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 June 30, 2022
or

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

Commission File Number 000-21937

CERUS CORPORATION
(Exact name of registrant as specified in its charter)

Delaware	**68-0262011**
(State or other jurisdiction of incorporation or organization)	**(I.R.S. Employer Identification No.)**
1220 Concord Avenue, Suite 600 Concord, California	**94520**
(Address of principal executive offices)	**(Zip Code)**

(925) 288-6000
(Registrant's telephone number, including area code)

Securities registered pursuant to Section 12(b) of the Act:

Title of Each Class	**Trading Symbol**	**Name of Each Exchange on Which Registered**
Common Stock, par value $0.001 per share	CERS	The Nasdaq Stock Market LLC

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 every Interactive Data File required to be submitted 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 such files). YES ☒ NO ☐

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

Large accelerated filer	☒	Accelerated filer	☐
Non-accelerated filer	☐	Smaller reporting company	☐
		Emerging growth company	☐

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 13(a) of the Exchange Act. ☐

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 July 22, 2022, there were 177,090,364 shares of the registrant's common stock outstanding.

CERUS CORPORATION

FORM 10-Q

For the Quarterly Period Ended June 30, 2022

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PART I: FINANCIAL INFORMATION

ITEM 1. FINANCIAL STATEMENTS

CERUS CORPORATION
CONDENSED CONSOLIDATED BALANCE SHEETS
(in thousands)

	June 30, 2022 (Unaudited)	December 31, 2021
ASSETS		
Current assets:		
Cash and cash equivalents	$ 32,309	$ 48,759
Short-term investments	74,738	80,600
Accounts receivable	26,837	25,129
Current inventories	27,758	26,793
Prepaid and other current assets	3,030	5,821
Total current assets	164,672	187,102
Non-current assets:		
Property and equipment, net	11,201	12,208
Operating lease right-of-use assets	13,259	12,971
Goodwill	1,316	1,316
Restricted cash	2,014	2,285
Other assets	23,994	21,617
Total assets	$ 216,456	$ 237,499
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities:		
Accounts payable	$ 29,355	$ 35,608
Accrued liabilities	18,275	25,673
Debt – current	28,680	14,697
Operating lease liabilities – current	1,994	1,905
Deferred product revenue	975	673
Total current liabilities	79,279	78,556
Non-current liabilities:		
Debt – non-current	41,065	54,724
Operating lease liabilities – non-current	16,221	16,260
Other non-current liabilities	3,130	2,342
Total liabilities	139,695	151,882
Commitments and contingencies		
Stockholders' equity:		
Common stock	177	174
Additional paid-in capital	1,062,760	1,048,936
Accumulated other comprehensive loss	(2,153)	(149)
Accumulated deficit	(985,015)	(964,342)
Total Cerus Corporation stockholders' equity	75,769	84,619
Noncontrolling interest	992	998
Total liabilities and stockholders' equity	$ 216,456	$ 237,499

See accompanying Notes to Condensed Consolidated Financial Statements.

CERUS CORPORATION
CONDENSED CONSOLIDATED STATEMENTS OF OPERATIONS
UNAUDITED
(in thousands, except per share data)

	Three Months Ended June 30,		Six Months Ended June 30,	
	2022	2021	2022	2021
Product revenue	$ 40,999	$ 31,484	$ 78,443	$ 54,863
Cost of product revenue	19,718	15,323	37,794	26,418
Gross profit on product revenue	21,281	16,161	40,649	28,445
Government contract revenue	6,632	6,279	12,208	12,466
Operating expenses:				
Research and development	15,216	17,083	29,273	32,831
Selling, general and administrative	19,532	19,758	40,267	38,928
Total operating expenses	34,748	36,841	69,540	71,759
Loss from operations	(6,835)	(14,401)	(16,683)	(30,848)
Non-operating expense, net:				
Foreign exchange (loss) gain	(104)	118	(302)	(278)
Interest expense	(1,348)	(1,338)	(2,728)	(2,310)
Other (expense) income, net	(30)	337	(812)	793
Total non-operating expense, net	(1,482)	(883)	(3,842)	(1,795)
Loss before income taxes	(8,317)	(15,284)	(20,525)	(32,643)
Provision for income taxes	78	77	154	175
Net loss	(8,395)	(15,361)	(20,679)	(32,818)
Net loss attributable to noncontrolling interest	(6)	—	(6)	—
Net loss attributable to Cerus Corporation	$ (8,389)	$ (15,361)	$ (20,673)	$ (32,818)
Net loss per share attributable to Cerus Corporation				
Basic and diluted	$ (0.05)	$ (0.09)	$ (0.12)	$ (0.19)
Weighted average shares outstanding:				
Basic and diluted	176,944	171,240	175,718	170,039

See accompanying Notes to Condensed Consolidated Financial Statements.

CERUS CORPORATION
CONDENSED CONSOLIDATED STATEMENTS OF COMPREHENSIVE LOSS
UNAUDITED
(in thousands)

	Three Months Ended June 30,		Six Months Ended June 30,	
	2022	2021	2022	2021
Net loss	$ (8,395)	$ (15,361)	$ (20,679)	$ (32,818)
Other comprehensive loss				
Unrealized losses on available-for-sale investments, net of taxes	(518)	(139)	(2,004)	(357)
Comprehensive loss	(8,913)	(15,500)	(22,683)	(33,175)
Comprehensive loss attributable to noncontrolling interest	(6)	—	(6)	—
Total comprehensive loss attributable to Cerus Corporation	$ (8,907)	$ (15,500)	$ (22,677)	$ (33,175)

See accompanying Notes to Condensed Consolidated Financial Statements.

CERUS CORPORATION
CONDENSED CONSOLIDATED STATEMENTS OF STOCKHOLDERS' EQUITY
UNAUDITED
(in thousands)

	Cerus Corporation Shareholders						
	Common Stock		Additional Paid-in	Accumulated Other Comprehensive	Accumulated	Noncontrolling	Total Stockholders'
	Shares	Amount	Capital	Loss	Deficit	Interest	Equity
Balances as of December 31, 2021	173,670	$ 174	$ 1,048,936	$ (149)	$ (964,342)	$ 998	$ 85,617
Issuance of common stock from exercise of stock options, vesting of restricted stock units, and ESPP purchases	3,134	3	2,135	—	—	—	2,138
Stock-based compensation	—	—	6,426	—	—	—	6,426
Other comprehensive loss	—	—	—	(1,486)	—	—	(1,486)
Net loss	—	—	—	—	(12,284)	—	(12,284)
Balances as of March 31, 2022	176,804	$ 177	$ 1,057,497	$ (1,635)	$ (976,626)	$ 998	$ 80,411
Issuance of common stock from exercise of stock options and vesting of restricted stock units	274	—	256	—	—	—	256
Stock-based compensation	—	—	5,007	—	—	—	5,007
Other comprehensive loss	—	—	—	(518)	—	—	(518)
Net loss	—	—	—	—	(8,389)	(6)	(8,395)
Balances as of June 30, 2022	177,078	$ 177	$ 1,062,760	$ (2,153)	$ (985,015)	$ 992	$ 76,761

	Cerus Corporation Shareholders					
	Common Stock		Additional Paid-in	Accumulated Other Comprehensive	Accumulated	Total Stockholders'
	Shares	Amount	Capital	Loss	Deficit	Equity
Balances as of December 31, 2020	168,170	$ 168	$ 1,012,932	$ 674	$ (909,968)	$ 103,806
Issuance of common stock from exercise of stock options, vesting of restricted stock units, and ESPP purchases	2,621	—	1,171	—	—	1,171
Stock-based compensation	—	—	5,333	—	—	5,333
Other comprehensive loss	—	—	—	(218)	—	(218)
Net loss	—	—	—	—	(17,457)	(17,457)
Balances as of March 31, 2021	170,791	$ 168	$ 1,019,436	$ 456	$ (927,425)	$ 92,635
Issuance of common stock from exercise of stock options and vesting of restricted stock units	781	4	1,290	—	—	1,294
Stock-based compensation	—	—	5,808	—	—	5,808
Other comprehensive loss	—	—	—	(139)	—	(139)
Net loss	—	—	—	—	(15,361)	(15,361)
Balances as of June 30, 2021	171,572	$ 172	$ 1,026,534	$ 317	$ (942,786)	$ 84,237

See accompanying Notes to Condensed Consolidated Financial Statements.

CERUS CORPORATION
CONDENSED CONSOLIDATED STATEMENTS OF CASH FLOWS
UNAUDITED
(in thousands)

	Six Months Ended June 30,	
	2022	2021
Operating activities		
Net loss	$ (20,679)	$ (32,818)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation and amortization	1,627	1,571
Stock-based compensation	11,433	11,141
Non-cash operating lease cost	704	706
Changes in valuation of warrant investment	236	(402)
Net loss on sale of available-for-sale securities	91	—
Unrealized gain on investments	(587)	(249)
Impairment of long-lived assets	542	—
Non-cash interest expense	921	481
Foreign currency remeasurement loss	571	197
Changes in operating assets and liabilities:		
Accounts receivable	(1,844)	(2,134)
Inventories	(2,722)	(8,006)
Prepaid and other assets	1,677	(2,580)
Accounts payable	(6,013)	7,389
Accrued liabilities and other non-current liabilities	(8,060)	(1,708)
Deferred product revenue	302	294
Net cash used in operating activities	(21,801)	(26,118)
Investing activities		
Capital expenditures	(191)	(225)
Purchases of investments	(13,216)	(2,026)
Proceeds from maturities and sale of investments	16,554	33,500
Net cash provided by investing activities	3,147	31,249
Financing activities		
Net proceeds from equity incentives	2,512	2,094
Offering costs from public offerings	(94)	(292)
Net proceeds on revolving line of credit	233	813
Proceeds from loans	—	15,000
Net cash provided by financing activities	2,651	17,615
Effect of exchange rates on cash, cash equivalents, and restricted cash	(718)	(363)
Net (decrease) increase in cash, cash equivalents, and restricted cash	(16,721)	22,383
Cash, cash equivalents, and restricted cash, beginning of period	51,044	38,903
Cash, cash equivalents, and restricted cash, end of period	$ 34,323	$ 61,286

See accompanying Notes to Condensed Consolidated Financial Statements.

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, its subsidiary, and its variable interest entity in which the Company is the primary beneficiary in accordance with the consolidation accounting guidance, after elimination of all intercompany accounts and transactions (together with Cerus Corporation, hereinafter "Cerus" or the "Company"). These condensed consolidated financial statements have been prepared in accordance with accounting principles generally accepted in the United States of America, or U.S. ("GAAP") for interim financial information and pursuant to the rules and regulations of the Securities and Exchange Commission ("SEC"). Accordingly, they do not include all of the information and footnotes required by GAAP for complete financial statements. In the opinion of management, all adjustments, consisting of normal recurring entries, considered necessary for a fair presentation have been made. Operating results for the three and six months ended June 30, 2022, are not necessarily indicative of the results that may be expected for the year ending December 31, 2022, or for any future periods.

These condensed consolidated financial statements and notes thereto should be read in conjunction with the Company's audited consolidated financial statements and notes thereto for the year ended December 31, 2021, which were included in the Company's 2021 Annual Report on Form 10-K, filed with the SEC on February 22, 2022. The accompanying condensed consolidated balance sheet as of December 31, 2021 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, including those related to the nature and timing of satisfaction of performance obligations, the timing when the customer obtains control of products or services, the standalone selling price ("SSP") of performance obligations, variable consideration, the collectability of accounts receivable, inventory classification and related reserves, fair values of investments, the allowance for credit losses, stock-based compensation, intangible assets and goodwill, useful lives of intangible assets and property and equipment, income taxes, accrued liabilities, and incremental borrowing rate, among others. The Company bases its estimates on historical experience, future projections, and on various other assumptions that are believed to be reasonable under the circumstances. Actual results may differ from those estimates under different assumptions or conditions.

Revenue

Revenue is recognized by applying the following five steps: (1) identify the contract(s) with a customer; (2) identify the performance obligations in the contract; (3) determine the transaction price; (4) allocate the transaction price to the performance obligations in the contract; and (5) recognize revenue when (or as) the entity satisfies a performance obligation.

The Company's main source of revenue is product revenue from sales of the INTERCEPT Blood System for platelets and plasma ("platelet and plasma systems" or "disposable kits"), UVA illumination devices ("illuminators"), INTERCEPT Fibrinogen Complex ("IFC"), spare parts and storage solutions, and maintenance services of illuminators. The Company sells its platelet and plasma systems directly to blood banks, hospitals, universities, government agencies, as well as to distributors in certain regions. The Company sells its IFC primarily to hospitals and blood banks. The Company uses a binding purchase order or signed sales contract as evidence of a contract and satisfaction of its policy. Generally, the Company's sales contracts for disposable kits and illuminators 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. The contracts with customers can include various combinations of products and, to a lesser extent, services. The Company must determine whether products or services are capable of being distinct and accounted for as separate performance obligations, or are accounted for as a combined performance obligation. The Company must allocate the transaction price to each performance obligation on a relative SSP basis and recognize the product revenue when the performance obligation is satisfied. The Company determines the SSP by using the historical selling price of the products and services. If the amount of consideration in a contract is variable, the Company estimates the amount of variable consideration that should be included in the transaction price using the most likely amount method, to the extent it is probable that a significant future reversal of cumulative product revenue under the contract will not occur. Product revenue is recognized upon transfer of control of promised products or services to customers in an amount that reflects the consideration to which the Company expects to receive in exchange for those products or services. Product revenue from the sale of illuminators, disposable kits, IFC, spare parts and storage solutions are recognized upon the transfer of control of the products to the customer. Product revenue from maintenance services are recognized ratably on a straight-line basis over the term of maintenance as customers simultaneously consume and receive benefits. Freight costs charged to customers are recorded as a component of product revenue. Taxes that the Company invoices to its customers and remits to governments are recorded on a net basis, which excludes such tax from product revenue.

The Company receives reimbursement under its U.S. government contracts that support research and development of defined projects. The contracts generally provide for reimbursement of approved costs incurred under the terms of the contracts. Revenue related to the cost reimbursement provisions under the Company's U.S. government contracts is recognized as the qualified direct and indirect costs on the projects are incurred. The Company invoices under its U.S. government contracts using the provisional rates in the government contracts and thus is subject to future audits at the discretion of the government. The Company believes that government contract revenue for periods not yet audited has been recorded in amounts that are expected to be realized upon final audit and settlement. However, these audits could result in an adjustment to government contract revenue previously reported, which adjustments could be potentially significant. Costs incurred related to services performed under the contracts are included as a component of research and development or selling, general and administrative expenses in the Company's condensed consolidated statements of operations. The Company's use of estimates in recording accrued liabilities for government contract activities (see "Use of Estimates" above) affects the revenue recorded from development funding and under the government contracts.

Disaggregation of Product Revenue

Product revenue by geographical locations of customers during the three and six months ended June 30, 2022 and 2021, was as follows (in thousands):

	Three Months Ended June 30,		Six Months Ended June 30,	
	2022	2021	2022	2021
Product revenue:				
North America	$ 25,579	$ 14,647	$ 47,777	$ 24,311
Europe, Middle East and Africa	14,898	16,231	29,700	29,508
Other	522	606	966	1,044
Total product revenue	$ 40,999	$ 31,484	$ 78,443	$ 54,863

Contract Balances

The Company invoices its customers based upon the terms in the contracts, which generally requires payment 30 to 60 days from the date of invoice. Accounts receivable are recorded when the Company's right to the consideration is estimated to be unconditional. The Company had no product revenue related contract assets at June 30, 2022 and December 31, 2021.

Contract liabilities mainly consist of deferred product revenue related to maintenance services, unshipped products, and uninstalled illuminators. Maintenance services are generally billed upfront at the beginning of each annual service period and recognized ratably over the contractual service period. The Company applies an optional exemption to not disclose the value of unsatisfied performance obligations for contracts that have an original expected duration of one year or less.

Research and Development Expenses

Research and development ("R&D") expenses are charged to expense when incurred, including cost incurred pursuant to the terms of the Company's U.S. government contracts. R&D expenses include salaries and related expenses for scientific and regulatory personnel, payments to consultants, supplies and chemicals used in in-house laboratories, costs of R&D facilities, depreciation of equipment and external contract research expenses, including clinical trials, preclinical safety studies, other laboratory studies, process development and product manufacturing for research use.

The Company's use of estimates in recording accrued liabilities for R&D activities (see "Use of Estimates" above) affects the amounts of R&D expenses recorded from development funding. Actual results may differ from those estimates under different assumptions or conditions.

Cash Equivalents

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

Investments

Investments with original maturities of greater than three months primarily include corporate debt and U.S. government agency securities that are designated as available-for-sale and classified as short-term investments. Available-for-sale securities are carried at estimated fair value. The Company views its available-for-sale portfolio as available for use in its current operations. Unrealized gains and losses derived by changes in the estimated fair value of available-for-sale securities are recorded in "Unrealized gains (losses) on available-for-sale investments, net of taxes" on the Company's condensed consolidated statements of comprehensive loss. Realized gains (losses) from the sale of available-for-sale investments, if any, are determined on a specific identification method, and are recorded in "Other (expense) income, net" on the Company's condensed consolidated statements of operations. The costs of securities sold are based on

the specific identification method, if applicable. The Company reported the amortization of any premium and accretion of any discount resulting from the purchase of debt securities as a component of interest income.

The Company also reviews its available-for-sale securities on a regular basis to evaluate whether any security in an unrealized loss position has expected credit loss by considering factors such as historical experience, market data, issuer-specific factors, and current economic conditions. Expected credit losses, if any, are recorded in “Other (expense) income, net” on the Company’s condensed consolidated statements of operations.

Deferred Compensation Plan

The Company’s deferred compensation plan, pursuant to which compensation deferrals began in 2020, is a nonqualified deferred compensation plan that allows highly compensated employees to defer up to 80 percent of their base salary and up to 100 percent of their variable compensation each plan year. The Company may make discretionary contributions to each participant in an amount determined each year. To fund the deferred compensation plan’s long-term liability, the Company purchases Company-owned life insurance contracts on certain employees. The insurance serves as an investment source for the funds being set aside. Participants in the deferred compensation plan select the mutual funds in which their compensation deferrals are deemed to be invested as a component of the insurance contracts. As of June 30, 2022 and December 31, 2021, $1.8 million and $1.1 million, respectively, were included in “Other assets” on the Company’s condensed consolidated balance sheets, which represents the cash surrender value of the associated life insurance policies. As of June 30, 2022 and December 31, 2021, $0.2 million and zero, respectively, were included in “Accrued liabilities” on the Company's condensed consolidated balance sheets, and $1.7 million and $1.2 million, respectively, were included in “Other non-current liabilities” on the Company's condensed consolidated balance sheets, which represents the carrying value of the liability for deferred compensation. Gains and losses on the investments related to the nonqualified deferred compensation plan are included in “Other income (expense), net”, on the Company’s condensed consolidated statements of operations, and corresponding changes in their deferred compensation liability are included in operating expenses.

