants to purchase an aggregate of 2.4 million and 3.7 million shares of common stock, respectively, in connection with offerings of our common stock. In August 2014, all 2.4 million warrants issued in August 2009 were exercised. As of September 30, 2015, 1.8 million warrants issued in November 2010 were outstanding. The fair value of the November 2010 outstanding warrants, which uses the Black-Scholes model, is classified as a liability on our unaudited condensed consolidated balance sheets and is adjusted at each subsequent reporting period, until such time the instruments are exercised or otherwise modified to remove the provisions which require this treatment. Upon the exercise or modification to remove the provisions which require the warrants to be treated as a liability, the fair value of the warrants will be reclassified from liabilities to stockholders' equity and no further adjustment to the fair value would be made in subsequent periods. Further changes in stock price will result in similar adjustment as needed.

We recorded a \$1.1 million non-cash gain from the revaluation of the warrant liability during the three months ended September 30, 2015, compared to a \$1.7 million non-cash gain during the three months ended September 30, 2014, and a \$4.7 million non-cash gain during the nine months ended September 30, 2015, compared to a \$14.3 million

non-cash gain during the nine months ended September 30, 2014.

*Foreign exchange (loss) gain*

We recorded negligible foreign exchange losses of less than \$0.1 million during the three months ended September 30, 2015, compared to foreign exchange losses of \$0.9 million during the three months ended September 30, 2014. We recorded \$0.6 million foreign exchange losses during the nine months ended September 30, 2015, compared to \$0.9 million foreign exchange losses during the nine months ended September 30, 2014.

*Other income, net*

Other income, net decreased during the three and nine months ended September 30, 2015 compared to the three months and nine months ended September 30, 2014, primarily as a result of higher Delaware Franchise tax costs period over period.

*Interest expense*

Interest expense increased for the three and nine months ended September 30, 2015 compared to the three and nine months ended September 30, 2014, primarily due to larger outstanding debt balance under our Term Loan Agreement (see Debt section below).

---

**Table of Contents***Provision for Income Taxes*

For the three months ended September 30, 2015, we recorded a tax expense of \$0.1 million and for the three months ended September 30, 2014, we recorded a tax expense of approximately \$0.01 million. For the nine months ended September 30, 2015, we recorded a tax benefit of \$1.9 million and for the nine months ended September 30, 2014, we recorded a tax expense of \$0.1 million. The tax expense and benefit recognized during the three and nine months ended September 30, 2015, is the result of intra-period allocation rules associated with the unrealized changes in the fair value of our investment in Aduro. These tax benefits are partially offset by the tax provision recorded in other comprehensive income which is also associated with the increased value of our Aduro investment.

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

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

**Liquidity and Capital Resources**

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

At September 30, 2015, we had cash and cash equivalents of \$50.8 million, compared to \$22.8 million at December 31, 2014. We had \$56.7 million of short-term investments at September 30, 2015, and \$28.5 million at December 31, 2014. We also had total indebtedness under our Term Loan Agreement of approximately \$19.9 million at September 30, 2015, and \$9.9 million at December 31, 2014. Our cash equivalents 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 September 30, 2015, our short-term investments included \$7.7 million related to our investment in Aduro.

*Operating Activities*

Net cash used in operating activities was \$42.3 million during the nine months ended September 30, 2015, compared to \$31.2 million during the nine months ended September 30, 2014. The increase in net cash used in operating activities was primarily related to the level of cash spent for development activities for our red blood cell program, support of our IDE studies, and selling and administrative expenses related to the U.S. commercial launch of our platelet and plasma systems. Also impacting this increase in net cash used in operating activities were changes in working capital resulting from a net decrease in the combined total for our accounts payable and accrued liabilities due to the timing of payments and increased activities, partially offset by an increase in accounts receivable collections during the nine months ended September 30, 2015, as compared to the corresponding period in 2014.

*Investing Activities*

Net cash used in investing activities was \$21.5 million for the nine months ended September 30, 2015, compared to \$0.5 million net cash provided by investing activities during the nine months ended September 30, 2014. The period-over-period change was primarily the result of investing the proceeds from our January 2015 public offering,

offset by fewer capital expenditures during the nine months ended September 30, 2015, as compared to the corresponding period in 2014.

*Financing Activities*

Net cash provided by financing activities was \$91.9 million during the nine months ended September 30, 2015, compared to \$23.5 million during the nine months ended September 30, 2014. The increase in net cash provided by financing activities was primarily due to the proceeds received from our January 2015 public offering of common stock. The net proceeds from this offering were approximately \$75.4 million, net of underwriting discounts and other issuance costs. Net cash provided from financing activities was further increased by our drawdown of Term Loan B of \$10.0 million in June 2015.

*Working Capital*

Working capital increased to \$108.5 million at September 30, 2015, from \$45.7 million at December 31, 2014, primarily due to increases in short term investments due to the investment of funds from the January 2015 public offering, our drawdown of Term Loan B of \$10.0 million in June 2015, and our equity investment in Aduro common stock resulting from Aduro's initial public offering in April 2015, coupled with a decrease in the fair value of our warrant liability.