Restricted Cash

As of June 30, 2022 and December 31, 2021, the Company’s “Restricted cash” consisted primarily of a letter of credit relating to an office building lease. As of June 30, 2022 and December 31, 2021, the Company also had certain non-U.S. dollar denominated deposits recorded as “Restricted cash” in compliance with certain foreign contractual requirements.

Concentration of Credit Risk

Financial instruments that potentially subject the Company to concentrations of credit risk consist primarily of cash equivalents, available-for-sale securities and accounts receivable.

Pursuant to the Company’s investment policy, substantially all of the Company’s cash, cash equivalents and available-for-sale securities are maintained at major financial institutions of high credit standing. The Company monitors the financial credit worthiness of the issuers of its investments and limits the concentration in individual securities and types of investments that exist within its investment portfolio. Generally, all of the Company’s investments carry high credit quality ratings, which is in accordance with its investment policy. At June 30, 2022, the Company does not believe there is significant financial risk from non-performance by the issuers of the Company’s cash equivalents and short-term investments.

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 condensed consolidated balance sheets and records a charge on its condensed consolidated statements of operations as a component of selling, general and administrative expenses.

The Company had three customers and two customers that accounted for more than 10% of the Company’s outstanding accounts receivable at June 30, 2022 and December 31, 2021, respectively. These customers cumulatively represented approximately 67% and 48% of the Company’s outstanding trade receivables at June 30, 2022 and December 31, 2021, respectively. To date, the Company has not experienced collection difficulties from these customers.

Inventories

At June 30, 2022 and December 31, 2021, inventory consisted of raw materials, work-in-process and finished goods. Finished goods include INTERCEPT disposable kits, illuminators, and certain replacement parts for the illuminators. Platelet and plasma systems’ disposable kits generally have 18 to 24 month shelf lives from the date of manufacture. Illuminators and replacement parts do not have regulated expiration dates. Raw materials and work-in-process includes certain components that are manufactured over a protracted length of time before being ultimately incorporated and assembled by Fresenius, Inc. (with their affiliates, “Fresenius”) into the finished

INTERCEPT disposable kits. It is not customary for the Company's production cycle for inventory to exceed 12 months, however, in certain circumstances the Company purchases inventory components it expects to consume beyond 12 months. The Company uses its best judgment to factor in lead times for the production of its raw materials, work-in-process and finished units to meet the Company's forecasted demands. Additionally, from time-to-time, the Company may engage in strategic longer-range inventory purchases due to concentration of supplier risk, obsolescence of materials or components, or simply as safety stock to mitigate disruption to supply. Based upon estimated production needs and current inventory levels, the Company determines the amount of inventory necessary for the next 12 months. Any amounts in excess of this 12 month rolling projection are classified as "Other assets" in the condensed consolidated balance sheets. Changes to those estimates could potentially impact amounts recorded as current or non-current assets.

Inventory is recorded at the lower of cost, determined on a first-in, first-out basis, or net realizable value. The Company uses 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 within "Cost of product revenue" on the Company's condensed consolidated statements of operations. At June 30, 2022 and December 31, 2021, the Company had $0.4 million and $0.2 million, respectively, recorded for potential obsolete, expiring or unsalable product.

Property and Equipment, net

Property and equipment is comprised of furniture, equipment, leasehold improvements, construction-in-progress, 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.

Goodwill

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 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 goodwill impairment test. The Company may choose not to perform the qualitative assessment to test goodwill for impairment and proceed directly to the quantitative impairment test; however, the Company may revert to the qualitative assessment to test goodwill for impairment in any subsequent period. The quantitative goodwill impairment test compares the fair value of each reporting unit with its respective carrying amount, including goodwill. The Company has determined that it operates as 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 considered not impaired. 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, limited to the carrying amount of goodwill in the Company's one reporting unit.

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.

Foreign Currency Remeasurement

The functional currency of the Company's foreign subsidiary is the U.S. dollar. Monetary assets and liabilities denominated in foreign currencies are remeasured in U.S. dollars using the exchange rates at the balance sheet date. Non-monetary assets and liabilities denominated in foreign currencies are remeasured in U.S. dollars using historical exchange rates. Product revenues and expenses are remeasured using average exchange rates prevailing during the period. Remeasurements are recorded in "Foreign exchange loss" on the Company's condensed consolidated statements of operations.

Stock-Based Compensation

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

See Note 8 for further information regarding the Company's stock-based compensation assumptions and expenses.

Consolidated Variable Interest Entity

In February 2021, the Company entered into an Equity Joint Venture Contract with Shandong Zhongbaokang Medical Implements Co., Ltd., or ZBK, to establish Cerus Zhongbaokang (Shandong) Biomedical Co., LTD., or the JV, for the purpose of developing, obtaining regulatory approval for, and eventual manufacturing and commercialization of the INTERCEPT blood transfusion for platelets and red blood cells in the People's Republic of China. The Company owns 51% of equity in the JV and consolidates the JV as it has determined that the investment is a variable interest entity, or VIE, and that the Company is the primary beneficiary.

During September 2021, the Company contributed certain intangible intellectual property rights with zero recorded cost basis and recognized the $1.0 million equity funding contributed by ZBK as cash and as Noncontrolling interest in the Stockholders' equity section of the condensed consolidated balance sheet. Operating expenses for the JV are de minimis for all periods presented.

Income Taxes

The provision for income taxes is accounted for using an asset and liability approach, under which deferred tax assets and liabilities are determined based on differences between the financial reporting and tax bases of assets and liabilities and are measured using the enacted tax rates and laws that will be in effect when the differences are expected to reverse. The Company does not recognize 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 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 consolidated statements of operations, nor has it accrued for or made payments for interest and penalties. Although the Company believes it more likely than not that a taxing authority would agree with its current tax positions, there can be no assurance that the tax positions the Company has taken will be substantiated by a taxing authority if reviewed. The Company's U.S. federal tax returns for years 2001 through 2020, California tax returns for years through 2020, and Netherlands tax returns for years 2018 through 2020 remain subject to examination by the taxing jurisdictions due to unutilized net operating losses and research credits. The Company continues to carry a valuation allowance on substantially all of its net deferred tax assets.

Net Loss Per Share Attributable to Cerus Corporation

Basic net loss per share attributable to Cerus Corporation is computed by dividing net loss attributable to Cerus Corporation by the weighted average number of common shares outstanding for the period. Diluted net loss per share attributable to Cerus Corporation 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 restricted stock units, which are calculated using the treasury stock method. For the three and six months ended June 30, 2022 and 2021, all potentially dilutive securities outstanding have been excluded from the computation of dilutive weighted average shares outstanding because such securities have an antidilutive impact due to losses reported.

The table below presents potential shares that were excluded from the calculation of the weighted average number of shares outstanding used for the calculation of diluted net loss per share. These are excluded from the calculation due to their anti-dilutive effect for the three and six months ended June 30, 2022 and 2021 (shares in thousands):

	Three Months Ended June 30,		Six Months Ended June 30,	
	2022	2021	2022	2021
Weighted average number of anti-dilutive potential shares:				
Stock options	16,051	16,863	15,716	16,760
Restricted stock units	7,775	6,777	7,568	6,581
Employee stock purchase plan rights	—	33	76	40
Total	23,826	23,673	23,360	23,381

Leases

The Company determines if an arrangement is a lease at inception. Operating leases are included in operating lease right-of-use ("ROU") assets and operating lease liabilities in the Company's condensed consolidated balance sheets. As of June 30, 2022 and December 31, 2021, the Company did not have finance leases.

ROU assets and operating lease liabilities are recognized at commencement date based on the present value of lease payments over the lease term. The Company uses its incremental borrowing rate based on the information available at commencement date in determining the present value of lease payments. The ROU asset also includes any lease payments made and excludes lease incentives. The lease terms may include options to extend or terminate the lease, when the options are reasonably certain to be exercised. Operating leases are recognized on a straight-line basis over the lease term.

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 disposable kits and illuminators covering defects in materials and workmanship. The Company accrues costs associated with warranty obligations when claims become known and are estimable. The Company has not experienced significant or systemic warranty claims nor is it aware of any existing current warranty claims. Accordingly, the Company had not accrued for any future warranty costs for its products at June 30, 2022 and December 31, 2021.

Fair Value of Financial Instruments

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

See Note 2 for further information regarding the Company's valuation of financial instruments.

Note 2. Available-for-sale Securities and Fair Value on Financial Instruments

Available-for-sale Securities

The following is a summary of available-for-sale securities at June 30, 2022 (in thousands):

	June 30, 2022				
	Amortized Cost	Gross Unrealized Gain	Gross Unrealized Loss	Allowance for Credit Loss	Fair Value
Money market funds	$ 6,351	$ —	$ —	$ —	$ 6,351
United States government agency securities	25,364	4	(618)	—	24,750
Corporate debt securities	48,354	4	(1,372)	—	46,986
Mortgage-backed securities	3,173	4	(175)	—	3,002
Total available-for-sale securities	$ 83,242	$ 12	$ (2,165)	$ —	$ 81,089

The following is a summary of available-for-sale securities at December 31, 2021 (in thousands):

	December 31, 2021				
	Amortized Cost	Gross Unrealized Gain	Gross Unrealized Loss	Allowance for Credit Loss	Fair Value
Money market funds	$ 7,170	$ —	$ —	$ —	$ 7,170
United States government agency securities	25,761	1	(77)	—	25,685
Corporate debt securities	52,611	105	(156)	—	52,560
Mortgage-backed securities	2,377	—	(22)	—	2,355
Total available-for-sale securities	$ 87,919	$ 106	$ (255)	$ —	$ 87,770

Available-for-sale securities at June 30, 2022 and December 31, 2021, consisted of the following by contractual maturity (in thousands):

	June 30, 2022		December 31, 2021	
	Amortized Cost	Fair Value	Amortized Cost	Fair Value
One year or less	$ 32,200	$ 32,044	$ 44,873	$ 44,952
Greater than one year and less than five years	51,042	49,045	43,046	42,818
Total available-for-sale securities	$ 83,242	$ 81,089	$ 87,919	$ 87,770

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

	June 30, 2022					
	Less than 12 Months		12 Months or Greater		Total	
	Fair Value	Unrealized Loss	Fair Value	Unrealized Loss	Fair Value	Unrealized Loss
Corporate debt securities	$ 44,197	$ (1,372)	$ —	$ —	$ 44,197	$ (1,372)
United States government agency securities	23,614	(618)	—	—	23,614	(618)
Mortgage-backed securities	2,702	(175)	—	—	2,702	(175)
Total	$ 70,513	$ (2,165)	$ —	$ —	$ 70,513	$ (2,165)

	December 31, 2021					
	Less than 12 Months		12 Months or Greater		Total	
	Fair Value	Unrealized Loss	Fair Value	Unrealized Loss	Fair Value	Unrealized Loss
Corporate debt securities	$ 27,909	$ (153)	$ 998	$ (3)	$ 28,907	$ (156)
United States government agency securities	18,367	(75)	1,019	(2)	19,386	(77)
Mortgage-backed securities	2,355	(22)	—	—	2,355	(22)
Total	$ 48,631	$ (250)	$ 2,017	$ (5)	$ 50,648	$ (255)

The Company typically invests in highly-rated securities, and its investment policy limits the amount of credit exposure to any one issuer. The policy generally requires investments to be investment grade, with the primary objective of minimizing the potential risk of principal loss. Fair values were determined for each individual security in the investment portfolio. When evaluating an investment for expected credit losses, 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. The Company also regularly reviews its investments in an unrealized loss position and evaluates the current expected credit loss by considering factors such as historical experience, market data, issuer-specific factors, and current economic conditions. During the three and six months ended June 30, 2022 and 2021, the Company did not recognize any expected credit losses. The Company has no current requirement or intent to sell the securities in an unrealized loss position. The Company expects to recover up to (or beyond) the initial cost of investment for securities held. The Company recorded no gross realized gains or losses from the sale or maturity of available-for-sale investments during the six months ended June 30, 2021. The Company recorded no gross realized gains and $0.1 million of gross realized losses from the sale or maturity of available-for-sale investments during the six months ended June 30, 2022.

Fair Value Disclosures

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

- Level 1: Quoted prices in active markets for identical instruments
- Level 2: Other significant observable inputs (including quoted prices in active markets for similar instruments)
- Level 3: Significant unobservable inputs (including assumptions in determining the fair value of certain investments)

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

To estimate the fair value of Level 2 debt securities as of June 30, 2022, the Company's primary pricing service relies on inputs from multiple industry-recognized pricing sources to determine the price for each investment. Corporate debt and U.S. government agency securities are systematically priced by this service as of the close of business each business day. If the primary pricing service does not price a specific asset a secondary pricing service is utilized.

To estimate the fair value of the Company's Level 3 warrant investments as of June 30, 2022, the Company uses a standard Black-Scholes option pricing model, using a class volatility consistent with the seniority and preference rights of the underlying preferred stock. Key assumptions used in the valuation include the privately held company's preferred stock price, warrant exercise price, equity volatility, expected term of warrant, risk-free interest rates, and details specific to the warrant. The Company recognizes the changes in the fair value of this warrant in "Other income, net" on the Company's condensed consolidated statements of operations.

The fair values of the Company's financial assets and liabilities were determined using the following inputs at June 30, 2022 (in thousands):

	Balance sheet classification	Total	Quoted Prices in Active Markets for Identical Assets (Level 1)	Significant Other Observable Inputs (Level 2)	Significant Unobservable Inputs (Level 3)
Money market funds	Cash and cash equivalents	$ 6,351	$ 6,351	$ —	$ —
United States government agency securities	Short-term investments	24,750	—	24,750	—
Corporate debt securities	Short-term investments	46,986	—	46,986	—
Mortgage-backed securities	Short-term investments	3,002	—	3,002	—
Total short-term investments		81,089	6,351	74,738	—
Warrants	Other assets	334	—	—	334
Total financial assets		$ 81,423	$ 6,351	$ 74,738	$ 334

The fair values of the Company's financial assets and liabilities were determined using the following inputs at December 31, 2021 (in thousands):

	Balance sheet classification	Total	Quoted Prices in Active Markets for Identical Assets (Level 1)	Significant Other Observable Inputs (Level 2)	Significant Unobservable Inputs (Level 3)
Money market funds	Cash and cash equivalents	$ 7,170	$ 7,170	$ —	$ —
United States government agency securities	Short-term investments	25,685	—	25,685	—
Corporate debt securities	Short-term investments	52,560	—	52,560	—
Mortgage-backed securities	Short-term investments	2,355	—	2,355	—
Total short-term investments		87,770	7,170	80,600	—
Warrants	Other assets	570	—	—	570
Total financial assets		$ 88,340	$ 7,170	$ 80,600	$ 570

The Company did not have any transfers among fair value measurement levels during the three and six months ended June 30, 2022 and 2021.

The following table provides a summary of the total gain recognized in the Company's condensed consolidated statements of operations due to changes in the fair value of the warrant (in thousands):

	Three Months Ended		Six Months Ended	
	June 30, 2022	June 30, 2021	June 30, 2022	June 30, 2021
(Loss) gain from changes in the fair value of level 3 investments	$ (44)	$ 182	$ (236)	$ 402

Note 3. Inventories, net

Inventories, net at June 30, 2022 and December 31, 2021, consisted of the following (in thousands):

	June 30, 2022	December 31, 2021
Raw materials	$ 13,557	$ 15,664
Work-in-process	14,337	5,044
Finished goods	17,570	22,129
Total inventories	45,464	42,837
Less: non-current inventories	17,706	16,044
Total current inventories	$ 27,758	$ 26,793

Non-current inventories, which primarily consists of raw materials and work-in-process, is included in "Other assets" in the condensed consolidated balance sheets.

Note 4. Accrued Liabilities

Accrued liabilities at June 30, 2022 and December 31, 2021, consisted of the following (in thousands):

	June 30, 2022	December 31, 2021
Accrued compensation and related costs	$ 12,330	$ 18,506
Other accrued expenses	5,945	7,167
Total accrued liabilities	$ 18,275	$ 25,673

Note 5. Debt

Term Loan Debt at June 30, 2022, consisted of the following (in thousands):

	Principal	Unamortized Discount	Total
Term Loan Credit Agreement	$ 55,000	$ (185)	$ 54,815
Less: current portion of term loan	(13,750)	—	(13,750)
Non-current portion of term loan	$ 41,250	$ (185)	$ 41,065

Term Loan Debt at December 31, 2021, consisted of the following (in thousands):

	Principal	Unamortized Discount	Net Carrying Value
Term Loan Credit Agreement	$ 55,000	$ (276)	$ 54,724
Less: current portion of term loan	—	—	—
Non-current portion of term loan	$ 55,000	$ (276)	$ 54,724

Principal, interest and fee payments on Term Loan Credit Agreement at June 30, 2022, are expected to be as follows (in thousands):

Year ended December 31,	Principal	Interest and Fees	Total
2022	$ —	$ 2,097	$ 2,097
2023	41,250	3,134	44,384
2024	13,750	1,826	15,576
Total	$ 55,000	$ 7,057	$ 62,057

Loan Agreements

On March 29, 2019, the Company entered into a Credit, Security and Guaranty Agreement (Term Loan) (the "Term Loan Credit Agreement") with MidCap Financial Trust ("MidCap") to borrow up to $70 million in three tranches (collectively "2019 Term Loan"), with a maturity date of March 1, 2024. The first advance of $40.0 million ("Tranche 1") was drawn by the Company on March 29, 2019, with the proceeds used in part to repay in full the outstanding term loans and fees under a prior loan agreement. The second advance of $15.0 million ("Tranche 2") was drawn by the Company on March 29, 2021. The third advance of $15.0 million ("Tranche 3") expired on December 31, 2021. The borrowings under the 2019 Term Loan bear interest at the sum of a fixed percentage spread and the greater of (i) 1.8% or (ii) one month LIBOR. At June 30, 2022, the effective interest rate on the Term Loan was approximately 7.50%. This debt requires interest-only payments through March 1, 2023, followed by 12 months of payments with interest and equal payment of principal. Prepayments of the 2019 Term Loan under the Term Loan Credit Agreement, in whole or in part, will be subject to early termination fees which decline each year until the fourth anniversary of the applicable funding date, at which time there is no early termination fee. Upon the final payment, the Company must also pay an exit fee calculated based on a percentage of the aggregate principal amount of all tranches advanced to the Company. The Company uses the effective interest method to recognize the final payment over the term of the debt.