---

**Table of Contents***Capital Requirements*

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

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

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



**Table of Contents****Commitments and Off-Balance Sheet Arrangements***Off-balance sheet arrangements*

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

*Contractual Commitments*

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

	<b>Total</b>	<b>&lt; 1 year</b>	<b>1 - 3 years</b>	<b>4 - 5 years</b>	<b>After 5 years</b>
Minimum purchase requirements	\$ 7,882	\$ 4,836	\$ 3,046	\$	\$
Debt	24,672	2,899	14,817	6,956	
Operating leases	1,893	926	806	161	
Other commitments	1,392	937	287	168	
<b>Total contractual obligations</b>	<b>\$ 35,839</b>	<b>\$ 9,598</b>	<b>\$ 18,956</b>	<b>\$ 7,285</b>	<b>\$</b>

*Minimum purchase requirements*

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

*Operating leases*

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

*Other commitments*

Our other commitments primarily consist of obligations for landlord financed leasehold improvements, which are in addition to the operating leases we have for office and laboratory space. We pay for the financed leasehold improvements as a component of rent and are required to reimburse our landlords over the remaining life of the respective leases. If we exercise our right to early terminate the Concord, California lease, we would be required to pay for any remaining portion of the landlord financed leasehold improvements at such time. At September 30, 2015, we had an outstanding liability of \$0.5 million related to these leasehold improvements. The agreements we had with Fresenius at September 30, 2015, imposed a royalty on sales of the INTERCEPT Blood System at rates that varied by product: 10% of product sales for the platelet system and 3% of product sales for the plasma system. Such royalties were calculated based on future product sales and are therefore not provided for in the table above. On October 19, 2015, we entered into an amended and restated manufacturing and supply agreement with Fresenius, pursuant to



which we are no longer required to make royalty payments to Fresenius for the sale of products after June 30, 2015. The table above does not include commitments resulting from the 2015 Agreement with Fresenius that was entered into in October 2015.

*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, or the Term Loans. On June 30, 2014, we received \$10.0 million, from the first tranche, or Term Loan A. On June 15, 2015, we received \$10.0 million from Term Loan B. On September 29, 2015, the Term Loan Agreement was amended to extend the period in which the third tranche can be drawn and the interest-only period for all advances under the Term Loan Agreement. As amended, the third tranche of \$10.0 million, or Term Loan C, would be available, subject to our achievement of the Revenue Event, from the date on which the Revenue Event is achieved, to the earlier of (i) June 30, 2016, and (ii) 60 days after the Revenue Event is achieved. Term Loan A bears an interest rate of 6.95%, and Term Loan B bears an interest rate of 7.01%. Term Loan C will bear an interest rate calculated at the greater of 6.95% or 6.72% plus the three month U.S. LIBOR rate in effect three business days prior to the funding date. All of the Term Loans mature on June 1, 2019. We are required to make interest only payments through June 2016 followed by thirty-six months of equal principal and interest payments thereafter; however, if the Revenue Event is achieved no later than May 31, 2016, then the interest-only period may be extended through December 31, 2016, and the amortization period will be reduced to thirty months. We are also required to make a final payment equal to 7% of the principal amounts of the Term Loans drawn payable on the earlier to occur of maturity or prepayment. We may prepay the Term Loans subject to declining prepayment fees over the term of the Term Loan Agreement. We pledged all current and future assets,

---

**Table of Contents**

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 September 30, 2015. All principal and interest payments related to Term Loan have been included in the table above.

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

**Financial Instruments**

Our investment policy is to manage our marketable securities portfolio to preserve principal and liquidity while maximizing the return on the investment portfolio to assist us in funding our operations. We currently invest our cash and cash equivalents in money market funds and interest-bearing accounts with financial institutions. Our money market funds are classified as Level 1 in the fair value hierarchy, in which quoted prices are available in active markets, as the maturity of money market funds are relatively short and the carrying amount is a reasonable estimate of fair value. As a result of Aduro's IPO in April 2015, our common shares of Aduro are designated as an available-for-sale marketable security and classified as Level 1 in the fair value hierarchy using its stock price in the market to determine fair value. 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 nine months ended September 30, 2015 or the year ended December 31, 2014. Adverse global economic conditions, including the sovereign debt crisis in Europe, have had, and may continue to have, a negative impact on the market values of potential investments.

**New Accounting Pronouncements**

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

In August 2014, the FASB issued ASU No. 2014-15, *Presentation of Financial Statements - Going Concern* (Subtopic 205-40): Disclosure of Uncertainties about an Entity's Ability to Continue as a Going Concern, which requires management to evaluate, in connection with preparing financial statements for each annual and interim reporting period, whether there are conditions or events, considered in the aggregate, that raise substantial doubt about an entity's ability to continue as a going concern within one year after the date that the financial statements are issued and provide related disclosures. This ASU will be effective for us in fiscal year 2016. Early adoption is permitted. The adoption of this ASU is not expected to have a material impact on our consolidated financial statements.

In April 2015, the FASB issued ASU No. 2015-03, *Interest - Imputation of Interest* (Subtopic 835-30): *Simplifying the Presentation of Debt Issuance Costs*, which requires debt issuance costs related to a recognized debt liability to be presented in the balance sheet as a direct deduction from the corresponding debt liability rather than as an asset. This ASU will be effective for us in fiscal year 2016. Early adoption is permitted. The adoption of this ASU is not expected to have a material impact on our consolidated financial statements.

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

---

**Table of Contents****ITEM 3. QUANTITATIVE AND QUALITATIVE DISCLOSURES ABOUT MARKET RISK**

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

**ITEM 4. CONTROLS AND PROCEDURES**

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

*Previously Reported Material Weaknesses*

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

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

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

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

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

---

**Table of Contents**

**PART II: OTHER INFORMATION**

**ITEM 1. LEGAL PROCEEDINGS**

None.

**ITEM 1A. RISK FACTORS**

**Risk Factors**

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

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

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

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

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

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

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

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

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

comply with other U.S. healthcare regulatory requirements.

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

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

**Table of Contents**

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

changed or increased regulatory restrictions or requirements;

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

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

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

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

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

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

***The INTERCEPT Blood System may not achieve broad market adoption.***

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



The use of the platelet system results in some processing loss of platelets. If the loss of platelets leads to increased costs for our customers, our customers or prospective customers believe that the loss of platelets reduces the efficacy of the transfusion unit, or our process requires changes in blood center or clinical regimens, prospective customers may not adopt our platelet system. Certain 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 or efficacy.

The INTERCEPT Blood System does not inactivate all known pathogens, and the inability of the INTERCEPT Blood System to inactivate certain pathogens may limit its market adoption. For example, our products have not been demonstrated to be effective in the reduction of certain non-lipid-enveloped viruses, including hepatitis A and E viruses, due to these viruses' biology. In addition, our products have not demonstrated a high level of reduction for human parvovirus B-19, which is also a non-lipid-enveloped virus. Although we have shown high levels of reduction of a broad spectrum of lipid-enveloped viruses, prospective customers may choose not to adopt our products based on considerations concerning inability to inactivate, or limited reduction, of certain non-lipid-enveloped viruses. Similarly, although our products have been demonstrated to effectively inactivate spore-forming bacteria, our products have not shown to be effective in 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. Such uncertainty may limit the market adoption of our products.

---

**Table of Contents**

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

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

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

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

third party payors to keep healthcare costs down, which may limit the adoption of new technologies, including our products. In some jurisdictions, including in the United States 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 reimbursement. The costs and expenses incurred by the blood center related to donor blood are typically included in the price that the blood center charges a hospital for a unit of blood. Even after blood components treated with our products are approved for reimbursement by governmental or commercial third party payors, the costs and expenses related to use of the INTERCEPT Blood System will not be directly reimbursed, but instead may be incorporated within the reimbursement structure for medical procedures and/or products at the site of patient care. If the costs to the hospital for INTERCEPT-processed blood products cannot be easily, readily, or fully incorporated into the existing reimbursement structure, hospital billing and/or reimbursement for these products could be impacted, thus negatively impacting hospitals' acceptance and uptake of our products.

The market for the INTERCEPT Blood System is highly concentrated with few customers, including often-dominant regional or national blood collection entities. Even where our products receive regulatory approval and reimbursement is available, failure to effectively market, promote, distribute, price or sell our products to any of these customers could significantly delay or even diminish potential product revenue in those geographies. In addition, the lack of widespread adoption of the INTERCEPT Blood System has adversely affected and may in the future adversely affect further market adoption of the INTERCEPT Blood System. Moreover, the

---

**Table of Contents**

market for pathogen reduction systems in the United States is highly concentrated and dominated by a small number of blood collection organizations. In the United States, the American Red Cross represents the largest single portion of the blood collection market. Although we currently have an agreement with the American Red Cross to support our IDE study in Puerto Rico to treat platelet donations with the INTERCEPT Blood System, there is no guarantee that the American Red Cross will continue to use our products commercially in conjunction with or following our IDE study, even if we successfully enroll and complete this study. In many countries in Western Europe and in Japan, various national blood transfusion services or Red Cross organizations collect, store and distribute virtually all of their respective nations' blood and blood components supply. In Europe, the largest markets for our products are in Germany, France, and England. In Germany, decisions on product adoption and subsequent reimbursement are made on a regional or even blood center-by-blood center basis, but depend on both local approvals and centralized regulatory approvals from the Paul Ehrlich Institute, or PEI. Product specifications that receive marketing authorization from the PEI may differ from product specifications that have been adopted in other territories where we rely on CE mark approval, thereby necessitating market specific modifications to the commercial product, which may not be economical or technically feasible for us. While INTERCEPT-treated platelets and plasma have received in-country regulatory approval and reimbursement rates have been established in France, adoption throughout France has been limited to certain blood centers. In 2011, we entered into a two-year contract with the EFS, a public organization responsible for all collection, testing preparation and distribution of blood products in France, to supply platelet and plasma disposable kits, which was extended until November 2015. We understand that the EFS is considering taking action to further protect platelet components from bacterial contamination, including potential use of bacterial culture detection methods or broader use of the platelet system. We cannot provide any assurance that a new supply agreement with the EFS will be entered into prior to the expiration of the current agreement in a timely manner or with reasonable terms, if at all. If we fail to enter into a new supply agreement with the EFS or we enter into a new supply agreement with the EFS with less favorable terms, including pricing, our financial results may be adversely impacted.