The Company also maintains a Credit, Security and Guaranty Agreement (Revolving Loan) (the "Revolving Loan Credit Agreement") with MidCap. The borrowing limit under the Revolving Loan Credit Agreement is $15.0 million. The amount borrowed under the Revolving Loan Credit Agreement can be increased, upon request by the Company, by up to an additional $5.0 million, subject to agent and lender approval and the satisfaction of certain conditions. The Revolving Loan Credit Agreement has a maturity date of March 1, 2024. Amounts drawn under the Revolving Loan Credit Agreement bear interest at the sum of a fixed percentage spread and the greater of (i) 1.80% or (ii) one-month LIBOR. There are also fractional fees based on the amounts either drawn or undrawn. If the Revolving

Loan Credit Agreement is terminated before maturity or the funding obligation is permanently reduced, there are termination fees which decline each anniversary until the third anniversary, at which time there is no termination fee. As of June 30, 2022 and December 31, 2021, the Company had borrowed $14.9 million and $14.7 million under the Revolving Loan Credit Agreement, respectively, which is included in "Debt – current" in the Company's condensed consolidated balance sheets.

The Term Loan Credit Agreement and Revolving Loan Credit Agreement contain certain financial and non-financial covenants, with which the Company was in compliance at June 30, 2022. Additionally, both agreements are secured by substantially all of the Company's assets, with some exclusions.

Note 6. Commitments and Contingencies

Operating Leases

The Company leases its office facilities, located in Concord, California and Amersfoort, the Netherlands, and certain equipment and automobiles 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 2030, with certain of the leases providing for renewal options, provisions for adjusting future lease payments based on the consumer price index, and the right to terminate the lease early. The Company does not assume renewals in determination of the lease term unless the renewals are deemed to be reasonably assured at lease commencement. The Company recorded the lease right-of-use asset and obligation at the present value of lease payments over the lease term. The rates implicit in the Company's leases are generally not readily determinable. The Company must estimate its incremental borrowing rate to discount the lease payments to present value. Operating lease assets also include lease incentives.

Supplemental cash flow information related to operating leases is as follows (dollars in thousands):

	Six Months Ended June 30,	
	2022	2021
Cash payments for operating leases	$ 1,686	$ 1,792
Right-of-use assets obtained in exchange for operating lease obligations	1,315	51

	Six Months Ended June 30,	
	2022	2021
Weighted-average remaining lease term	6.9 years	8.1 years
Weighted-average discount rate	8.4%	8.9%

Future minimum non-cancelable payments under operating leases as of June 30, 2022, were as follows (in thousands):

	Operating Leases
2022 (remainder)	$ 2,173
2023	3,452
2024	3,313
2025	2,975
2026	3,010
Thereafter	10,765
Total future lease payments	25,688
Less imputed interest	7,473
Present value of lease liabilities	$ 18,215

The operating lease expense for the three and six months ended June 30, 2022 and 2021, were as follows:

	Three Months Ended June 30,		Six Months Ended June 30,	
	2022	2021	2022	2021
Operating lease expense	$ 721	$ 843	$ 1,569	$ 1,645

As of June 30, 2022, the Company had no leases that have not yet commenced.

Purchase Commitments

The Company is party to agreements with certain providers for certain components of the INTERCEPT Blood System. Certain of these agreements require minimum purchase commitments from the Company. As of June 30, 2022, the Company had $19.0 million of short-term purchase commitments and $2.7 million of long-term purchase commitments, which are not recorded in the Company's condensed consolidated balance sheets.

Note 7. Stockholders' Equity

Sales Agreement

On December 11, 2020, the Company entered into the Controlled Equity Offering[SM] Sales Agreement (the "Sales Agreement") with Cantor Fitzgerald & Co. and Stifel, Nicolaus & Company, Incorporated (each a "Sales Agent" and collectively, the "Sales Agents"), under which the Company may issue and sell from time to time up to $100.0 million of the Company's common stock through or to the Sales Agents, as sales agent or principal. Under the Sales Agreement, each Sales Agent receives compensation based on an aggregate of 2% of the gross proceeds on the sale price per share of the Company's common stock. The issuance and sale of these shares by the Company pursuant to the Sales Agreement are deemed an "at-the-market" offering and are registered under the Securities Act of 1933, as amended. During the six months ended June 30, 2022, no shares of the Company's common stock were sold under the Sales Agreement. At June 30, 2022, the Company had approximately $96.8 million of common stock available to be sold under the Sales Agreement.

Note 8. Stock-Based Compensation

Employee Stock Plans

Employee Stock Purchase Plan

The Company maintains an Employee Stock Purchase Plan (the "Purchase Plan"), which is intended to qualify as an employee stock purchase plan within the meaning of Section 423(b) of the Internal Revenue Code. Under the Purchase Plan, the Company's Board of Directors may authorize participation by eligible employees, including officers, in periodic offerings. Under the Purchase Plan eligible employee participants may purchase shares of common stock of the Company at a purchase price equal to 85% of the lower of the fair market value per share on the start date of the offering period or the fair market value per share on the purchase date. The Purchase Plan consists of a fixed offering period of 12 months with two purchase periods within each offering period. In June 2020, 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 1.5 million shares. At June 30, 2022, the Company had 1.5 million shares available for future issuance.

2008 Equity Incentive Plan and Inducement Plan

The Company also maintains an equity compensation plan to provide long-term incentives for employees, contractors, and members of its Board of Directors. The Company currently grants equity awards from one plan, the 2008 Equity Incentive Plan and its subsequent amendments (collectively, the "Amended 2008 Plan"). The Amended 2008 Plan allows for the issuance of non-statutory and incentive

stock options, restricted stock, restricted stock units ("RSUs"), stock appreciation rights, other stock-related awards, and performance awards which may be settled in cash, stock, or other property. In June 2019, the Company's stockholders approved an amendment and restatement of the Amended 2008 Plan that increased the aggregate number of shares of common stock authorized for issuance by 11.8 million shares. In June 2020, the Company's stockholders approved an amendment and restatement of the Amended 2008 Plan that increased the aggregate number of shares of common stock authorized for issuance by 5.0 million shares. In June 2021, the Company's stockholders approved an amendment and restatement of the Amended 2008 Plan that increased the aggregate number of shares of common stock authorized for issuance by 7.6 million shares. In June 2022, the Company's stockholders approved an amendment and restatement of the Amended 2008 Plan that increased the aggregate number of shares of common stock authorized for issuance by 12 million shares. Option awards under the Amended 2008 Plan generally have a maximum term of ten years from the date of the award. The Amended 2008 Plan generally requires options to be granted at 100% of the fair market value of the Company's common stock subject to the option on the date of grant. Options granted by the Company to employees generally vest over four years. RSUs are measured based on the fair market value of the underlying stock on the date of grant. RSUs granted by the Company to employees generally vest over three to four years. Performance-based stock granted under the Amended 2008 Plan are limited to 500,000 shares of common stock per calendar year. Performance-based cash awards granted under the Amended 2008 Plan are limited to $1.0 million per recipient per calendar year. At June 30, 2022, 1.4 million shares of performance-based stock awards were outstanding.

At June 30, 2022, the Company had approximately 39.4 million shares of its common stock subject to outstanding options or unvested RSUs, or remaining available for future issuance under the Amended 2008 Plan, of which approximately 16.1 million shares and 7.9 million shares were subject to outstanding options and unvested RSUs, respectively, and approximately 15.4 million shares were available for future issuance under the Amended 2008 Plan. The Company's policy is to issue new shares of common stock upon the exercise of options or vesting of RSUs.

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

	Number of Options Outstanding	Weighted Average Exercise Price per Share
Balance at December 31, 2021	15,092	$ 5.02
Granted	1,624	5.62
Exercised	(507)	3.85
Forfeited/canceled	(86)	6.05
Balance at June 30, 2022	16,123	5.11

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

	Number of RSUs Unvested	Weighted Average Grant Date Fair Value per Share
Balance at December 31, 2021	6,689	$ 5.90
Granted [(1)]	4,382	5.72
Vested [(1)]	(2,788)	5.65
Forfeited [(1)]	(420)	5.90
Balance at June 30, 2022	7,863	5.90

(1) Includes shares issuable under performance-based restricted stock unit awards.

Valuation Assumptions for Stock-based Compensation

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

Note 9. Income Taxes

The Company recorded income tax expense of $0.1 million for the three months ended June 30, 2022 and 2021, primarily related to the operating profit of the Company's Cerus Europe B.V. subsidiary. The Company recorded income tax expense of $0.2 million for the six months ended June 30, 2022 and 2021, primarily related to the operating profit of the Company's Cerus Europe B.V. subsidiary.

Note 10. Development and License Agreements

Agreements with Fresenius

In May 2022, the Company entered into the Second Amended and Restated Supply and Manufacturing Agreement ("2022 Agreement") with Fresenius Kabi AG, Fenwal France SAS, and Fenwal International, Inc. (collectively, "Fresenius") for the manufacture and

production of disposable sets for the INTERCEPT Blood System until December 31, 2031. Under the terms of the 2022 Agreement, Fresenius is obligated to manufacture, and Company is obligated to purchase, finished disposable kits for the platelet and plasma systems. Fresenius sources most of the components used in the production of disposable kits, except for certain other components that the Company sources from other third-parties and provides to Fresenius for inclusion into the finished disposable kits. The 2022 Agreement permits the Company to purchase sets for the 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. Fresenius will expand manufacturing of the disposable sets to three production facilities, following qualification and licensure of such additional facilities. The term of the 2022 Agreement will automatically renew for successive two-year periods unless terminated by either party upon two years' prior written notice, in the case of the initial term, or one year prior written notice, in the case of any successive renewal term. Each party has normal and customary termination rights, including termination for material breach. Pricing under the 2022 Agreement for the initial term is based on volume purchases by the Company and subject to an annual adjustment based on variation in a price index.

Government contracts

In June 2016, the Company entered into an agreement with Biomedical Advanced Research and Development Authority ("BARDA") to support the Company's development and implementation of pathogen reduction technology for platelet, plasma, and red blood cells.

The agreement with BARDA and its subsequent modifications include a base period (the "Base Period") and option periods (each, an "Option Period"). The agreement includes committed funding for clinical development of the INTERCEPT Blood System for red blood cells (the "red blood cell system"). In June 2022, BARDA committed an additional $23 million raising the committed funding to up to $149.5 million as of June 30, 2022, and the potential for the exercise by BARDA of subsequent Option Periods that, if exercised by BARDA and completed, would bring the total funding opportunity to $246.5 million through December 31, 2025. If exercised by BARDA, subsequent Option Periods would fund activities related to broader implementation of the platelet and plasma system or the red blood cell system in areas of emerging pathogens, clinical and regulatory development programs in support of the potential licensure of the red blood cell system in the U.S., and development, manufacturing and scale-up activities for the red blood cell system. The Company could be responsible for up to $10 million of co-investment if certain Option Periods are exercised. BARDA will make periodic assessments of the Company's progress and the continuation of the agreement is based on the Company's success in completing the required tasks under the Base Period and each exercised Option Period. BARDA has rights under certain contract clauses to terminate the agreement, including the ability to terminate the agreement for convenience at any time.

As of June 30, 2022 and December 31, 2021, $5.7 million and $4.7 million, respectively, of billed and unbilled amounts were included in accounts receivable on the Company's condensed consolidated balance sheets related to BARDA.

In September 2020, the Company entered into a five-year agreement with the U.S. Food and Drug Administration for the development of next-generation compounds to optimize pathogen reduction treatment of whole blood to reduce the risk of transfusion-transmitted infections. The total potential contract value is $11.1 million. As of June 30, 2022 and December 31, 2021, $0.3 million and $0.2 million, respectively, of billed and unbilled amounts were included in accounts receivable on the Company's condensed consolidated balance sheets related to FDA.

Note 11. Segment, Customer and Geographic Information

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

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

The Company had the following significant customers that accounted for more than 10% of the Company's total product revenue, during the three and six months ended June 30, 2022 and 2021:

	Three Months Ended June 30		Six Months Ended June 30	
	2022	2021	2022	2021
American Red Cross	35%	27%	35%	24%
Établissement Français du Sang	12%	18%	13%	20%

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

This discussion and analysis should be read in conjunction with our condensed consolidated financial statements and the accompanying notes included in this Quarterly Report on Form 10-Q and the audited consolidated financial statements and accompanying notes included in our Annual Report on Form 10-K for the year ended December 31, 2021. Operating results for the three and six months ended June 30, 2022, 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. These forward-looking statements may include, but are not limited to, statements about:

- *the impact of the COVID-19 pandemic on our business and operations as well as the business or operations of our customers, manufacturers, research partners, and other third parties with whom we conduct business;*
- *future sales of and anticipated demand for, and our ability to effectively commercialize and achieve market acceptance of the INTERCEPT™ Blood System, including our ability to comply with applicable United States, or U.S., and foreign laws, regulations and regulatory requirements;*
- *our ability to successfully complete the development of, receive regulatory approvals for and commercialize the red blood cell system or other plasma-derived biological products using the INTERCEPT Blood System;*
- *our ability to successfully commercialize INTERCEPT Fibrinogen Complex, or IFC, and pathogen reduced cryoprecipitate-poor plasma;*
- *our strategy and the potential therapeutic applications for the INTERCEPT Blood System, including the potential of INTERCEPT-treated coronavirus convalescent plasma as a therapeutic or prophylactic treatment option for COVID-19 patients;*
- *our ability to manage the growth of our business and attendant cost increases, including in connection with the commercialization of the INTERCEPT Blood System in the U.S., as well as our ability to manage the risks attendant to our international operations;*
- *the timing or likelihood of regulatory submissions and approvals and other regulatory actions or interactions, including whether or not existing clinical data will be sufficient in order to obtain a CE Certificate of Conformity and affix a CE Mark to the red blood cell system;*
- *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 for a particular product or component they manufacture;*
- *the initiation, scope, rate of progress, results and timing of our ongoing and proposed preclinical and clinical trials of the INTERCEPT Blood System;*
- *the successful completion of our research, development and clinical programs and our ability to manage cost increases associated with preclinical and clinical development of the INTERCEPT Blood System;*
- *the amount and availability of funding we may receive under our agreement with the Biomedical Advanced Research and Development Authority, or BARDA;*
- *our ability to transition distribution of the INTERCEPT Blood System from third parties to a direct sales model in certain international markets;*
- *the ability of our products to inactivate the emerging viruses and other pathogens that we may target in the future, including SARS-CoV-2;*
- *our ability to protect our intellectual property and operate our business without infringing upon the intellectual property rights of others;*
- *our estimates regarding the sufficiency of our cash resources, our ability to continue as a going concern and our need for additional funding; and*
- *our plans, objectives, expectations and intentions and any other statements that are not historical facts.*

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 such forward-looking statements. Forward-looking statements reflect our current views with respect to future events, are based on assumptions, and are subject to risks and uncertainties. There can be no assurance that any of the events anticipated by forward-looking statements will occur or, if any of them do occur, what impact they will have on our business, results of operations and financial condition. Certain important factors could cause actual results to differ materially from those discussed in such statements, including the rate of customer adoption in the U.S. and our ability to achieve market acceptance of our products in the U.S. and international markets, whether our preclinical and clinical data or data from commercial use will be considered sufficient by regulatory authorities to grant marketing approvals for our products or for product extensions or additional claims for our products, our ability to obtain and maintain reimbursement approvals for our products, our ability to complete the development and testing of additional configurations or redesigns of our products, our need for additional financing and our ability to access funding under our agreement with BARDA, 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 and third parties to manufacture or supply certain components or compounds for the INTERCEPT Blood System, incompatibility of our platelet system with some commercial platelet collection methods, our need to complete our red blood cell system’s commercial design, more effective product offerings by, or clinical setbacks of, our competitors, product liability, our use of hazardous materials in the development of our products, business interruption due to earthquake, our expectation of continuing losses, protection of our intellectual property rights, volatility in our stock price, on-going compliance with the requirements of the Sarbanes-Oxley Act of 2002 and other factors discussed below and under the caption “Risk Factors” in Item 1A of this Quarterly Report on Form 10-Q. We discuss many of these risks in this Quarterly Report on Form 10-Q in greater detail in the section entitled “Risk Factors” under Part II, Item 1A below. 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. Our actual future results may be materially different from what we expect. Except as required by law, we assume no obligation to update or revise any forward-looking statements to reflect new information or future events, even if new information becomes available in the future. You should not assume that our silence over time means that actual events are bearing out as expressed or implied in such forward-looking statements.

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. Our INTERCEPT Blood System is intended for use with blood components and certain of their derivatives: plasma, platelets, red blood cells and to produce IFC, and pathogen reduced plasma, cryoprecipitate reduced. The INTERCEPT Blood System for platelets, or platelet system, and the INTERCEPT Blood System for plasma, or plasma system, have received a broad range of regulatory approvals and certifications, including but not limited to U.S. Food and Drug Administration, or FDA, approval in the U.S., and CE Certificates of Conformity for our Class III products allowing us to affix the CE Mark to these products in the European Union, or the EU, and approvals or certifications in other jurisdictions that recognize the CE Mark, and are being marketed and sold in a number of countries around the world, including the U.S., certain countries in Europe, the Commonwealth of Independent States, or CIS, the Middle East, and Latin America and selected countries in other regions of the world. Additionally, we have received FDA approval for the INTERCEPT Blood System for Cryoprecipitation. The INTERCEPT Blood System for Cryoprecipitation uses our plasma system to produce IFC for the treatment and control of bleeding, including massive hemorrhage, associated with fibrinogen deficiency. In addition, the INTERCEPT Blood System for Cryoprecipitation is used to produce pathogen reduced plasma, cryoprecipitate reduced. We currently sell the platelet and plasma systems using our direct sales force and through distributors and we sell IFC or disposable kits to manufacture IFC in the U.S. using our direct sales force.