Decisions on product adoption in England are centralized with the National Blood Service, or NHSBT, which has implemented bacterial detection testing for platelets instead of pathogen reduction. In September, 2015, we submitted a proposal to the NHSBT for the treatment of platelets using the INTERCEPT platelet system. We also understand that a separate tender process for bacterial detection testing was issued at the same time. It is likely that the NHSBT will make a single decision for their operations, choosing either bacterial detection testing or pathogen reduction. There is no certainty that the NHSBT will choose pathogen reduction over bacterial detection testing or that if pathogen reduction is chosen, that INTERCEPT would be chosen technology. In addition, decision timelines have been published regarding the outcome of the tenders, there is no assurance that the NHSBT will make a final decision to adopt either bacterial detection or pathogen reduction within those timelines, if ever. In Japan, the Japanese Red Cross controls a significant majority of blood transfusions and exerts a high degree of influence on the adoption and use of blood safety measures in Japan. The Japanese Red Cross has been reviewing preclinical and clinical data on pathogen reduction of blood over a number of years and has yet to make a formal determination to adopt any pathogen reduction approach. We also understand that the Japanese Red Cross has begun formal evaluation of a competing technology. Before the Japanese Red Cross considers our products, we understand that we may need to commit to making certain product configuration changes, which may not be economically or technologically feasible for us to accomplish.

***We expect to continue to generate losses.***

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

---

**Table of Contents**

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

Sales of our products are dependent on purchasing decisions of and/or reimbursement from government health administration authorities, distribution partners and other organizations. As a result of adverse conditions affecting the global economies and credit and financial markets, including the sovereign debt crisis in certain countries in Europe, disruptions due to political instability, 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 one or more member countries from the European Union, or the failure of the Euro as a common European currency or an otherwise diminished value of the Euro could materially and adversely affect our product revenue.

Additionally, a meaningful amount of our revenue currently comes 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 European Union, United States 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.

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

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

development;

testing;

manufacturing;

labeling;

storage;

clinical trials;

product safety;

pre-market clearance or approval;

sales and distribution;

use standards and documentation;

conformity assessment procedures;

product traceability and record keeping procedures;

post-launch surveillance and post-approval studies;

quality;

advertising and promotion;

product import and export; and

reimbursement.

Our products must satisfy rigorous standards of safety and efficacy and we must adhere to quality standards regarding manufacturing and customer-facing business processes in order for the FDA and international regulatory authorities to approve them for commercial use. For our product candidates, we must provide the FDA and international regulatory authorities with preclinical, clinical and

---

**Table of Contents**

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

*Clinical and Preclinical*

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

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

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



studies to further demonstrate our products' safety, which could delay or preclude 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 United States, or if we obtain approval for expanded label claims for the platelet system or plasma system, the FDA may require one or more post-approval clinical studies as a condition of approval, such as the post-approval clinical study we are required to conduct in connection with the approval of the platelet system, which could involve significant expense and may require us to secure adequate funding to complete. Other regulatory authorities outside of the United States may also require post-marketing studies. Governments or regulatory authorities may impose new regulations or other changes or we may discover that we are subject to additional regulations that could further delay or preclude regulatory approval and subsequent adoption of our potential products. We cannot predict the adoption, implementation or impact of adverse governmental regulation that might arise from future legislative or administrative action.

---

**Table of Contents**

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

*Red Blood Cell System*

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

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

---

**Table of Contents**

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

We completed our European Phase III clinical trial of our red blood cell system for acute anemia patients and have another European Phase III clinical trial of our red blood cell system for chronic anemia patients ongoing. Although we plan to complete development and CMC 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 do not expect to receive any regulatory approvals of our red blood cell system for a few years, if ever. We understand that while the acute anemia Phase III clinical trial in Europe may be sufficient to receive CE mark approval in Europe, a successful outcome with potentially more safety data in the ongoing Phase III chronic anemia clinical trial may also be required for our red blood cell system to achieve broad market acceptance. Failure to enroll sufficient patients and generate a body of data in chronic patients 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. As part of our development and CMC activities, we will need to complete a number of *in vitro* studies, finalize development of the final commercial configuration of the red blood cell system and manufacture and validate sufficient quantities of the final red blood cell system prior to receiving any regulatory approvals in Europe and may have to complete additional activities prior to receiving regulatory approvals in the United States. Many of these activities may require capital beyond that which we currently have, and we may be required to obtain additional capital in order to complete the development of and obtain any regulatory approvals for the red blood cell system. If we are unsuccessful in advancing the red blood cell system through clinical trials, resolving process and product design issues or in obtaining subsequent regulatory approvals and acceptable reimbursement rates, we may never realize a return on our research and development expenses incurred to date for the red blood cell system program. Regulatory delays can also materially impact our product development costs. If we experience delays in testing, conducting trials or approvals, our product development costs will increase. Even if we were to successfully complete and receive approval for our red blood cell system, potential customers may object to working with a potent chemical, like S-303, the active compound in the red blood cell system, or may require modifications to automate the process, which would result in additional development costs, any of which could limit any market acceptance of the red blood cell system.

*Platelet and Plasma Systems*

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

mark as being adequate for commercializing the INTERCEPT Blood System in those countries. The level of additional product testing varies by country, but could be expensive or take a long time to complete. In addition, regulatory agencies are able to withdraw or suspend previously issued approvals due to changes in regulatory law.

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

In December 2014, the FDA approved the platelet system for *ex vivo* preparation of pathogen-reduced apheresis platelet components in order to reduce the risk of transfusion-transmitted infection, or TTI, including sepsis, and to potentially reduce the risk of transfusion-associated graft versus host disease, or TA-GVHD. Also in December 2014, the FDA approved the plasma system for *ex vivo* preparation of plasma in order to reduce the risk of TTI when treating patients requiring therapeutic plasma transfusion. We are conducting *in vitro* studies for our platelet system to potentially expand our label claims to include, among others, platelets suspended in 100% plasma, platelets collected from pooled random donors, storage of INTERCEPT-treated platelets for up to seven days rather than five days, and a new processing set for triple dose collections. In this regard, we submitted a premarket approval application, or

---

**Table of Contents**

PMA, supplement to the FDA to seek approval of an expanded label claim to support platelets suspended in 100% plasma. We have received questions from the FDA regarding our PMA supplement to support platelets suspended in 100% plasma. If we are unable to answer the FDA's satisfactorily or timely, we may have to resubmit the PMA supplement which would cause a significant and possibly long-term approval delay. 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 FDA approval of the platelet systems, 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 jeopardize our ability to complete the study in a timeframe acceptable to the FDA. 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 and/or plasma systems. In addition to these studies, the FDA may also require us to commit to perform other lengthy post-marketing studies, for which we would have to expend significant additional resources, which could have an adverse effect on our operating results, financial condition and stock price. In addition, there is a risk that these studies will show results inconsistent with our previous studies. Should this happen, potential customers may delay or choose not to adopt the INTERCEPT Blood System and existing customers may cease use of the INTERCEPT Blood System.

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

#### *Post-Marketing Approval*

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

be damaged and adoption of the products could be impaired. Although our policy is to refrain from statements that could be considered off-label promotion of our products, the FDA or another regulatory agency could disagree and conclude that we have engaged in off-label promotion. In addition, the off-label use of our products may increase the risk of product liability claims. Product liability claims are expensive to defend and could divert our management's attention, result in substantial damage awards against us, and harm our reputation.

If a regulatory agency discovers problems with a product, such as adverse events of unanticipated severity or frequency, or problems with the facility or the manufacturing process at the facility where the product is manufactured, or problems with the quality of product manufactured, or disagrees with the promotion, marketing, or labeling of a product, a regulatory agency may impose restrictions on use of that product, including requiring withdrawal of the product from the market. Our failure to comply with applicable regulatory requirements could result in enforcement action by regulatory agencies, which may include any of the following sanctions:

adverse publicity, warning letters, fines, injunctions, consent decrees and civil penalties;

repair, replacement, recall or seizure of our products;

operating restrictions or partial suspension or total shutdown of production;

delaying or refusing our requests for approval of new products, new intended uses or modifications to our existing products;

**Table of Contents**

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 regulatory requirements, 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.

***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 United States, our products are required to be manufactured in FDA-approved facilities. If any of our suppliers fail to comply with FDA's good manufacturing practice 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 United States 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 United States or elsewhere, our suppliers will have to pass an audit by the FDA or other regulatory agencies. We are dependent on our suppliers' cooperation and ability to pass such audits. Such audits and any audit remediation may be costly. Failure to pass such audits by any of our suppliers would affect our ability to obtain licensure in the United States or elsewhere.

---

**Table of Contents**

***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 will likely need to redesign the illuminators used in the platelet and plasma systems. In addition, in order to address the entire market in the United States, we will need to develop and test additional configurations of the platelet system, including making the platelet system compatible with platelets suspended in 100% plasma, triple dose collections and random donor platelets. We are conducting in vitro studies for our platelet system to potentially expand our label claims to include, among others, platelets suspended in 100% plasma, platelets collected from pooled random donors, storage of INTERCEPT-treated platelets for up to seven days rather than five days, and a new processing set for triple dose collections. In this regard, we submitted a PMA supplement to the FDA to seek approval of an expanded label claim to support platelets suspended in 100% plasma. We have received questions from the FDA regarding our PMA supplement to support platelets suspended in 100% plasma. If we are unable to answer the FDA's satisfactorily or timely, we may have to resubmit the PMA supplement which would cause a significant and possibly long-term approval delay. 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.

***We operate a complex global commercial organization, with limited experience in many countries, including the United States. 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 United States, 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 United States. We have recently begun building out our commercial organization in the United States and as a result our team based in the United States has limited to no experience selling and marketing our platelet and plasma systems. We will need to maintain and may need to increase our competence in a number of functions, including sales, marketing, regulatory, inventory and logistics, customer service, credit and collections, risk management, and quality assurance systems 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 United States, European Union, 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.