The platelet system is approved in the U.S. for ex vivo preparation of pathogen-reduced apheresis platelet components collected and stored in 100% plasma or InterSol in order to reduce the risk of transfusion-transmitted infection, or TTI, including sepsis, and as an alternative to gamma irradiation for prevention of transfusion-associated graft versus host disease or TA-GVHD. The plasma system is approved in the U.S. for ex vivo preparation of pathogen-reduced, whole blood derived or apheresis plasma in order to reduce the risk of TTI when treating patients requiring therapeutic plasma transfusion, and as an alternative to gamma irradiation for prevention of TA-GVHD.

The INTERCEPT Blood System for red blood cells, or the red blood cell system, is currently in development and has not been commercialized anywhere in the world. We filed our application to obtain a CE Certificate of Conformity to affix the CE Mark to the red blood cell system in December 2018 under the Medical Device Directive, or MDD, and in June 2021, we completed the resubmission of our application under the new European Union Medical Device Regulation, or MDR. However, we do not expect a decision concerning certification will occur for at least another 12 months, if ever. See also the risk factor entitled “The red blood cell system is currently in development and may never receive any marketing approvals or CE Certificates of Conformity” under “Item 1A—Risk Factors” of this Quarterly Report on Form 10-Q for additional information with respect timing of the ultimate decision on our CE Certificate of Conformity application. In 2017, we initiated a Phase 3 clinical, double-blind study in the U.S., known as the RedeS study, to assess the safety and efficacy of INTERCEPT-treated red blood cells when compared to conventional, red blood cells. Also in 2017,

we received investigational device exemption, or IDE, approval from the FDA to initiate a Phase 3 clinical trial, known as the ReCePI study that is designed to evaluate the efficacy and safety of INTERCEPT-treated red blood cells in patients requiring transfusion for acute blood loss during surgery. Due to the COVID-19 pandemic, many of the hospital sites conducting our RedeS and ReCePI studies suspended enrollment to focus on their response to the pandemic. Should the COVID-19 pandemic persist or heighten, we could see renewed or further delays to trial enrollment. In addition, we will need to generate acceptable Phase 3 clinical data from chronic anemia patients in the U.S. before the FDA will consider our red blood cell system for approval. In part, we will seek to introduce supplemental clinical data we obtained from European clinical trials, though we cannot assure you that we will be able to demonstrate comparability or that the FDA will allow supplemental clinical European data. We must demonstrate to the FDA an ability to define, test and meet acceptable specifications for our current Good Manufacturing Practice and ISO standards for the manufactured compounds used to prepare INTERCEPT-treated red blood cells before we can submit and seek regulatory approval of our red blood cell system from the FDA.

In June 2022, we extended portions our agreement with BARDA, part of the U.S. Department of Health and Human Services' Office of the Assistant Secretary for Preparedness and Response, through December 2025. The agreement provides funding from BARDA to support the development of our red blood cell system, including clinical and regulatory development programs in support of potential licensure, and development, manufacturing and scale-up activities, as well as activities related to broader implementation of all three INTERCEPT systems in areas of emerging pathogens. The RedeS and ReCePI and other studies are being funded as part of our agreement with BARDA. Under the contract, BARDA reimburses us for allowable direct contract costs, as such costs are incurred, and for allowable indirect costs. See the discussion under "BARDA" below for more information. Successful completion of these activities may require capital beyond that which we currently have or that may be available to us under our agreement with BARDA, and we may be required to obtain additional capital in order to complete the development of and obtain any regulatory approvals for the red blood cell system. In addition, if we are unable to obtain from our suppliers sufficient clinical quantities of the active compounds for our red blood cell system meeting defined quality and regulatory specifications, if our suppliers are not able to maintain regulatory compliance or if we experience additional delays in enrollment for the RedeS and ReCePI studies because of the COVID-19 pandemic or any other reason, we may experience delays in testing, conducting trials or obtaining approvals, and our product development costs would likely increase.

In November 2020, we received FDA approval for the INTERCEPT Blood System for Cryoprecipitation. Beginning in 2021, we began supplying INTERCEPT Blood System for Cryoprecipitation to select blood centers that manufacture IFC for us, and in 2021, we completed our first sale of IFC to a hospital customer. We plan to sell the finished IFC made by our manufacturing blood center partners directly to hospitals. Similar to our platelet and plasma products, any blood center manufacturing IFC will need to complete its process validations and obtain site-specific licenses from FDA Center for Biologics Evaluation and Research, or CBER, before we or they can sell finished IFC to hospital customers outside of the states producing IFC. While three of our manufacturing partners received their Biologics License Application, or BLAs from CBER, we plan to continue working with our other U.S.-based blood centers manufacturing partners to support these activities and any delay in obtaining these licenses would adversely impact the nationwide availability of our finished IFC in the U.S. In addition, we have entered into certain agreements with blood centers and blood center affiliate organizations to sell the INTERCEPT Blood System for Cryoprecipitation kits which will allow those blood centers and blood center affiliate organizations to produce finished IFC for their own sales efforts to hospitals.

We have borrowed and, in the future, may borrow additional capital from institutional and commercial banking sources to fund future growth, including pursuant to the Credit, Security and Guaranty Agreement (Term Loan), or the Term Loan Credit Agreement, and Credit, Security and Guaranty Agreement (Revolving Loan), or the Revolving Loan Credit Agreement, 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, financial performance covenants 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, political change, and other factors, including uncertainty associated with the COVID-19 pandemic, we do not know whether additional capital will be available when needed, or that, if available, whether we will be able to obtain additional capital on reasonable terms. Specifically, the COVID-19 pandemic and the ensuing monetary policies of many countries has significantly disrupted global financial markets, and may limit our ability to access capital, which could in the future negatively affect our liquidity. As a result of stimulus programs and global events over the past two years, the U.S. and many countries are currently experiencing an inflationary environment. In addition, the U.S. Federal Reserve has raised, and may again raise, interest rates in response to concerns about inflation, which in turn has negatively impacted equity values, including the value of our common stock. Furthermore, we expect that the costs of our business may increase as labor rates and prices rise in the current inflationary environment, transportation costs increase, and global supply chain constraints impact availability of our products. If we

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

Although we received FDA approval of our platelet and plasma systems in December 2014, our U.S. commercial efforts continue to be largely focused on enabling blood centers that are using INTERCEPT to optimize production and increase the number of platelet units produced and made available to patients and continuing to develop awareness of INTERCEPT's product profile relative to other platelet and plasma products, including conventional, un-treated components. In addition, to address the entire market in the U.S., customers will need to modify their operating practices, or we will need to develop, test and obtain FDA approval of additional configurations of the platelet system. On October 1, 2021, all U.S. blood centers had to be compliant with the FDA guidance document, "Bacterial Risk Control Strategies for Blood Collection Establishments and Transfusion Services to Enhance the Safety and Availability of Platelets for Transfusion," or the Final Guidance Document. Although the INTERCEPT Blood System is one of the options available to U.S. blood centers for compliance, we cannot predict if U.S. customers will continue to adopt INTERCEPT over other options or at what levels. Should we be unable to manufacture INTERCEPT in sufficient quantities in a timely manner, or have adequate resources to assist customers with implementing the INTERCEPT Blood System, U.S. blood centers may be forced to use alternate options allowed by the guidance document, which could permanently impact our ability to convert those blood centers to INTERCEPT users. Hospitals in regions seeing a surge in COVID-19 cases may disallow access to their sites or personnel which will delay our ability to market and sell our products, including IFC. Should the COVID-19 pandemic persist or heighten, customers may not be able to implement new technologies such as INTERCEPT and may instead choose to utilize other allowable methods with which they may have more familiarity.

Outside of the U.S., we recognize product revenues from the sale of our platelet and plasma systems in a number of countries around the world including those in Europe, the CIS, and the Middle East. We utilize both our direct sales organization and regional distributors to market and sell our platelet and plasma systems in these international markets. Our commercial efforts outside the U.S. are focused on increasing market adoption with our existing customer relationships and building demand in new geographies.

Generally, we enter into customer agreements for a specified term and varying options or extensions beyond the initial term. We cannot assure that all customers will use our products at historical levels or at all since securing long-term purchase volume commitments is not always possible, given the unpredictable nature of blood collection and usage. We also cannot provide any assurance that we will be able to secure any subsequent contracts with our customers or that the terms, including the pricing or committed volumes, if any, of any future contract will be equivalent or superior to the terms under our current contracts.

If we are unable to gain widespread commercial adoption in markets where our blood safety products are approved for commercialization, including the U.S., we will have difficulties achieving profitability. In order to commercialize all of our products and product candidates, we will be required to conduct significant research, development, preclinical and clinical evaluation, commercialization and regulatory compliance activities for our products and product candidates, which, together with anticipated selling, general and administrative expenses, are expected to result in substantial losses. Accordingly, we may never achieve a profitable level of operations in the future.

In addition to the anticipated product revenues from sales of our platelet and plasma systems and sales of IFC, we anticipate that we will continue to recognize revenue from our government contracts. We recognize government contract revenue associated with the government contracts as qualified costs are incurred for reimbursement over the performance period.

Fresenius

Fresenius Kabi AG, Fenwal France SAS, and Fenwal International, Inc., or Fresenius, manufactures and supplies the platelet and plasma systems to us under our Second Amended and Restated Supply and Manufacturing Agreement, or the 2022 Agreement, until December 31, 2031. Fresenius is obligated to sell, and we are obligated to purchase finished disposable kits for the platelet and plasma systems. The 2022 Agreement permits us to purchase sets for the 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. The term of the 2022 Agreement will automatically renew for successive two-year periods unless terminated by either party upon two years' prior written notice, in the case of the initial term, or one year prior written notice, in the case of any successive renewal term. Each party has normal and customary termination rights, including termination for material breach. Pricing under the 2022 Agreement for the initial term is based on volume purchases by us and subject to an annual adjustment based on variation in a price index. For a discussion of the risks presented to our supply chain by the COVID-19 pandemic, see "Item 1A—Risk Factors" of this Quarterly Report on Form 10-Q.

See Note 10, *Development and License Agreements*, in Part I of this Quarterly Report on Form 10-Q for further information regarding the Supply Agreement with Fresenius.

Government contracts

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

This agreement with BARDA provides for the reimbursement of certain amounts incurred by us in connection with our satisfaction of certain contractual milestones. Under the agreement, we are reimbursed and recognize revenue as qualified direct contract costs are incurred plus allowable indirect costs, based on approved provisional indirect billing rates, which permit recovery of fringe benefits, overhead and general and administrative expenses. As of June 30, 2022, BARDA has committed to reimburse certain of our expenses related to the clinical development of the red blood cell system during a base period, or the Base Period, and under exercised option periods, or Option Periods, in an aggregate amount of up to $149.5 million. If we satisfy subsequent milestones and BARDA were to exercise additional Option Periods, the total funding opportunity under the BARDA agreement could reach up to $246.5 million through December 31, 2025. If exercised by BARDA in its sole discretion, each subsequent Option Period would fund activities related to broader implementation of the platelet and plasma system or the red blood cell system in areas of emerging pathogens, clinical and regulatory development programs in support of the potential licensure of the red blood cell system in the U.S., and development, manufacturing and scale-up activities for the red blood cell system. If certain additional Option Periods are exercised by BARDA, we will be responsible for up to $10 million of co-investment. See Note 10, *Development and License Agreements*, in Part I of this Quarterly Report on Form 10-Q for further information regarding the agreement with BARDA.

In September 2020, we entered into a five-year agreement with the FDA for the development of next-generation compounds to optimize pathogen reduction treatment of whole blood to reduce the risk of transfusion-transmitted infections. Under the agreement, we are reimbursed and will recognize revenue as qualified direct contract costs are incurred plus allowable indirect costs, based on approved provisional indirect billing rates, which permit recovery of fringe benefits, overhead and general and administrative expenses. The total potential contract value is $11.1 million. See Note 10, *Development and License Agreements*, in Part I of this Quarterly Report on Form 10-Q for further information regarding the agreement with the FDA.

Equity Agreements

See Note 7, *Stockholders' Equity*, in Part I of this Quarterly Report on Form 10-Q for further information regarding the Controlled Equity Offering^{SM} Sales Agreement with Cantor Fitzgerald & Co. and Stifel, Nicolaus & Company, Incorporated, or the Sales Agreement, for the issuance and sale of our common stock.

Debt Agreement

See *Note 5, Debt,* in Part I of this Quarterly Report on Form 10-Q for more information on the debt under our Term Loan Credit Agreement and the Revolving Loan Credit Agreement.

COVID-19

The current COVID-19 pandemic has affected and will continue to affect economies and business around the world. At times, various governmental authorities and private enterprises have implemented numerous measures to contain the pandemic, such as travel bans and restrictions, quarantines, shelter-in-place orders and non-essential business shutdowns, which have led to severe disruptions to the global and U.S. economies that may continue for a prolonged duration and has triggered a recession or a period of economic slowdown. We do not yet know the full extent of potential impacts on our product revenues, business operations, clinical trials, or overall financial projections. Should our employees, notably laboratory-based personnel, experience a surge in infections, our ability to complete research and development activities may be impaired. As such, certain studies and trials may be delayed for an extended period of time. Furthermore, key deployment and technical service personnel, if infected, will not be able to support customers timely or effectively which could negatively impact our ability to support customers looking to begin INTERCEPT use or those experiencing any operational difficulties. The extent and duration of the pandemic is highly uncertain and difficult to predict. We are actively monitoring and managing our response and assessing actual and potential impacts to our operating results and financial condition, which could also impact trends and expectations as described in more detail below.

Critical Accounting Policies and Management Estimates

Our critical accounting policies and significant estimates are detailed in our Annual Report on Form 10-K for the year ended December 31, 2021. Our critical accounting policies and significant estimates have not changed substantially from those previously disclosed in our Annual Report on Form 10-K for the year ended December 31, 2021.

Results of Operations

Three and six months ended June 30, 2022 and 2021

Revenue

	Three Months Ended June 30,				Six Months Ended June 30,			
(in thousands, except percentages)	2022	2021	Change		2022	2021	Change	
Product revenue	$ 40,999	$ 31,484	$ 9,515	30%	$ 78,443	$ 54,863	$ 23,580	43%
Government contract revenue	6,632	6,279	353	6%	12,208	12,466	(258)	(2%)
Total revenue	$ 47,631	$ 37,763	$ 9,868	26%	$ 90,651	$ 67,329	$ 23,322	35%

Product revenue increased during the three and six months ended June 30, 2022, compared to the three and six months ended June 30, 2021, primarily due to year-over-year sales volume growth in disposable platelet system kit sales to U.S. customers, due in part to the FDA Guidance Document on platelet safety that went into effect on October 1, 2021. We anticipate product revenue for INTERCEPT disposable kits will increase in future periods driven by the expected continued expansion of U.S. sales, increased market acceptance of the INTERCEPT Blood System and adoption of the INTERCEPT Blood System in geographies where commercialization efforts are underway. In addition, we expect to see IFC product revenue increase in future periods. However, a deterioration of the Euro relative to the U.S. dollar has in the recent past, and could in the future, have a material impact on our product revenues, as a significant portion of our product revenue is still expected to be derived from European based customers. As a result of these and other factors, the historical results may not be indicative of INTERCEPT Blood System product revenue in the future.

Government contract revenue remained relatively flat during the three and six months ended June 30, 2022, compared to the three and six months ended June 30, 2021. Given the ongoing effects that the COVID-19 pandemic has on our BARDA funded activities, we do not anticipate that government contracts revenue will materially change from historical long-term trends.

Cost of Product Revenue

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

	Three Months Ended June 30,				Six Months Ended June 30,			
(in thousands, except percentages)	2022	2021	Change		2022	2021	Change	
Cost of product revenue	$ 19,718	$ 15,323	$ 4,395	29%	$ 37,794	$ 26,418	$ 11,376	43%

Cost of product revenue increased during the three and six months ended June 30, 2022, compared to the three and six months ended June 30, 2021. The increase was primarily due to the volume of product sold driven largely by a year-over-year increase in platelet kit sales to U.S. customers, and the negative impact of foreign exchange rates.

Our gross margin on product sales was 52% during the three months ended June 30, 2022, compared to 51% during the three months ended June 30, 2021. Our gross margin on product sales was 52% during the six months ended June 30, 2022, compared to 52% during the six months ended June 30, 2021. Margins were impacted by the mix of geographies into which products were sold, with the U.S. kit sales growing over sales in other regions and, to a lesser extent product mix, with platelet kit sales representing a larger proportion of overall sales during the three and six months ended June 30, 2022, compared to the three and six months ended June 30, 2021. In addition, freight costs during the three and six months ended June 30, 2022, were higher than the same period in the prior year. Changes in our gross margin on product sales are affected by various factors, including selling prices to customers, the volume of product manufactured, pricing with suppliers, the timing of inventory purchases related to the underlying exchange rate of the Euro relative to the U.S. dollar, manufacturing and supply chain costs, the mix of product sold, and the mix of customers to which products are sold. Furthermore, we may experience cost pressure due to the inflationary environment, increased transportation costs and an adverse impact on the efficiency of our supply chain. Additionally, we may encounter unforeseen manufacturing difficulties, including those related to the COVID-19 pandemic, which, at a minimum, may lead to higher than anticipated costs, scrap rates, delays in manufacturing products, or lower production levels of manufacturing than would be needed to meet demand. We may also decide to make investments with our manufacturing partners to identify longer-term efficiencies, but result in near-term increased costs. In addition, we may face competition which may limit our ability to maintain existing selling prices for our products which in turn would negatively affect our reported gross margins on product sales. Our gross margins on product sales may be impacted in the future based on all of these and other criteria.

We expect to build inventory levels that will be sufficient to meet forecasted demand. While our suppliers have initiated business continuity plans with minimal disruption to our supply to date, we cannot be certain that any prolonged, intensified or worsened effect from the COVID-19 pandemic would not significantly impact our supply chain. At times, we may purchase quantities of materials, components or finished products that are expected to be on-hand for longer than one year. We may procure and carry this inventory to mitigate obsolescence, supply chain disruption and for business continuity reasons.

Research and Development Expenses

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

	Three Months Ended June 30,				Six Months Ended June 30,			
(in thousands, except percentages)	2022	2021	Change		2022	2021	Change	
Research and development	$ 15,216	$ 17,083	$ (1,867)	(11%)	$ 29,273	$ 32,831	$ (3,558)	(11%)

Research and development expenses decreased during the three and six months ended June 30, 2022, compared to the three and six months ended June 30, 2021, primarily due to reduced spend due to the completion of certain activities in the prior year and the timing of activities related to new product development.