---

**Table of Contents*****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 who we feel are capable of improved performance relative to their predecessors. Because the new distribution partners have limited experience marketing and selling our products, we cannot be certain that any new distribution partners will perform better than their predecessors. In other territories, we have transitioned to a Cerus direct sales model. We believe this transition will provide us with an opportunity to gain visibility into customer expectations and adoption criteria. Implementing such changes may be disruptive to customers or our operations and may negatively impact the volume of INTERCEPT disposable kit sales in future periods if our assumptions are incorrect. 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 and 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. 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.

---

**Table of Contents**

***Our products are a novel technology in the United States and blood centers and clinicians have little to no experience with pathogen reduction systems. Further, we have no prior experience commercializing products in the United States. We may be unable to develop and maintain an effective and qualified U.S. based commercial organization or educate blood centers or clinicians. 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 United States.***

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 United States. As a company, we have no prior experience in commercializing any products in the United States. We are also still in the process of establishing a U.S. based sales and marketing organization. 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 our MSL team and grow and sustain our sales and marketing organization. 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 United States. 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 United States.

***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.

Our manufacturing and supply agreement with Ash Stevens extends through December 31, 2015, and is automatically renewable thereafter for periods of two years each, but may be terminated by Ash Stevens provided that Ash Stevens notifies us in writing at least two years in advance. Although we are not subject to minimum annual purchase requirements under the manufacturing and supply agreement with Ash Stevens, we may be required to pay a maintenance fee of up to \$50,000 a year if specified quantities of amotosalen are not purchased in any year. We have incurred these maintenance fees in the past and may incur these maintenance fees in future periods.

Our supply agreement with Porex was amended in 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. 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 manufactures our illuminators, extends through September 2015 and is automatically renewable for one year terms, but may be terminated by NOVA on at least twelve months prior written notice.

---

**Table of Contents**

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 of our products and components, we do not have qualified suppliers beyond those on which we currently rely, and we understand that Fresenius relies substantially on sole suppliers of certain materials for our products. Identification and qualification of alternate suppliers will be time consuming and costly. If we conclude that supply of the INTERCEPT Blood System or components from Fresenius and others is uncertain, we may choose to build and maintain inventories of raw materials, work-in-process components, or finished goods, which would consume capital resources 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. Future supply of illuminators is limited to availability of components, some of which are in short supply or are no longer manufactured. Certain of our components are in limited supply and are used as spare parts for the maintenance of illuminators used by our customers. We and our customers rely on the availability of spare parts to ensure that customer platelet and plasma production is not interrupted. If we are not able to supply spare parts for the maintenance of customer illuminators, our ability to keep existing customers or sign up new customers may be negatively impacted. Certain parts used in our illuminator are obsolete. Accordingly, our product lifecycle management plans include development of upgraded versions of the illuminator, initially focused on utilizing more readily available components. The upgraded version of the illuminator is not expected to be in production until at least the first half of 2016. Although we have sufficient inventory of parts to manufacture the current generation of illuminators for anticipated demand in the United States and other geographies, the successful completion of the upgraded versions of the illuminator may be expensive and will require approval of a new PMA or PMA supplement. Our failure to obtain FDA and foreign regulatory approvals of a new illuminator could 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.

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 sources of supply to Fresenius, NOVA, or other suppliers without having to redesign certain elements of the platelet and plasma systems. Such redesign may be costly, time consuming and require further regulatory review and approvals. 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

---

**Table of Contents**

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 production 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. We will need to destroy or consume outdated inventory in product demonstration activities, which may in turn lead to elevated product demonstration costs or reduced gross margins.

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

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

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;

---

**Table of Contents**

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, European Union member states and other foreign jurisdictions, including Switzerland, have adopted data protection laws and regulations which impose significant compliance obligations. For example, the EU Data Protection Directive, as implemented into national laws by the European Union 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 EU Data Protection Directive prohibits the transfer of personal data to countries outside of the European Economic Area, or EEA, such as the United States, 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 United States, a recent judgment of the European Court of Justice that invalidated the EC decision on the United States 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 EU to entities in the United States that rely on safe harbor certification as a legal basis for the transfer of such data. In addition, data protection authorities from the different EU member states may interpret the EU 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 EU. 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 United States (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 EU Data Protection Regulation, intended to replace the current EU Data Protection Directive, is currently under consideration. The proposed EU 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 EU 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 EU 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

## **Table of Contents**

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 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 United States 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 United States;



**Table of Contents**

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 United States 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 United States. Our platelet system is designed to work with platelets collected and stored in storage solutions, called InterSol and SSP+, and for platelets suspended in 100% plasma, although our label indications in the United States do not currently provide 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 United States, Japan, and potentially elsewhere, we will need to develop and test additional configurations of the platelet system. For example, in the United States, we understand a significant number of platelet concentrates are derived from larger volumes collected from apheresis donors split into three therapeutic transfusable doses. Future configurations of the platelet system will be needed to treat platelet donations with such processing parameters. We estimate that the majority of platelets used in the United States are collected by apheresis, though a significant minority are prepared from pooled random donor platelets derived from whole blood collections. In addition, many blood centers may view pooled random donor platelets treated with INTERCEPT as an optimized approach for safety and economics. In the United States, our platelet system is currently only approved for apheresis collections and for use with platelets suspended in a storage solution. In order to gain regulatory approvals for a pathogen reduction system compatible with triple dose collections, platelets suspended in 100% plasma, and random donor platelets, we will need to perform additional product development and testing, including additional clinical trials. For example, we are conducting in vitro studies for our platelet system to potentially expand our label claims to include, among others, platelets suspended in 100% plasma, platelets collected from pooled random donors, storage of INTERCEPT-treated platelets for up to seven days rather than five days, and a new processing set for triple dose collections. In this regard, we submitted a PMA supplement to the FDA to seek approval of an expanded label claim to support platelets suspended in 100% plasma. We have received questions from the FDA regarding our