We expect to incur additional research and development costs associated with our pursuit of potential regulatory approvals in other geographies where we do not currently sell our platelet and plasma systems, planning and conducting *in vitro* studies and clinical development of our red blood cell system in Europe and the U.S., in support of our completed application for a CE Mark for our red blood cell system in the EU, new product development and product enhancements, including potential new label claims, design efforts on our illuminator, and costs associated with performing the activities under our government contracts, and inflationary pressures on labor and study costs. Due to the inherent uncertainties and risks associated with developing biomedical products, including, but not limited to, intense and changing government regulation, the impact of the COVID-19 pandemic, uncertainty of future preclinical studies and clinical trial results and uncertainty associated with manufacturing, it is not possible to reasonably estimate the costs to complete these research and development projects. We face numerous risks and uncertainties associated with the successful completion of our research and development projects, which risks and uncertainties are discussed in further detail under “Item 1A—Risk Factors” in Part II of this Quarterly Report on Form 10-Q.

Selling, General and Administrative Expenses

Selling, general and administrative expenses include salaries and related expenses for administrative personnel, non-cash stock-based compensation, expenses for our commercialization efforts in a number of countries around the world including those in U.S., Europe, the CIS and the Middle East, Asia, Latin America, and expenses for accounting, tax, internal control, legal, and facility and infrastructure related expenses, and insurance premiums. We expect to incur additional selling, general and administrative costs associated with inflationary pressures on labor and vendor costs.

	Three Months Ended June 30,				Six Months Ended June 30,			
(in thousands, except percentages)	2022	2021	Change		2022	2021	Change	
Selling, general and administrative	$ 19,532	$ 19,758	$ (226)	(1%)	$ 40,267	$ 38,928	$ 1,339	3%

Selling, general and administrative expenses remained relatively flat during the three months ended June 30, 2022, compared to the three months ended June 30, 2021. Selling, general and administrative expenses increased during the six months ended June 30, 2022, compared to the six months ended June 30, 2021, primarily driven by increased labor costs associated and non-cash stock-based compensation.

Non-Operating Expense, Net

Non-operating expense, net consists of foreign exchange gains and losses, interest charges incurred on our debt, and other non-operating gains and losses, including interest earned from our short-term investment portfolio, and gains and losses due to changes in the fair value of certain investments.

(in thousands, except percentages)	June 30, 2022	June 30, 2021	Change		June 30, 2022	June 30, 2021	Change	
Foreign exchange (loss) gain	$ (104)	$ 118	$ (222)	(188%)	$ (302)	$ (278)	$ (24)	9%
Interest expense	(1,348)	(1,338)	(10)	1%	(2,728)	(2,310)	(418)	18%
Other (expense) income, net	(30)	337	(367)	(109%)	(812)	793	(1,605)	(202%)
Total non-operating expense, net	$ (1,482)	$ (883)	$ (599)	68%	$ (3,842)	$ (1,795)	$ (2,047)	114%

Foreign Exchange (Loss) Gain

We experienced foreign exchange losses during the three months ended June 30, 2022, compared to foreign exchange gains during the three months ended June 30, 2021. Foreign exchange losses increased during the six months ended June 30, 2022, compared to the six months ended June 30, 2021. These are primarily due to foreign exchange variations between the Euro and the U.S. dollar which began during the second half of 2021 and has steepened during the quarter ended June 30, 2022.

Interest Expense

Interest expense remained flat during the three months ended June 30, 2022, compared to the three months ended June 30, 2021. Interest expense increased during the six months ended June 30, 2022, compared to the six months ended June 30, 2021, primarily due to the interest expense related to our Term Loan Credit Agreement, Tranche 2, of $15.0 million drawn on March 29, 2021. Should interest rates continue to increase, the rates that we are obligated to pay under our Credit Agreements may increase, potentially leading to higher interest expense.

Other (Expense) Income, Net

Other (expenses) income, net decreased during the three and six months ended June 30, 2022, compared to the three and six months ended June 30, 2021, primarily due to the decrease in fair value of our investments in certain preferred stocks and warrants.

Provision for Income Taxes

(in thousands, except percentages)	Three Months Ended June 30, 2022	Three Months Ended June 30, 2021	Change		Six Months Ended June 30, 2022	Six Months Ended June 30, 2021	Change	
Provision for income taxes	$ 78	$ 77	$ 1	1%	$ 154	$ 175	$ (21)	(12%)

The tax expenses were primarily a result of our Cerus Europe B.V. subsidiary's operating profit.

Due to our history of cumulative operating losses, management has concluded that, after considering all of the available objective evidence, it is not likely that all our net deferred tax assets as of June 30, 2022 will be realized. Accordingly, substantially all of our U.S. deferred tax assets continue to be subject to a valuation allowance as of June 30, 2022.

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, cash from product sales and reimbursements under our government agreements.

As of June 30, 2022 and December 31, 2021, we had the following cash and cash equivalents, short-term investments and restricted cash (in thousands):

	June 30, 2022	December 31, 2021
Cash and cash equivalents	$ 32,309	$ 48,759
Short-term investments	74,738	80,600
Restricted cash	2,014	2,285
Total	$ 109,061	$ 131,644

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.

As of June 30, 2022 and December 31, 2021, we had the following indebtedness (in thousands):

	June 30, 2022	December 31, 2021
Debt – current	$ 28,680	$ 14,697
Debt – non-current	41,065	54,724
Total	$ 69,745	$ 69,421

Operating Activities

	Six Months Ended	
(in thousands)	**June 30, 2022**	**June 30, 2021**
Net cash used in operating activities	$ (21,801)	$ (26,118)

The decrease in net cash used in operating activities was primarily related to the increased product sales and underlying gross profit, and the timing of payments and continued inventory related purchases and payments related to incentive compensation, during the six months ended June 30, 2022, compared to the same period in 2021. We expect to continue to make investments in inventory ahead of our future forecasted demand and to ensure component availability and mitigate obsolescence, if any.

Investing Activities

	Six Months Ended	
(in thousands)	**June 30, 2022**	**June 30, 2021**
Net cash provided by investing activities	$ 3,147	$ 31,249

The decrease in net cash provided by investing activities was primarily the result of lower proceeds from the maturity and sale of our investments to support operations, during the six months ended June 30, 2022, compared to the same period in 2021.

Financing Activities

	Six Months Ended	
(in thousands)	**June 30, 2022**	**June 30, 2021**
Net cash provided by financing activities	$ 2,651	$ 17,615

The decrease in net cash provided by financing activities for the six months ended June 30, 2022, was primarily due to the borrowings under our Term Loan Credit Agreement of $15.0 million during the six months ended June 30, 2021. See *Note 5, Debt,* in Part I of this Quarterly Report on Form 10-Q for more information.

Working Capital

(in thousands)	**June 30, 2022**	**December 31, 2021**
Working capital	$ 85,393	$ 108,546

Working capital decreased as of June 30, 2022, compared to December 31, 2021, primarily due to continued overall use of cash from operations to support the costs associated with product enhancements, costs associated with increasing inventory levels, including securing a reliable supply of components, capital investments with suppliers, initiatives for expanded platelet label claims, preliminary design efforts on our next generation illuminator, and investments associated with the commercial launch of IFC, offset by proceeds from increased product sales and collections.

Capital Requirements

Our near-term capital requirements are dependent on various factors, including operating costs and working capital investments associated with developing and commercializing the INTERCEPT Blood System, including in connection with the continuing U.S. commercialization of our platelet, plasma systems and IFC, costs to develop different configurations of existing products and new products, including our illuminator, costs associated with planning, enrolling and completing ongoing studies, and the post-approval studies we are required to conduct in connection with the FDA approval of the platelet system, costs associated with pursuing potential regulatory approvals in other geographies where we do not currently sell our platelet and plasma systems, costs associated with conducting *in vitro* studies and clinical development of our red blood cell system in Europe and the U.S., costs associated with performing the agreed-upon activities under our government agreements, and costs related to creating, maintaining and defending our intellectual property. In addition, both our near and long-term capital requirements will require that we continue to invest in capital purchases to support ongoing and proposed studies, in addition to manufacturing capacity expansion to support our growing business. 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, required post-approval studies, market

preparedness and product launch activities for any of our product candidates and 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 funds under our government contracts and the public and private equity and debt capital markets, as well as on collaborative arrangements with partners, augmented by cash generated from operations, if at all, and interest income earned on the investment of our cash balances. While we believe that our available cash and cash equivalents and short-term investments, as well as cash received from product sales and under our government contracts, will be sufficient to meet our capital requirements for at least the next 12 months. However, if we are unable to generate sufficient product revenue, or access sufficient funds under our government contracts or the public and private equity and debt capital markets, we may be unable to execute successfully on our operating plan. We have based our cash sufficiency estimate on assumptions that may prove to be incorrect, therefore, 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 the Term Loan Credit Agreement and Revolving Loan Credit Agreement, 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, financial performance covenants and repayment provisions that reduce cash resources and limit future access to capital markets. In addition, unless we restructure our credit facility prior to April 1, 2023, the principal amounts outstanding under our term debt facility will begin amortizing and will require us to pay amounts as they come due in cash.

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.

In December 2020, we entered into the Sales Agreement under which we may issue and sell up to $100.0 million of our common stock through or to Cantor Fitzgerald & Co. or Stifel, Nicolaus & Company, Incorporated, as sales agent or principal. To date, we have sold 0.4 million shares of our common stock under the Sales Agreement for net proceeds of $3.1 million.

While we expect to receive significant funding under our agreement with BARDA, our ability to obtain the funding we expect to receive under this agreement is subject to various risks and uncertainties, including with respect to BARDA's ability to terminate the agreement for convenience at any time and our ability to achieve the required milestones under this agreement, and including with respect to the conduct of the RedeS and ReCePI studies, enrollment for which has been suspended or slowed at many of the hospital sites due to the COVID-19 pandemic. In addition, access to federal contracts is subject to the authorization of funds and approval of our research plans by various organizations within the federal government, including the U.S. Congress. The general economic environment and uncertainty associated with the COVID-19 pandemic, coupled with tight federal budgets, has led to a general decline in the amount available for government funding. If BARDA were to eliminate, reduce or delay funding under our agreement, this would have a significant negative impact on the programs associated with such funding and could have a significant negative impact on our revenues and cash flows. Furthermore, should we be unable to deploy personnel or derive a benefit from fixed study costs or generate data from clinical sites and studies reimbursed by BARDA, our cash flows would be negatively impacted or we may have to initiate furloughs and layoffs which would likely prove disruptive to our management and operations. In addition, if we are unable to generate sufficient prerequisite Phase 3 clinical data, our agreement with BARDA will be severely limited in scope or could be terminated altogether, and our ability to complete the development activities required for licensure in the U.S. may require additional capital beyond which we currently have. Furthermore, while BARDA has provided funding for and has indicated a potential for future funding for many activities associated with combating COVID-19, the availability and focus for any BARDA funding will likely be finite and may require us to compete with other technologies, both similar and disparate. If alternative sources of funding are not available, or if we determine that the cost of alternative available capital is too high, we may be forced to suspend or terminate development activities related to the red blood cell system in the U.S.

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.

As a result of economic conditions, general global economic uncertainty, political change, global pandemics, natural disasters, and other factors, we do not know whether additional capital will be available when needed, or that, if available, we will be able to obtain additional capital on reasonable terms. If we are unable to raise additional capital due to the volatile global financial markets, general economic uncertainty or other factors, we may need to curtail planned development or commercialization activities. Specifically, the COVID-19 pandemic has significantly disrupted global financial markets, and may limit our ability to access capital, which could in the future

negatively affect our liquidity. A recession or market correction resulting from the spread of COVID-19 could materially affect our business and the value of our common stock.

In addition, we may need to obtain additional funds to complete development activities for the red blood cell system necessary for potential regulatory approval or certification in the EU if costs are higher than anticipated or we encounter delays. We may need to obtain additional funding to conduct additional randomized controlled clinical trials for existing or new products, particularly if we are unable to access any additional portions of the funding contemplated by our government agreements, and we may choose to defer such activities until we can obtain sufficient additional funding or, at such time, our existing operations provide sufficient cash flow to conduct these trials.

Commitments

See *Note 5, Debt*, in Part I of this Quarterly Report on Form 10-Q for more information on the debt under our Term Loan Credit Agreement and the Revolving Loan Credit Agreement.

See *Note 6, Commitments and Contingencies*, in Part I of this Quarterly Report on Form 10-Q for more information on the operating leases and purchase commitments.

We did not have any off-balance sheet arrangements as of June 30, 2022.

Financial Instruments

Our investment policy is to manage our marketable securities portfolio to preserve principal and liquidity while maximizing the return on the investment portfolio to assist us in funding our operations. We currently invest our cash and cash equivalents in money market funds and interest-bearing accounts with financial institutions. Our money market funds are classified as Level 1 in the fair value hierarchy, in which quoted prices are available in active markets, as the maturity of money market funds are relatively short and the carrying amount is a reasonable estimate of fair value. Our available-for-sale securities related to corporate debt and U.S. government agency securities are 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 credit losses during the three and six months ended June 30, 2022 and 2021, respectively. Adverse global economic conditions have had, and may continue to have, a negative impact on the market values of potential investments.

ITEM 3. QUANTITATIVE AND QUALITATIVE DISCLOSURES ABOUT MARKET RISK

During the six months ended June 30, 2022, 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, 2021.

ITEM 4. CONTROLS AND PROCEDURES

Evaluation of Disclosure Controls and Procedures

Our management, with the participation of our chief executive officer, or CEO, and chief financial officer, or CFO, has evaluated the effectiveness of our disclosure controls and procedures (as defined in Exchange Act, Rule 13a–15(e) and 15d-15(e)), as of the end of the period covered by this Quarterly Report on Form 10-Q. Based on such evaluation, our CEO and CFO have concluded that as of June 30, 2022, our disclosure controls and procedures are designed at a reasonable assurance level and are effective to provide reasonable assurance that information we are required to disclose in reports that we file or submit under the Exchange Act is recorded, processed, summarized, and reported within the time periods specified in the rules and forms of the Securities and Exchange Commission, or SEC, and that such information is accumulated and communicated to our management, including our CEO and CFO, as appropriate, to allow timely decisions regarding required disclosure.

Changes in Internal Control over Financial Reporting

There were no changes in our internal control over financial reporting identified in management's evaluation pursuant to Rules 13a-15(d) and 15d-15(d) of the Exchange Act which occurred during our fiscal quarter ended June 30, 2022, which have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

Limitations on the Effectiveness of Controls

In designing and evaluating the disclosure controls and procedures and internal control over financial reporting, management recognizes that any controls and procedures, no matter how well designed and operated, can provide only reasonable assurance of achieving the desired control objectives. In addition, the design of disclosure controls and procedures and internal control over financial reporting must reflect the fact that there are resource constraints and that management is required to apply judgment in evaluating the benefits of possible controls and procedures relative to their costs.

PART II: OTHER INFORMATION

ITEM 1. LEGAL PROCEEDINGS

None.

Item 1A. *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 quarterly report on Form 10-Q. 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.

Summary of Risk Factors

- The evolving effects of the COVID-19 pandemic have materially affected and may continue to materially affect how we, our customers, and our suppliers are operating our businesses, and the duration and extent to which these effects will impact our future results of operations and overall financial performance remains uncertain.
- We depend substantially upon the commercial success of the INTERCEPT Blood System for platelets, plasma and cryoprecipitation in the U.S., and our inability to successfully commercialize the INTERCEPT Blood System in the U.S. would have a material adverse effect on our business, financial condition, results of operations and growth prospects.
- The INTERCEPT Blood System may not achieve broad market adoption.
- We are exposed to risks associated with the highly concentrated market for the INTERCEPT Blood System.
- We may be unable to develop and maintain an effective and qualified U.S. based commercial organization or educate blood centers, clinicians and hospital personnel. As a result, we may not be able to successfully educate the market on the value of pathogen reduction or commercialize our products in the U.S.
- We have no prior experience selling directly to hospitals or expertise complying with regulations governing finished biologics, and our inability to successfully commercialize the INTERCEPT Blood System for cryoprecipitation in the U.S. would have a material adverse effect on our business, financial condition, results of operations and growth prospects.
- If our competitors develop products superior to ours, market their products more effectively, or receive regulatory approval before our products, our commercial opportunities could be reduced or be eliminated.
- Clinical trials are costly and time consuming, may take longer than we expect or may not be completed at all, and their outcomes are uncertain. A failure to generate data in clinical trials to support expanded label claims or to support marketing approvals or CE Certificates of Conformity for our product candidates could materially and adversely affect our business, financial condition, results of operations and growth prospects.
- The red blood cell system is currently in development and may never receive any marketing approvals or CE Certificates of Conformity.
- Our company, our products, and blood products treated with the INTERCEPT Blood System are subject to extensive regulation by domestic and foreign authorities.
- If we or our third-party suppliers fail to comply with the U.S. Food and Drug Administration's, or FDA's, or other regulatory authorities' good manufacturing practice regulations, it could impair our ability to market our products in a cost-effective and timely manner.
- 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.
- 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.
- A significant portion of the funding for the development of the red blood cell system is expected to come from our BARDA agreement, and if BARDA were to eliminate, reduce or delay, or object to extensions for funding of our agreement, it would have a significant, negative impact on our government contract revenues and cash flows, and we may be forced to suspend or terminate our U.S. red blood cell development program or obtain alternative sources of funding.
- We rely on third parties to market, sell, distribute and maintain our products and to maintain customer relationships in certain countries.

- Our manufacturing supply chain exposes us to significant risks.
- We expect to continue to generate losses and we may never achieve a profitable level of operations.
- 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.
- We operate a complex global commercial organization, with limited experience in many countries. We have limited resources and experience complying with regulatory, legal, tax and political complexities as we expand into new and increasingly broad geographies. We may be distracted by expansion into new geographies where we do not have experience and we may be unsuccessful in monetizing such opportunities for the benefit of our organization at large.
- Risks associated with our operations outside of the United States could adversely affect our business.
- We may not be able to protect our intellectual property or operate our business without infringing intellectual property rights of others.