---

**Table of Contents**

PMA supplement to support platelets suspended in 100% plasma. If we are unable to answer the FDA's satisfactorily or timely, we may have to resubmit the PMA supplement which would cause a significant and possibly long-term approval delay. Our failure to obtain FDA and foreign regulatory approvals of these 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, 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.

***We have used prototype components in our preclinical studies and clinical trials of the red blood cell system and have not completed the components commercial design. We will be required to identify and enter into agreements with third parties to further develop and manufacture the red blood cell system. Failure to maintain these relationships, poor performance by these third parties or disputes with these third parties could negatively impact our business.***

The red blood cell systems that have been used and are currently being used in our clinical trials have been and are prototypes of the system expected to be used in the final product. As a result, we plan to perform additional preclinical studies and clinical trials using the commercial version of the system to demonstrate the acceptability of the commercial configuration and the equivalence of the prototypes and the commercial product, which will increase our expenses and delay the potential commercialization of our red blood cell system. We may determine that the red blood cell system may not be commercially feasible from potential customers' perspectives. If we fail to develop commercial versions of the red blood cell system in a timely manner, our potential revenue would be delayed or diminished and our potential competitors may be able to bring products to market before we do.

The design and engineering effort required to complete the final commercial version of our red blood cell system will likely be substantial and time-consuming. As with any complex development effort, we expect to encounter design, engineering and manufacturing issues, which issues could be exacerbated if the partners with whom we will be working have competing or conflicting priorities or ideas on the development and design of the system. Such issues have previously arisen, sometimes unexpectedly, and solutions to these issues have not always been readily forthcoming. We cannot guarantee that if such issues arise, they will be resolved in a commercially viable manner. Additional unforeseen design, engineering and manufacturing issues may arise in the future, which could increase the development cost and delay commercialization of our red blood cell system. We will need to identify and contract with manufacturers who can develop processes to manufacture components and the compounds used in the red blood cell system. For commercial manufacturing, we will need to demonstrate to regulatory authorities that the commercial scale manufacturing processes comply with government regulations and that the compounds are equivalent to originally licensed compounds. It may be difficult to economically manufacture the red blood cell system on a commercial scale and such costs may ultimately exceed the price the market is willing to pay for such a system.

***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

---

**Table of Contents**

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 recently 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. 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 S-303, or believe they have been or could be harmed by S-303, our insurance coverage may be insufficient to provide coverage for any related potential liabilities. S-303 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.

---

**Table of Contents**

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



---

**Table of Contents**

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

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

***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 revenue to meet the condition required in order to access the final loan available under the agreement and may also 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 provides for up to \$30.0 million in term loans due on June 1, 2019, of which \$20.0 million in term loans has been borrowed to date. 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. Moreover, our ability to access the final \$10.0 million under the loan and security agreement is subject to our ability to achieve a certain revenue threshold, which condition we may not be able to meet and which could adversely affect our liquidity. In addition, although we expect to borrow additional funds under the loan and security agreement, before we do so, we must first satisfy ourselves that we will have access to

future alternate sources of capital, including cash flow from our own operations, equity capital markets or debt capital markets in order to repay any principal borrowed, which we may be unable to do, in which case, our liquidity and ability to fund our operations may be substantially impaired.

***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.

---

**Table of Contents**

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

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

We also rely on our ability to attract, retain and motivate skilled and highly qualified personnel in order to grow our company. Competition for qualified personnel in the medical device and pharmaceutical industry is very intense. If we are unable to attract, retain and motivate quality individuals, our business, financial condition, results of operations and growth prospects could be adversely affected. 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 United States, including in France, where labor and employment laws are relatively stringent and, in many cases, grant significant job protection to certain employees, including rights on termination of employment. In addition, one of our manufacturing partners 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 previous enterprise resource planning system, a critical system used to run our business, is no longer supported by the developer of that system. Accordingly, we recently implemented a new enterprise resource planning system (the ERP System). The new ERP System is extremely complex and impacts a significant number of our

business processes. Should we experience unforeseen difficulties with our new 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 and 383 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.

**Table of Contents**

*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 United States patent issued to a third-party that covers methods to remove psoralen compounds from blood products. We have reviewed the patent and believe there 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 United States and foreign patents relating to the INTERCEPT Blood System, which expire at various dates between now to 2024. Due to the extensive time required for development, testing and regulatory review of our potential products, our patents may expire or remain in existence for only a short period following commercialization. This would reduce or eliminate any advantage of the patents.