Risks Related to Our Business and Industry

The evolving effects of the COVID-19 pandemic have materially affected and may continue to materially affect how we, our customers, and our suppliers are operating our businesses, and the duration and extent to which these effects will impact our future results of operations and overall financial performance remains uncertain.

As global economic conditions recover from the COVID-19 pandemic, business activity may not recover as quickly as anticipated, and it is not possible at this time to estimate the long-term impact that COVID-19 could have on our business, as the impact will depend on future developments, which are highly uncertain and cannot be predicted. Continued remote work policies, quarantines, shelter-in-place and similar government orders, shutdowns or other restrictions on the conduct of business operations related to the effects of the COVID-19 pandemic has materially affected and may continue to materially affect how we, our customers, and our suppliers are operating our businesses.

Our sales efforts have historically involved significant in-person interaction with potential customers and distributors. With respect to our commercial activities, many of our hospital and blood bank customers continue to have requirements or restrictions on vendors and visitors meeting with their personnel in person. We have attempted to shift our sales activities to video conferencing and other similar customer interaction models and we have found these alternative approaches to have varying degrees of effectiveness in comparison to in-person sales efforts. In addition, many of our blood center and hospital customers and study sites have experienced staffing shortages. As a result, our ability to reinitiate sales and marketing efforts may be slower than expected or may require compliance with new credentialing certifications by our personnel. To the extent that our employees' ability to gain access to hospitals and their personnel remains limited, our commercial and sales interactions with those hospitals and our ability to introduce the INTERCEPT Blood System, including IFC, may continue to be impaired. We have deferred certain of our customer events and many planned trade shows have been cancelled and we may further defer or cancel additional customer, employee or industry events, or our participation in such events, in the future. In addition, many new customers and prospective customers have been impacted by the COVID-19 pandemic and their ability to on-board, train staff and implement new technologies, including INTERCEPT, has and may continue to be negatively impacted, which may lead such customers to instead choose to utilize other allowable methods with which they have more familiarity. Moreover, we understand that due to the COVID-19 pandemic, many hospitals are consolidating, are laying off workers or are filing for bankruptcy protection, and other hospitals may have such significant budget shortages that they are unable to afford pathogen-reduced blood components. Blood products are currently in extremely short supply which is impacting our customers. Customers whose operations have been impacted may have difficulty paying timely, may ask for price reductions or may delay or cancel public tenders. In addition, we understand that use of blood components may at times be negatively impacted due to the COVID-19 pandemic and the resulting deferrals of elective procedures requiring use of blood components, including those treated with INTERCEPT. These events, in turn, may negatively impact our potential product revenues from existing and prospective customers. Conversely, during the pendency of the pandemic, certain existing, new and prospective customers have and may continue to ask for increased utilization of our products beyond what was forecast, and we may not be able to timely satisfy this increase in demand. In addition, while our suppliers have initiated business continuity plans with minimal expected disruption to our supply, we cannot be certain that any prolonged, intensified or worsened effect from the pandemic including the impact of emerging variant strains of the SARS-CoV-2 virus would not negatively impact our supply chain. For example, Fresenius, our primary manufacturing partner for our disposable kits, had to reconfigure production workflow to safely produce INTERCEPT disposable kits and in the future, restrictions and other limitations on Fresenius' ability to conduct business in the ordinary course could negatively impact production of INTERCEPT disposable kits. All of the aforementioned could adversely affect our sales, operating results and overall financial performance.

The COVID-19 pandemic has also negatively impacted our ability to perform many clinical trials, studies and activities, including those covered by our agreement with BARDA. Our ongoing and anticipated clinical trials, the post-approval platelet studies, as well as studies to support label expansion for the platelet system in the U.S. have been delayed because of COVID-19. For example, for a brief time, several of the hospital clinical trial sites for our RedeS and ReCePI studies suspended enrollment and several red blood cell production

partners for the studies suspended production in order to conserve red blood cells to meet hospital demand during the pandemic. Many hospital sites are proceeding at a reduced capacity and many are experiencing staffing shortages. Accordingly, many of the activities expected by BARDA have been delayed and will require an extension of time and/or additional funds under the contract to complete. In addition, as the clinical studies and other activities supported by our BARDA contract get further delayed as a result of the COVID-19 pandemic, we will need to continue to rely on modifications and extensions to the BARDA agreement to fund the completion of those activities. Should BARDA disallow any modification or extension, we will need to pay for the costs to complete the activities or stop pursuing them altogether. Further delays may recur in the future if patient enrollment sites need to pause participation in our clinical trials and studies and we cannot be certain that further disruption due to the COVID-19 pandemic can be avoided. Should the COVID-19 pandemic persist, continue to worsen, or resurface at locations where we conduct studies or clinical trials, our ability to commence and complete any contemplated studies may be negatively impacted. Furthermore, should we be unable to deploy personnel, derive a benefit from fixed study costs or generate data from clinical sites and studies reimbursed under our contract with BARDA, our cash flows would be negatively impacted and/or we may have to initiate furloughs and layoffs, which would prove disruptive to our management and operations. This in turn would impair our ability to complete ongoing studies or commence new studies.

The duration and extent of the impact from the COVID-19 pandemic depends on future developments that cannot be accurately predicted at this time, such as the severity and transmission rate of the virus, including any variants, and the extent and effectiveness of containment actions. Despite the increased availability of vaccines, due to the continuing and evolving nature of the COVID-19 pandemic and the potential for periods of increases in case numbers and emergence and spread of virus variants in markets and communities in which we and our customers operate, it is not possible for us to accurately predict the duration or magnitude of the adverse impacts of the pandemic and its effects on our business, results of operations, or financial condition. In addition, while the potential economic impact brought by the COVID-19 pandemic may be difficult to assess or predict, it has significantly disrupted global financial markets, and may limit our ability to access capital, which could in the future negatively affect our liquidity. As a result of stimulus programs put in place over the past two years, the U.S. and many countries are currently experiencing an inflationary environment. This has led to the U.S. Federal Reserve taking action to raise interest rates which in turn has negatively impacted equity values, including the value of our common stock. Furthermore, our labor and vendor costs may rise in an inflationary environment, costs to transport our products may increase, and availability and timeliness of shipping may be negatively impacted. To the extent the COVID-19 pandemic adversely affects our business and results of operations, it may also have the effect of heightening many of the other risks and uncertainties described elsewhere in this ‘‘Risk Factors’’ section.

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

Our business is dependent on our ability to grow and sustain commercialization of the INTERCEPT Blood System in the U.S. Significant product revenue from customers in the U.S. may not occur consistently, if at all, if we are unable to demonstrate that our products are economical, safe and efficacious for potential customers. Similar to our experience in foreign jurisdictions, some potential customers in the U.S. have chosen to first validate our technology or conduct other pre-adoption activities prior to purchasing or deciding whether to adopt the INTERCEPT Blood System for commercial use, which may never occur. Further, new hospital customers of any of our blood center customers will need to go through the administrative process of generating internal tracking codes to integrate INTERCEPT-treated products into their inventories, which may further delay customer adoption in the U.S. These administrative processes necessary for implementation of INTERCEPT are further strained due to the staffing shortages seen globally.

On October 1, 2021, all U.S. blood centers were required to be compliant with the FDA guidance document, “Bacterial Risk Control Strategies for Blood Collection Establishments and Transfusion Services to Enhance the Safety and Availability of Platelets for Transfusion,” or the Final Guidance Document. Although the INTERCEPT Blood System is one of the options available to U.S. blood centers for compliance with the Final Guidance Document, we cannot predict if U.S. customers will continue to adopt INTERCEPT over other options or at what levels. If we are unable to successfully support the commercialization of our platelet system to U.S. customers that have elected to use the INTERCEPT Blood System, then those customers may be required to adopt competing products in order to comply with the Final Guidance Document. Further, U.S. blood centers will be required to change their historical operating practices to conform to our product specifications, or they or their hospital customers may be required to elect more than one option under the Final Guidance Document in order to comply, or they or their hospital customers may choose competing products to comply with the Final Guidance Document. We may be unable to subsequently convert blood centers that chose competing products to the platelet system, which would limit our market potential. If we are not successful in achieving market adoption of the INTERCEPT Blood System in the U.S., we may never generate substantial product revenue, and our business, financial condition, results of operations and growth prospects would be materially and adversely affected.

In any event, our ability to successfully commercialize the INTERCEPT Blood System for platelets, plasma, and cryoprecipitation in the U.S. will depend on our ability to:

- adequately respond in the event of potential increased U.S. customer demand resulting from the implementation of the Final Guidance Document;

- 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;
- support blood center manufacturing partners in obtaining Biologics License Application, or BLAs, for interstate commerce;
- effectively create market demand for the INTERCEPT Blood System through our education, marketing and sales activities;
- hire, train, deploy, support and maintain a qualified U.S.-based commercial organization and field sales force;
- expand the labeled indications of use for the INTERCEPT Blood System and/or design, develop, test and obtain regulatory approval for 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, plasma and cryoprecipitation in the U.S. is subject to a number of risks and uncertainties, including those related to:

- the COVID-19 pandemic and its effect on customers, hospitals, suppliers and our employees;
- staffing shortages at blood centers, hospitals, study sites or suppliers;
- the highly concentrated U.S. blood collection market that is dominated by a small number of blood collection organizations;
- availability of donors;
- regulatory and licensing requirements, including the FDA Center for Biologics Evaluation and Research, or CBER, licensing processes and its BLA requirements, that U.S.-based blood centers are required to follow in order to obtain and maintain the required site-specific licenses to engage in interstate transport of blood components processed using the INTERCEPT Blood System;
- changed or increased regulatory restrictions or requirements;
- the amount available for reimbursement pursuant to codes we have obtained under the Healthcare Common Procedure Coding System, or HCPCS, or New Technology Add-On Payment, or NTAP, 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 qualified suppliers for the particular product or component they manufacture, including the ability of our 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;
- our and our suppliers ability to produce sufficient quantity of product to meet the growing demand for our products, especially in light of the Final Guidance Document;
- ability of our contracted blood center manufacturing partners to produce IFC at sufficient quantities and at acceptable quality levels;
- dependency upon any third-party manufacturer that supplies products required by blood centers to process and store blood components consistent with our approved specifications and claims, including but not limited to, apheresis collection devices, disposable blood bags and reagents, and platelet additive solution, or PAS;
- our ability to obtain patents, protect trade secrets, prevent others from infringing on our proprietary rights, and operate without infringing the proprietary rights of third parties;
- 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.

The INTERCEPT Blood System may not achieve broad market adoption.

In order to maintain or increase market adoption of the INTERCEPT Blood System and to increase market demand, 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/or outweigh their risks.

The use of the platelet system results in some processing loss of platelets. As a result, customers or prospective customers may adopt competing solutions if they perceive that:

- the loss of platelets leads to increased costs, or the perception of increased costs for our customers;
- the use of our product in any way constrains the availability of platelets due to platelet loss;
- our customers or prospective customers believe that the loss of platelets reduces the efficacy of the transfusable unit; or
- our process requires changes in blood center collection processes or clinical regimens to address platelet loss.

Additionally, existing customers may not believe they can justify any perceived operational change or inefficiency either generally or in conjunction with a blood component availability shortage. This concern may be exacerbated during the current blood shortage crisis. 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 other factors.

The INTERCEPT Blood System does not inactivate all known pathogens, which 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, and human parvovirus B-19, due to the biology of these viruses. Although we have shown high levels of reduction of a broad spectrum of lipid-enveloped viruses, INTERCEPT's inability to inactivate, or limited reduction of certain non-lipid-enveloped viruses may negatively impact the decision to adopt by prospective customers. Similarly, although our products have been demonstrated to effectively inactivate spore-forming bacteria, our products have not been shown to be effective in reducing bacterial spores once formed. Furthermore, due to limitations of detective tests, we cannot exclude that a sufficient quantity of pathogen or pathogens beyond the detection limits may still be present in active form, which could present a risk of infection to the transfused patient. Should INTERCEPT-treated components contain detectable levels of pathogens after treatment, the efficacy of INTERCEPT may be called into question, whether or not any remaining pathogens are the result of INTERCEPT's efficacy, the limitations of testing methodologies or other factors. Such uncertainties may limit the market adoption of our products.

We have conducted studies of our products in both *in vitro* and in vivo environments using well-established tests that are accepted by regulatory bodies. However, we cannot be certain that the results of these *in vitro* and *in vivo* studies accurately predict the actual results in humans in all cases. In addition, strains of infectious agents in living donors may be different from those strains commercially available or for which we have tested and for which we have received approval of the inactivation claims for our products. To the extent that actual results in human patients differ, commercially available or tested strains prove to be different, or customers or potential customers perceive that actual results differ from the results of our *in vitro* or *in vivo* testing, market acceptance of our products may be negatively impacted.

If customers experience operational or technical problems with the use of INTERCEPT Blood System products, market acceptance may be reduced or delayed. For example, if adverse events arise from incomplete reduction of pathogens, improper processing or user error, or if testing of INTERCEPT-treated blood samples fails to reliably confirm pathogen reduction, whether or not directly attributable to the INTERCEPT Blood System, customers may refrain from purchasing our products. We have recently learned of instances where, following treatment with INTERCEPT, mishandling of the treated blood components has introduced environmental bacterium. We must help our blood center customers to remain or increase their vigilance in adopting best practices regarding blood component handling. Failure to adequately address this risk may call into question the efficacy of using pathogen reduction.

Furthermore, should customers communicate operational problems or suspected product failure, we will need to investigate and report imputability to the relevant regulatory authorities in a timely manner. We or others may be required to file reports on such complaints or product failure before we have the ability to obtain conclusive data as to imputability which may cause concern with existing and prospective customers or regulators. Should customers feel that INTERCEPT treatment has a negative impact on the number of transfusable platelet units able to be manufactured from available donors, our ability to educate a blood center on the benefits of treating increasing proportions of its platelet units may be negatively impacted. Moreover, there is a risk that further studies that we or others may conduct, including the post-approval studies we are required to conduct as a condition to the FDA approval of the platelet system, will show results inconsistent with previous studies. Should this happen, potential customers may delay or choose not to adopt our products and existing customers may cease using our products. In addition, some hospitals may decide to purchase and transfuse both INTERCEPT-treated blood components and conventional blood components, including IFC which we have no experience selling directly to hospitals. Managing such a dual inventory of blood products may be challenging, and hospitals may need to amend their product labels and inventory management systems before being able to move forward with INTERCEPT. This may require coordination

between hospital suppliers, blood centers, or us, which in turn may cause delays in market adoption. In addition, customers may require certain changes to our products for any number of reasons. Complying with such requests may prove costly, and may create complexities surrounding the manufacturing of disposable kits, compliance with regulatory authorities, blood center usage, or inventory management. Conversely, failure to comply with such requests from customers may result in damage to our relationship or the potential loss of customer business.

Market adoption of our products is also affected by blood center and healthcare facility budgets and the availability of coverage and adequate reimbursement from governments, managed care payors, such as insurance companies, and/or other third parties. In many jurisdictions, due to the structure of the blood products industry, we have little control over budget and reimbursement discussions, which generally occur between blood centers, healthcare facilities such as hospitals, and national or regional ministries of health and private payors. Even if a particular blood center is prepared to adopt the INTERCEPT Blood System, its hospital customers may not accept or may not have the budget to purchase INTERCEPT-treated blood products. Since blood centers would likely not eliminate the practice of screening donors or testing blood for some pathogens prior to transfusion, even after implementing our products, some blood centers may not be able to identify enough cost offsets or hospital pricing increases to afford to purchase our products. Budgetary concerns may be further exacerbated by economic legislation in certain countries and by proposals by legislators at both the federal and, in some cases, 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, commercial use of our products may not be covered by governmental or commercial third-party payors for health care services and may never be covered. In addition, 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 specific to 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. Governmental or third-party payors may change reimbursement rates, year-over-year, or in reaction to submitted claims for reimbursement of costs and expenses related to blood components treated with INTERCEPT. If the costs to the hospital for INTERCEPT processed blood products cannot be easily, readily, or fully incorporated into the existing reimbursement structure, or if reimbursement rates are insufficient or decreased in any given year for blood components treated with INTERCEPT, hospital billing and/or reimbursement for these products could be impacted, thus negatively impacting hospitals' acceptance and uptake of our products. In addition, even if we are able to achieve market acceptance in the U.S. or newly commercialized markets, we have provided and may in the future provide adoption incentives which may negatively impact our reported sales.

We are exposed to risks associated with the highly concentrated market for the INTERCEPT Blood System.

The market for the INTERCEPT Blood System is highly concentrated with few customers, including often-dominant regional or national blood collection entities. Failure to effectively market, promote, distribute, price or sell our products to any of these customers could significantly delay or even diminish potential product revenue in those geographies. Moreover, the market for pathogen reduction systems in the U.S. is highly concentrated and dominated by a small number of blood collection organizations. In the U.S., the American Red Cross represents the largest single portion of the blood collection market. Our ability to gain and maintain significant market penetration in the U.S. is largely dependent on utilization of INTERCEPT and distribution of INTERCEPT-treated blood components by the American Red Cross. The American Red Cross is a large organization. Given the large relative size of the American Red Cross, our resources may be inadequate to fulfill the American Red Cross' and other customers' demands, which could result in a loss of product revenues or customer contracts, or both.

In many countries in Western Europe and in Japan, various national blood transfusion services or Red Cross organizations collect, store and distribute virtually all of their respective nations' blood and blood components supply. In Europe, the largest markets for our products are in Germany, France, and England. In Germany, decisions on product adoption 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. Obtaining these approvals requires support and coordination from local blood centers, and may take a significant period of time to obtain, if ever. Product specifications that receive marketing authorization from the PEI may differ from product specifications that have been adopted in other parts of the EU and other third countries where we rely on CE Certificates of Conformity and the CE Mark, thereby necessitating market specific modifications to the commercial product, which may not be economical or technically feasible for us. Following the inclusion of pathogen-inactivated platelets for national reimbursement by the German Institute for the Hospital Remuneration System as of January 1, 2018, German customers who do not currently have an approved marketing authorization application, or MAA, will first need to obtain one before using our products. The review period for a new MAA can be 12 months or longer following submission and we cannot assure that any of the potential German customers submitting a new MAA will obtain it. Without approvals of MAA applications obtained by potential German customers, our ability to successfully commercialize INTERCEPT in Germany will be negatively impacted, which may adversely affect our business, results of operations and financial condition. In addition, the reimbursement awarded to INTERCEPT in Germany may not be considered by German blood centers as attractive enough to implement pathogen reduction or cover the entirety of their blood center platelet collections which may in turn limit the market acceptance in Germany. Similar to the U.S., German blood centers will need to successfully market and sell to their hospital customers and understand and assist with the steps that are needed at the hospital level in Germany to administer pathogen-reduced platelets.

While we have entered into agreements with Établissement Français du Sang, or EFS, to supply illuminators and platelet and plasma disposable kits and maintenance services for illuminators to EFS, we cannot provide any assurance that the national deployment of the platelet system in France will be sustainable or that we will be able to secure any contracts subsequent to our existing contract with EFS. If we are unable to continue to successfully support EFS' national adoption of the platelet system, EFS' use of the plasma system, our business, results of operations and financial condition may be adversely impacted. Our contracts with EFS do not contain purchase volume commitments and as such, we may see variability in purchase levels or an altogether cessation. In addition, we understand that EFS is inspecting and testing samples of each lot that it purchases from us prior to accepting the products shipped to fulfill orders. We have little insight into the time to test, testing conditions or ultimate results. Other customers may require similar conditions of purchase. Testing may have a negative impact on our ability to recognize product revenue either due to the time it takes to test and approve the release of a shipment or if the customer experiences problems with testing or if testing results are outside of the customer acceptance criteria.

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. Before the Japanese Red Cross would consider our products, we understand that we may need to commit to making certain product configuration changes, which are currently under development but may not be economically or technologically feasible for us to accomplish.

Significant increases in demand may occur given the concentrated nature of many of the largest potential customers and the potential for a mandate by public health agencies to adopt pathogen reduction technologies. Should those customers choose to adopt and standardize their production on the INTERCEPT Blood System or be required to adopt and standardize on the INTERCEPT Blood System, our ability to meet associated increases in demand will likely be constrained due to a variety of factors, including production capacity at approved manufacturing sites, supply issues, manufacturing disruptions, availability of disposable kits manufactured from the obsolete plastic materials in jurisdictions that have not approved the use of alternate plastics for our disposable kits, or other obsolescence of parts, among others. If we encounter sustained growth or accelerated growth, our production capacity may be strained, at least temporarily or should we encounter disruptions, supply shortages, or shipping delays, we may have to allocate available products to customers, which could negatively impact our business and reputation or cause those customers to adopt competing products.

We may be unable to develop and maintain an effective and qualified U.S. based commercial organization or educate blood centers, clinicians and hospital personnel. As a result, we may not be able to successfully educate the market on the value of pathogen reduction or commercialize our products in the U.S.

Successfully commercializing our products in the U.S. has taken more time than anticipated and has required us to continue to invest in commercialization efforts to build and maintain relationships, additional routine-use data and trust from the industry. We continue to need to attract, retain, train and support sales, marketing and scientific and hospital affairs personnel and other commercial talent. For example, we still need to attract and retain hospital affairs professionals to help educate hospitals and physicians on our products, clinical trial history and publications. Hospital affairs professionals are highly educated and trained professionals and the hiring and employment market for hospital affairs professionals is highly competitive. As such, we need to commit significant additional management and other resources in order to maintain and potentially expand our hospital affairs team and sales and marketing functions. We may be unable to develop and maintain adequate hospital affairs, 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, plasma or cryoprecipitation systems in the U.S. The current labor shortage in the U.S. and in many countries where we have commercialized our products has exacerbated the challenge of attracting and retaining these personnel. In any event, 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 commercial products in the U.S. which would materially and adversely affect our business, financial condition, results of operations and growth prospectus.

We have no prior experience selling directly to hospitals or expertise complying with regulations governing finished biologics, and our inability to successfully commercialize the INTERCEPT Blood System for cryoprecipitation in the U.S. would have a material adverse effect on our business, financial condition, results of operations and growth prospects.

While we are beginning to develop an understanding about marketing and selling directly to hospitals, we have no prior experience selling directly to hospitals nor do we have prior experience or expertise complying with regulations governing finished biologics. In order to be successful with a direct-to-hospital sales effort, we may need to contemplate the replacement of expired IFC with new units of IFC at no cost or a reduced cost. We have no experience selling products under this consignment model. The introduction of these new models of doing business require extensive training of our personnel and may lengthen the time it takes for this business unit to be fully operational. In this regard, our blood center customers may view the sale of biologics directly to hospitals as a competitive threat, which may adversely affect our customer relationships, could negatively impact our business prospects and could result in loss of business and revenue. Conversely, we may also sell the disposable kits directly to blood centers for the manufacture of IFC for their own account. As a result, we may be directly competing with these blood centers for the sale of IFC. These blood centers have more experience and existing contracts with hospitals and may be able to offer synergies that we cannot, each of which may negatively impact our ability to compete successfully.

In addition, until we are successful in selling INTERCEPT Blood System for Cryoprecipitation kits to blood center affiliate organizations or hospitals with in-house blood centers, our ability to directly commercialize finished IFC throughout the U.S. is dependent on the approval of manufacturing site BLAs by the FDA. While certain sites have received their BLAs, we cannot be sure that all of the sites will receive such authorizations in a timely manner, if at all. In addition, in order to market and sell finished IFC to hospital customers throughout the U.S., we may need to identify and validate additional manufacturing partners or sell INTERCEPT Blood System for Cryoprecipitation kits to blood center affiliate organizations or hospitals with in-house blood centers. We cannot guarantee that we will be able to successfully negotiate additional agreements with manufacturing partners on terms that are acceptable to us. IFC is a product derived from our INTERCEPT Blood System for plasma. As such, any supply disruptions or failures that could impact our plasma system will have a direct negative impact on the production of IFC. Such supply disruptions could negatively impact our ability to fulfill customer orders, which will have an adverse effect on our business reputation and the successful introduction and adoption of our new products. Further, unless or until we negotiate committed volume purchase agreements with our customers, we can provide no assurance that sales of IFC product will occur in consistent or predictable manner.

If we are unable to successfully market the INTERCEPT Blood System for cryoprecipitation to hospitals or comply with unique regulations governing finished biologics, our ability to monetize and deliver the INTERCEPT Blood System for cryoprecipitation will be negatively impacted which would materially and adversely affect our business, financial condition, results of operations and growth prospects. In addition, we may never achieve market acceptance and adoption of IFC by U.S. hospitals to generate product revenue sufficient to cover its costs.

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

We are exposed to potential liability risks inherent in the testing and marketing of medical devices and biologic products. We may be liable if any of our products cause injury, illness or death. Although we complete 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, or CE Certificate of Conformity has been received or after affixing the CE Mark to our products. For example, in cases where we have obtained regulatory approval or have affixed the CE Mark to 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. In addition, even if our products inactivate all pathogens in a blood product, it is often difficult to determine if pathogens are introduced after treatment with INTERCEPT due to blood center or hospital mishandling, shipping or other possibilities. For example, we have recently learned of instances where, following treatment with INTERCEPT, mishandling of the treated blood components has introduced environmental bacterium. We must help our blood center customers to remain or increase their vigilance in adopting best practices regarding blood component handling. Failure to adequately address this risk may call into question the efficacy of using pathogen reduction. There is also no way to determine whether any residual amount of a pathogen remains in the blood component treated by our products and there is no way to exclude that such residual amount would be enough to cause disease in the transfused patient or was a result of a potential defect or lack of efficacy of our products. We could be subject to a claim from a patient that tests positive, even though that patient did not contract a disease. In addition, should personnel at clinical study sites or ultimately, potential customers, be harmed by amustaline, or believe they have been or could be harmed by amustaline, our insurance coverage may be insufficient to provide coverage for any related potential liabilities. Amustaline is considered a potent chemical and is the active compound of our red blood cell system.

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

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

A recall of our products, either voluntarily or at the direction of the FDA, the competent authorities of an EU Member State, or another governmental authority, including foreign regulatory authority or the discovery of serious safety issues with our products that leads to corrective actions, could have a significant adverse impact on us.

Any adverse event involving our products, whether in the U.S. or abroad, could result in future voluntary corrective actions, such as recalls or customer notifications, or agency action, such as inspection, mandatory recall or other enforcement action. Any corrective

action, whether voluntary or involuntary, as well as defending ourselves in a lawsuit, will require the dedication of our time and capital, distract management from operating our business and may harm our reputation and financial results.

Under the FDA's 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. 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. We may initiate a product recall under our own initiative if any material deficiency in our product is found, such as a component failure, malfunctions, manufacturing errors, design or labeling defects or other deficiencies and issues, or withdraw a product to improve device performance or for other reasons. If we do not adequately address problems associated with our products, we may face additional regulatory enforcement action, including FDA warning letters, product seizure, injunctions, administrative penalties, or civil or criminal fines. Similar actions and obligations may be imposed by the competent authorities of an EU Member State, or a foreign regulatory authority.

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. Such events could impair our ability to supply our products in a cost-effective and timely manner in order to meet our customers' demands.

If our competitors develop products superior to ours, market their products more effectively, or receive regulatory approval before our products, our commercial opportunities could be reduced or be 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 depends 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. In addition, competitors or potential competitors may have substantially greater financial and other resources than we have. If competitive pathogen reduction 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 or human parvovirus B-19, which our products have not demonstrated an ability to inactivate or have not demonstrated a high level of inactivation. If our customers determine that competitor's products inactivate a broader range of pathogens that are of particular interest to the transfusion medicine community, market adoption of our platelet and plasma products may be adversely impacted. 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. Moreover, regulatory agencies may mandate use of competing products which would limit our ability to sell our products in those markets.

In addition, while we believe that IFC has many advantages over competitors, traditional cryoprecipitate and fibrinogen concentrates are well established within hospital use. Hospitals may not perceive the advantage of IFC over the competing products, we may be ineffective in selling biological agents directly to hospitals or be unable to demonstrate the economic or patient advantages to customers relative to the competitors. Further, competitors may have more experience marketing and selling products directly to hospitals.

Our platelet and plasma products and product candidates are not compatible with some collection, production and storage methods or combinations thereof. Further, blood centers using INTERCEPT must have access to those certain devices, blood bags, assays or platelet additive solutions that are compatible with our products.

The equipment and materials used to collect platelets vary by manufacturer and by geographic region. Platelets may be collected from a single donor by apheresis using an automated collection machine. Apheresis devices currently used in the U.S. and European markets differ, among other characteristics, in their ability to collect platelets in reduced volumes of plasma. Platelet collection device manufacturers may need to modify device collection parameters or software before a prospective customer could use INTERCEPT. If these manufacturers are not cooperative or are resistant to assist their customers or do not assist with making such modifications, the potential market for our products may be limited. Platelet concentrates may also be prepared from whole blood by pooling together platelets from multiple donors. There are two commonly used methods for preparing whole blood platelets: the buffy coat method, which is used extensively in Europe, and the pooled random donor method, which is used in the U.S. Our platelet system is designed to work with platelets collected and stored in storage solutions, called InterSol and SSP+, and for platelets suspended in 100% plasma. Fresenius is the exclusive manufacturer of InterSol and MacoPharma of SSP+, both widely-used PAS. Many of our customers and

prospective customers use InterSol or SSP+ in connection with INTERCEPT treatment. Similarly, some of our customers combine multiple platelet or plasma components before treating the combined product with INTERCEPT. Further, blood centers using INTERCEPT must have access to those certain devices, blood bags, assays or platelet additive solutions that are compatible with our products.

We understand that several third-party manufacturers of pooling sets are planning to discontinue producing pooling sets due to the requirement to comply under the new European Union Regulation (EU) 2017/745, the Medical Device Regulation, or MDR. Our customers' ability to use our INTERCEPT products may be impaired should manufacturers of those products cease production or if our customers are unable to find an alternate pooling set meeting their quality and production requirement for their production of INTERECEPT-treated blood components. In addition, should other manufacturers of collection devices, compatible assays and blood bags, pooling sets or platelet additive solutions fail to obtain or maintain regulatory approval, including a CE Certificate of Conformity necessary for affixing the CE Mark to our product under the MDR, experience unexpected production disruption, or decide to cease distribution of those respective products to customers and prospective customers, or prohibitively increase costs, our ability to sell the INTERCEPT Blood System may be impaired and acceptance within the marketplace could be harmed.

In order to address the entire market in the U.S., Japan, and potentially elsewhere, we will need to develop and test additional configurations of the platelet system. For example, in the U.S., we understand a significant number of platelet concentrates are derived from larger volumes collected from apheresis donors split into three therapeutic transfusable doses. While we have trained many customers to break down such donations to volumes and doses compatible with our products other prospective customers may not want to modify their operating practices and may therefore choose alternative compliant practices. In order to address these customers, we would need to develop future configurations of the platelet system to treat platelet donations with such processing parameters, which is not in our current plans. We estimate that the majority of platelets used in the U.S. are collected by apheresis, though a significant minority is prepared from pooled random donor platelets derived from whole blood collections. In addition, many blood centers may view pooled random donor platelets treated with INTERCEPT as an economically optimal approach. In order to gain regulatory approvals for a pathogen reduction system compatible with triple dose collections, and random donor platelets, we will need to perform additional product development and testing, including additional clinical trials. In the U.S, our approved labels for the platelet system from the FDA limit our current approvals to certain platelet collection platforms and a particular storage solution for the particular collection platform. For instance, our approved claims permit apheresis collection of platelets on the Fresenius Amicus device while stored in an additive solution or for apheresis collection of platelets collected on the Terumo Trima device and stored in 100% plasma. While we are seeking to generate acceptable data for Amicus collected platelets stored in 100% plasma, we cannot assure you that the data will be acceptable to the FDA or that we will receive timely approval, if ever. We may be required to provide the FDA with data for each permutation for which blood banking treatment practices exist which may be time consuming, costly and limit the potential size of the U.S. market that can use our products. In addition, 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. Given the current blood component shortage, increased collection volumes may not be achievable or use of INTERCEPT may be considered less efficient than other operating practices. 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. We may also 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. In any event, any failures or delays in obtaining FDA, CE Certificates of Conformity and other regulatory approvals for any new configurations would adversely affect our ability to introduce new or enhanced products in a timely manner, which in turn could materially harm our product revenue and prospects for potential future profitability.

Clinical trials are costly and time consuming, may take longer than we expect or may not be completed at all, and their outcomes are uncertain. A failure to generate data in clinical trials to support expanded label claims or to support marketing approvals for our product candidates could materially and adversely affect our business, financial condition, results of operations and growth prospects.

We are currently conducting multiple clinical trials for our products and product candidates and plan to commence additional clinical trials of our products and product candidates in the future. We cannot be certain that the design or conduct of, or data collected from, these trials will be sufficient to support FDA, a CE Certificate of Conformity prior to affixing a CE Mark or any other regulatory approvals outside the U.S. If we fail to produce positive results in our ongoing or planned clinical trials, the development timeline and regulatory approval and commercialization prospects for our products and our product candidates, and, correspondingly, our business, financial condition, results of operations and growth prospects, would be materially adversely affected. 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 ethics committee approval to conduct a study at a prospective clinical site, delays in recruiting subjects to participate in a study, delays in the conduct of the clinical trial by personnel at the clinical site or due to our inability to actively and timely monitor clinical trial sites because of travel restrictions, extreme weather or other natural forces, terrorist activity or general concerns over employee safety. In this regard, we have experienced delays

in our RedeS and ReCePI studies related to the COVID-19 pandemic and other factors. For example, in addition to COVID-19 related delays, some clinical sites for the RedeS study are located in areas that are subject to disruption by severe weather such as flooding, hurricanes or other natural forces such as earthquakes, which have delayed enrollment and progress of the RedeS study in the past. In addition, our ReCePI study in complex cardiovascular surgery patients had been slower to enroll due to a variety of factors including low frequency of administering red blood cells to the patient population and reticence to participate in research studies. If we are unable to enroll a sufficient number of patients from the ReCePI study to generate the data needed for licensure, we will need to reach agreement with the FDA on a new pathway to generate sufficient data for the red blood cell system, including the potential for additional Phase 3 clinical trials beyond what is currently contemplated with the RedeS and ReCePI studies. In any event, we cannot be certain that further delays in the RedeS study, the ReCePI study or other clinical trials will not occur because of the COVID-19 pandemic or other factors.

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 impacted the speed with which we were able to enroll patients in our European Phase 3 red blood cell system trial in chronic anemia patients, and may impact other studies. Given the need to phenotypically match donations and patients and the existing burden of managing the production and supply to sickle-cell anemia patients, donor recruitment in chronic anemia patients may be difficult or impractical, which may be costly or significantly delay or preclude our ability to obtain any FDA approval of our red blood cell system.

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 and larger clinical trials or in the results of routine use. 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 or Notified Bodies may require further toxicology or other studies to further demonstrate our products' safety, which could delay or preclude regulatory approval and commercialization. Furthermore, any major changes to components used in our products or configuration changes to our products may require additional toxicology studies which may not produce acceptable results. In addition, the FDA or foreign regulatory authorities may alter guidance at any time as to what constitutes acceptable clinical trial endpoints or trial design, which may necessitate a redesign of our product or proposed clinical trials and cause us to incur substantial additional expense or time in attempting to gain regulatory approval. Regulatory agencies weigh the potential risks of using our pathogen reduction products against the incremental benefits, which may be difficult or impossible to quantify.

If any additional product candidates receive approval for commercial sale in the U.S., or if we obtain approval for expanded label claims for the platelet system or plasma system, the FDA may require one or more post-approval clinical or *in vitro* studies as a condition of approval, such as the post-approval clinical study we are conducting in connection with the approval of the platelet system and the additional post-approval study that we are required to conduct on recovery and survival of platelets suspended in 100% plasma in connection with the expanded label claim that we received for the platelet system. In addition, the FDA has required that we successfully complete a recovery and survival study of platelets suspended in platelet additive solutions stored at five days. Each of these studies and any additional studies that the FDA may require could involve significant expense, may require us to secure adequate funding to complete and may not be successful. In addition, enrollment of post-marketing studies may be difficult to complete timely if customers of blood centers are reluctant to accept conventional, non-INTERCEPT-treated products once INTERCEPT products become available to them. Other regulatory authorities or Notified Bodies outside of the U.S. may also require post-marketing studies. Failure to successfully complete post-marketing studies may place certain restrictions on the use of our products or regulators could suspend or revoke our approvals.

The red blood cell system is currently in development and may never receive any marketing approvals or CE Certificates of Conformity.