We cannot be certain that we were the first to make the inventions covered by each of our issued patents or pending patent applications or that we were the first to file patent applications for such inventions. We may need to license the right to use third-party patents and intellectual property to continue development and commercialization of our products, including in connection with our planned commercialization of the platelet and plasma systems in the United States. 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 United States, 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 United States Patent and Trademark Office to determine the priority of inventions relating to our patent applications. Litigation or interference proceedings could be expensive and time consuming, and we could be unsuccessful in our efforts to enforce our intellectual property rights. We may rely, in certain circumstances, on trade secrets to protect our technology. However, trade secrets are difficult to protect. We protect our proprietary technology and processes, in part, by confidentiality agreements with employees, consultants and contractors. These agreements may be breached and we may not have adequate remedies for any breach or our trade secrets may otherwise become known or be independently discovered by competitors. To the extent that our employees, consultants or contractors use intellectual property owned by others, disputes also may arise as to the rights in related or resulting know-how and inventions.

---

**Table of Contents**

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

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

Product sales of the INTERCEPT blood system sold outside of the United States are typically invoiced to customers in Euros. In addition, we purchase finished INTERCEPT disposable kits for our platelet and plasma systems and incur certain operating expenses in Euros and other foreign currencies. Our exposure to foreign exchange rate volatility is a direct result of our product sales, cash collection and cash payments for expenses to support our international operations. Foreign exchange rate fluctuations are recorded as a component of other income, net on our consolidated statements of operations. Significant fluctuations in the volatility of foreign currencies relative to the United States dollar may materially affect our results of operations. In addition, in a period where the U.S. dollar is strengthening/weakening as compared to Euros, our revenues and expenses denominated in Euros are translated into U.S. dollars at a lower/higher value than they would be in an otherwise constant currency exchange rate environment. Currently we do not have a formal hedging program to mitigate the effects of foreign currency volatility.

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

Our shares of common stock are currently quoted on the Nasdaq Global Market under the symbol CERS. The market for our common stock has been limited due to low trading volume and the small number of brokerage firms acting as market makers. Active trading markets generally result in lower price volatility and more efficient execution of buy and sell orders. The absence of an active trading market increases price volatility and reduces the liquidity of our common stock. As long as this condition continues, the sale of a significant number of shares of common stock at any particular time could be difficult to achieve at the market prices prevailing immediately before such shares are offered, which may limit our ability to effectively raise money. In addition, due to the limitations of our market and the volatility in the market price of our stock, investors may face difficulties in selling shares at attractive prices when they want to sell. As a result of this lack of trading activity, the quoted price for our common stock is not necessarily a reliable indicator of its fair market value.

***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. If we are unable to remediate these material weaknesses, or other material weaknesses are identified in the future or we are not able to comply with the requirements of Section 404 in a timely manner, our reported financial results could be materially misstated, we would continue to receive an adverse opinion regarding our internal controls over financial reporting from our independent registered public accounting firm, and we could be subject to investigations or sanctions by regulatory authorities, which would require additional financial and management resources, and the value of our common stock could decline. In addition, because we have concluded that our internal control over financial reporting was not effective as of December 31, 2014, and 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.



**Table of Contents**

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

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

**Table of Contents****ITEM 6. EXHIBITS**

<b>Exhibit Number</b>	<b>Description of Exhibit</b>
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 (7)	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).
4.5 (6)	Form of 2010 Warrant to Purchase Common Stock.
10.1#	Second Amendment to Loan and Security Agreement, dated September 29, 2015, by and among Cerus Corporation and Oxford Finance LLC, as collateral agent and a lender.
10.2**	Employment Letter, by and between Cerus Corporation and Richard J. Benjamin MBChB, PhD, FRCPATH, dated May 12, 2015.
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 (8)	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.

Edgar Filing: CERUS CORP - Form 10-Q

- (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 Current Report on Form 8-K (File No. 000-21937), filed with the SEC on November 12, 2010.
- (7) 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.

**Table of Contents**

(8) 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.

# Registrant has requested confidential treatment for portions of this exhibit.

\*\* Compensatory plan.

**Table of Contents**

**SIGNATURES**

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

CERUS CORPORATION

Date: November 6, 2015

/s/ Kevin D. Green

Kevin D. Green

Vice President, Finance and Chief Financial Officer

(on behalf of registrant and as Principal Financial Officer)

**Table of Contents****EXHIBIT INDEX**

<b>Exhibit Number</b>	<b>Description of Exhibit</b>
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 (7)	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).
4.5 (6)	Form of 2010 Warrant to Purchase Common Stock.
10.1#	Second Amendment to Loan and Security Agreement, dated September 29, 2015, by and among Cerus Corporation and Oxford Finance LLC, as collateral agent and a lender.
10.2**	Employment Letter, by and between Cerus Corporation and Richard J. Benjamin MBChB, PhD, FRCPATH, dated May 12, 2015.
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 (8)	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

Edgar Filing: CERUS CORP - Form 10-Q

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.

**Table of Contents**

- (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 Current Report on Form 8-K (File No. 000-21937), filed with the SEC on November 12, 2010.
  - (7) 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.
  - (8) 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.
- # Registrant has requested confidential treatment for portions of this exhibit.
- \*\* Compensatory plan.