While we are in the process of submitting for a CE Certificate of Conformity prior to affixing a CE Mark to our red blood cell system, it has not been approved for marketing or 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 CE Certificate of

Conformity and other regulatory approvals for the product. For instance, regulators or Notified Bodies may require clinical data for our red blood cell system under each collection and processing method using various additive or storage solutions before they would grant approval for any such configuration. The clinical data we have generated thus far and submitted for a Certificate of Conformity does not support multiple configurations of collection processes, storage solutions and kits. If we are required to and are ultimately unable to collect data under each configuration or if we limit our pursuit of certain configurations over others, our market opportunity may be limited. In any event, any failure or further delays in completing the development activities for the red blood cell system would prevent or continue to delay its commercialization, which would materially and adversely affect our business, financial condition, results of operations, growth prospects and potential future market adoption of any of our products, including the red blood cell system.

In some instances, we are relying on contract research organizations and other third parties to assist us in designing, managing, monitoring and otherwise carrying out our clinical trials and development activities for the red blood cell system. We do not control these third parties and, as a result, they may not treat our activities as their highest priority, or in the manner in which we would prefer, which could result in delays, inefficient use of our resources and could distract personnel from other activities. Additionally, if we, our contract research organizations, 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 or Notified Bodies may require us to perform additional clinical trials before delivering a CE Certificate of Conformity or 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. We must also be able to demonstrate stability of our active compounds manufactured under the FDA's cGMP regulations and similar requirements outside of the U.S. which meets release specifications. If we are unable to demonstrate an ability to manufacture according to our specifications under cGMP with acceptable stability data, we may be unable to satisfy regulatory questions and requirements which could prevent or delay the potential approval of or our ability to commercialize the red blood cell system. In addition, existing lots of these red blood cell compounds manufactured under cGMP may be dispositioned by regulators or ourselves as unsuitable for clinical use which would impact our ability to produce INTERCEPT-treated red blood cells for ongoing and future clinical trials and may require changes to the manufacturing process of our red blood cell compounds or new production of the compounds, all of which would be costly and time consuming and impact our ability to perform under our BARDA contract.

In 2003, we terminated Phase 3 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. While we successfully completed the European Phase 3 acute anemia clinical trial and the European Phase 3 chronic anemia clinical trial, we cannot assure you that the adverse events observed in the terminated 2003 Phase 3 clinical trials of our earlier red blood cell system will not be observed in current and potential future clinical trials using our modified process. We also cannot assure you that patients receiving INTERCEPT-treated red blood cells will not develop allergic reactions to the transfusion.

We will need to successfully conduct and complete license enabling Phase 3 clinical trials in the U.S. and to generate sufficient chronic anemia data for licensure. Given the need to phenotypically match donations and patients and the existing burden of managing the production and supply to sickle-cell anemia patients, donor recruitment in chronic anemia patients may be difficult or impractical, which could significantly delay or preclude our ability to obtain any FDA approval of our red blood cell system. In any event, there can be no assurance that we will be able to successfully complete these prerequisite Phase 3 clinical trials or otherwise generate sufficient Phase 3 clinical data. In part, we will seek to introduce supplemental clinical data we obtained from European clinical trials, though we cannot assure you that we will be able to demonstrate comparability or that the FDA will allow supplemental clinical European data. If treatment emergent antibody reactions associated with hemolysis are observed in any of our Phase 3 trials, the FDA will require us to place a clinical hold and we will need to investigate the underlying cause. Such investigations may be difficult for us to assess imputability which may lead to a complete halt of the clinical trial, may irreparably harm our red blood cell product's reputation and may force us to suspend or terminate development activities related to the red blood cell system in the U.S., which would have a material adverse effect on our business and business prospects. To date, several S-303 antibody events without evidence of hemolysis have been detected in the RedeS and ReCePI studies. We do not yet know if the S-303 antibody events were in the control or test arm, and we cannot provide any assurance that additional S-303 antibody events will not occur, or if they do occur, will not be clinically significant.

We completed our European Phase 3 clinical trials of our red blood cell system for acute anemia patients and separately for chronic anemia patients. We filed our application for a CE Certificate of Conformity related to the red blood cell system in December 2018 under the Medical Device Directive, or MDD, and in June 2021, we completed the resubmission of our application under the new MDR. While a Notified Body has agreed to review our CE Certificate of Conformity application for the red blood cell system, delays can occur for multiple reasons, including due to clock stops for questions on our application for a CE Certificate of Conformity or work load for the Notified Body. In addition, we are currently in discussions with our sole supplier of key components of the red blood cell system with respect to a dispute over its willingness to continue to supply us with such components, without changes, throughout the application process for our CE Certificate of Conformity. Because our CE Certificate of Conformity application under the new MDR for the red blood cell system is specific to this supplier's existing manufacturing site and manufacturing processes, if we are unable to reach satisfactory resolution of this dispute, or if this supplier is otherwise unable or unwilling to supply us with these components using its

existing manufacturing site and manufacturing processes, any approval decision on our CE Certificate of Conformity application would be delayed beyond our current expectations, and we may be required to engage and validate a new supplier for these components, which would substantially delay the timing of a decision on our CE Certificate of Conformity application, perhaps indefinitely. Accordingly, the timing of the ultimate decision on our CE Certificate of Conformity application and the related timing at which we may be able to affix the CE Mark to our product, remains subject to the satisfactory resolution of this dispute, including our current supplier's willingness to continue to supply us with these components using its existing manufacturing site and manufacturing processes throughout our CE Certificate of Conformity application and afterwards, if obtained, or alternatively, the engagement and validation of a new supplier of these key components, and in any event will be based on questions about our application for a CE Certificate of Conformity and the timing of the responses, and we do not otherwise expect a related decision will occur for at least another 12 months, if ever. Moreover, we do not yet know whether the data generated from our European Phase 3 clinical trials will be sufficient to support a CE Certificate of Conformity, even if limited to a target patient population having chronic anemia. Furthermore, we do not yet know if the clinical data we have generated will be sufficient to satisfy the stricter standards imposed by the MDR. If such data is deemed insufficient, we may need to generate additional safety data in clinical trials to satisfy the MDR standards. We will likely need to generate additional safety and efficacy data in order to achieve broad label claim or market acceptance. In addition, the European Phase 3 clinical trials in acute, and separately, chronic anemia patients, may need to be supplemented by additional, successful Phase 3 clinical trials for approval in certain countries. These data may need to be supplemented by additional, successful Phase 3 clinical trials for approval in certain countries. If such additional Phase 3 clinical trials are required, they would likely need to demonstrate non-inferiority of INTERCEPT red blood cells compared to conventional red blood cells and the significantly lower lifespan for INTERCEPT red blood cells compared to conventional red blood cells may limit our ability to obtain any regulatory approvals in certain countries for the red blood cell system. 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.

If we are unsuccessful in advancing the red blood cell system through clinical trials, resolving process and product design issues, securing commercial manufacturing for sufficient volumes or in obtaining subsequent regulatory approvals and acceptable reimbursement rates, we may never realize a return on our R&D expenses incurred to date for the red blood cell system program. Regulatory delays can also materially impact our product development costs. When we experience delays in testing, conducting trials or approvals, our product development costs will increase, which may exceed the budgets or timeframe under our BARDA agreement or which costs may otherwise not be reimbursable to us under the BARDA agreement. Even if we were to successfully complete and receive approval for our red blood cell system, potential blood center customers may object to working with a potent chemical, like amustaline, the active compound in the red blood cell system, or may require modifications to automate the process, which would result in additional development costs, any of which could limit any market acceptance of the red blood cell system. If the red blood cell system were to face such objections from potential customers, we may choose to pay for capital assets, specialized equipment or personnel for the blood center, which would have a negative impact on any potential contribution margin from red blood cell system sales. Moreover, customers may not accept the manual configuration of the product and require us to develop a more operationally scalable version of the system which would be expensive and may not be successful. Additionally, the use of the red blood cell system may result in some processing loss of red blood cells. If the loss of red blood cells leads to increased costs, or the perception of increased costs for potential customers, or potential customers believe that the loss of red blood cells reduces the efficacy of the transfusion unit, or our process requires changes in blood center or clinical regimens, potential customers may not adopt our red blood cell system, even if approved for commercial sale.

Risks Related to Regulatory Approval, CE Certificates of Conformity, and Oversight, and Other Legal Compliance Matters

Our company, our products, and blood products treated with the INTERCEPT Blood System are subject to extensive regulation by domestic, foreign authorities and Notified Bodies.

Our products, both those sold commercially and those under development are subject to extensive and rigorous regulation by local, state and federal regulatory authorities in the U.S. and by foreign regulatory bodies and Notified Bodies. 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 and Notified Bodies to approve them for commercial use. For our product candidates, we must provide the FDA and international regulatory authorities and Notified Bodies with preclinical, clinical and manufacturing data demonstrating that our products are safe, effective and in compliance with government regulations before the products can be approved for commercial sale. The process of obtaining required regulatory approvals and certifications 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, certifications or licenses, or we may not be successful at all. In addition, our labeling claims may not be consistent across markets. We have developed our products with the aim to standardize the volume of platelets treatable by our system, wherever possible, which may not be accepted by all regulators or customers, may require additional data to support approval or certifications or may not produce optimal transfusable blood components. For example, jurisdictions differ in the definition of what constitutes a transfusable unit of platelets and in certain jurisdictions, our approved label claims and the definition of a viable platelet unit for transfusion may allow for a significantly lower or higher platelet count per volume than certain jurisdictions may allow. This variability in platelet count per volume may result in differences in platelet quality once processed and stored using INTERCEPT, and if customers experience sub-optimal platelet quality following INTERCEPT treatment, they may limit their adoption of INTERCEPT or consider adoption of competing blood safety technologies over INTERCEPT.

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 or certifications and subsequent adoption of our potential products. We cannot predict the adoption, implementation or impact of adverse governmental regulation that might arise from future legislative or administrative action.

Outside of the U.S., regulations vary by country, including the requirements for regulatory and marketing approvals, certifications or clearance, the time required for regulatory review and the sanctions imposed for violations. In addition to technical documentation supporting the CE Marking of our product, countries outside the EU may require clinical data submissions, registration packages, import licenses or other documentation. Regulatory authorities in Japan, China, Taiwan, South Korea, Vietnam, Thailand, Singapore and elsewhere may require in-country clinical trial data, among other requirements, or that our products be widely adopted commercially in Europe and the U.S., or may delay such approval decisions until our products are more widely adopted. In addition to the regulatory requirements applicable to us and to our products, there are regulatory requirements in several countries around the world, including the U.S., Germany, Canada, Austria, Australia and other countries, applicable to prospective customers of INTERCEPT Blood System products and 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. Significant product changes or changes in the way customers use our products may require amendments or supplemental approvals to licenses already obtained. Blood centers that do submit applications, supplements or amendments 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.

In March 2020, we received extensions of our CE Certificate of Conformity for the platelet and plasma systems to 2024 that was issued on the basis of the MDD. We submitted our CE Certificate of Conformity application for approval of the platelet system under the new MDR in November 2021 and subsequently completed our CE Certificate of Conformity submission for the plasma system under the new MDR, but cannot currently assure you that our products will timely meet the requirements of the new MDR prior to the expirations of our CE Certificate of Conformity that was issued on the basis of the MDD. Our failure to meet the requirements of the new MDR could materially and adversely affect our business, financial condition, results of operations and growth prospects. We or our customers have received approval for the sale and/or use of INTERCEPT-treated platelets and plasma within Europe in France, Switzerland, Germany and Austria. However, we have recently learned that Swiss regulators will no longer accept CE Certificates of Conformity issued on the basis of the MDR for EU based medical devices on the basis of the mutual recognition agreement concluded between the parties. While we are currently in the process of completing the requirements to maintain regulatory approval of our products in Switzerland, we cannot assure you that we will be successful in doing so. In addition, we or our customers may also be required to conduct additional testing in order to obtain regulatory approval in countries that do not recognize the CE Mark as being adequate for commercializing the INTERCEPT Blood System in those countries. The level of additional product testing varies by country, but could be expensive or take a long time to complete. In addition, regulatory agencies are able to withdraw or suspend previously issued approvals due to changes in regulatory law, our inability to maintain compliance with regulations or other factors. In 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 business, financial condition, results of operations and growth prospects would be materially and adversely impacted.

The advertising and promotion of medical devices in the EU is subject to the national laws of EU Member States applying the MDR, Directive 2006/114/EC concerning misleading and comparative advertising, and Directive 2005/29/EC on unfair commercial practices, as well as other national legislation of individual EU Member States governing the advertising and promotion of medical devices. EU Member State legislation may also restrict or impose limitations on our ability to advertise our products directly to the general public. In addition, voluntary EU and national Codes of Conduct provide guidelines on the advertising and promotion of our products to the general public and may impose limitations on our promotional activities with healthcare professionals.

Moreover, we may be required to conduct costly post-market testing and surveillance to monitor the safety or effectiveness of our products in the EU. We must comply with medical device reporting requirements, including the reporting of adverse events and malfunctions related to our products. Later discovery of previously unknown problems with our products, including unanticipated adverse events or adverse events of unanticipated severity or frequency, manufacturing problems, or failure to comply with regulatory requirements may result in changes to labeling, restrictions on such products or manufacturing processes, withdrawal of the products from the market, voluntary or mandatory recalls, a requirement to repair, replace or refund the cost of any medical device we manufacture or distribute, fines, suspension of regulatory clearances or approvals, product seizures, injunctions or the imposition of civil or criminal penalties which would adversely affect our business, operating results and prospects.

As a condition to the initial FDA approval of the platelet system, we were required to submit data from a post-approval clinical study of the platelet system – a haemovigilance study to evaluate the incidence of acute lung injury following transfusion of INTERCEPT-treated platelets. While that post marketing study was successful, we are also required to conduct a post-approval recovery and survival

clinical study in connection with the label expansion approval for the use of the platelet system to treat platelets suspended in 100% plasma as well as a recovery and survival study of platelets suspended in platelet additive solutions stored at five days. Successful enrollment and completion of these additional post-approval studies will require that we identify and contract with hospitals that have the desire and ability to participate and contribute to the study in a timely manner and who are willing to purchase INTERCEPT-treated platelets from our blood center customers, which we may be unable to do in a timely manner or at all. In addition, 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 financial condition and results of operations. In addition, there is a risk that post-approval studies will be unsuccessful or 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. Failure to successfully complete post-marketing studies may place certain restrictions on the use of our products or regulators could suspend or revoke our approvals.

We are also required to comply with applicable FDA and other regulatory post-approval requirements relating 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 authorities' requirements, including, in the U.S., ensuring that quality control and manufacturing procedures conform to cGMP and current QSR requirements. We must also 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. 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, or a violation or any other federal or state law that applies to us, such as laws prohibiting false claims for reimbursement. In addition, our reputation could be damaged and adoption of the products could be impaired.

If a regulatory authority or Notified Body suspects or discovers problems with a product, such as adverse events of unanticipated severity or frequency, or problems with the facility or the manufacturing process at the facility where the product is manufactured, or problems with the quality of product manufactured, or disagrees with the promotion, marketing, or labeling of a product, a regulatory authority 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, seizure, 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 and regulatory strategies;
- exclusion from participation in government programs, such as Medicare and Medicaid;
- refusal to grant export or import approval for our products or refusal to allow us to enter into government contracts;
- additional reporting obligations and oversight if we become subject to a corporate integrity agreement or other agreement to resolve allegations of non-compliance;
- withdrawing or variation in marketing approvals or CE Certificates of Conformity 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.

Should we obtain approval or a CE Certificate of Conformity for our red blood cell system, we will likely be required by regulators or Notified Bodies to collect additional data in patients receiving INTERCEPT-treated red blood cells. In addition, assuming approval or certification, we will be required to develop a registry of patients receiving INTERCEPT-treated red blood cells for future data collection and evaluation. To commence, enroll and complete such a registry, we may incur significant costs. Further, introducing and implementing use of such a registry may face data collection challenges or resistance from transfusing physicians, hospitals or patients. We cannot ensure that the data collected in such a registry would support continued use of INTERCEPT-treated red blood cells.

In addition, the regulations to which we are subject are complex and have become more stringent over time. Regulatory changes could result in restrictions on our ability to carry on or expand our operations, increased operation costs or lower than anticipated sales. For example, complying with the new MDR will require considerable time, attention and effort by our manufacturers and us and may limit or delay any contemplated changes to our products or expansion of label claims. In addition, regulators have been impacted by the global staffing shortage, further constraining their ability to review submissions timely.

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

In order to be used in clinical studies or sold in the U.S., our products are required to be manufactured in FDA-approved facilities. If any of our suppliers fail to comply with FDA's cGMP regulations or otherwise fail to maintain FDA approval, we may be required to identify an alternate supplier for our products or components. Our products are complex and difficult to manufacture. Finding alternate facilities and obtaining FDA approval for the manufacture of the INTERCEPT Blood System at such facilities would be costly and time-consuming and would negatively impact our ability to generate product revenue from the sale of our platelet, plasma or cryoprecipitation system in the U.S. and achieve operating profitability. Our red blood cell system also needs to be manufactured in FDA-approved facilities, several of which are not currently FDA-approved. Failure of our suppliers to meet cGMP regulations and failure to obtain or maintain FDA approval will negatively impact our ability to achieve FDA approval for our red blood cell system or may require that we identify, qualify and contract with alternative suppliers, if they are available, which would be time consuming, costly and result in further approval delays.

We and our third-party suppliers are also required to comply with the 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 and other regulatory authorities, including third country authorities and Notified Bodies, audit compliance with cGMP and QSR requirements through periodic announced and unannounced inspections of manufacturing and other facilities. These audits and inspections may be conducted at any time. The manufacturing facility which produces our platelet and plasma systems was recently audited by the FDA. While there were not objectionable conditions observed during the audit, the FDA or other regulatory authorities may inspect and audit facilities manufacturing or products or components at any time. Complying with and resolving any audit findings may result in additional costs, changes to our manufacturers' quality management systems or both. Failure to timely resolve and comply to audit findings, if any, may result in enforcement actions and may result in a disruption to the supply of our products. In any event, 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 or other regulatory agency 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 or variation of marketing approvals or CE Certificates of Conformity 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, results of operations and growth prospects.

If we modify our FDA-approved or CE Marked 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, plasma or cryoprecipitation systems could be determined to significantly affect their safety or effectiveness, including significant design and manufacturing changes, or determined to constitute a major change in their intended use, manufacture, design, components, or technology which would require approval of a new premarket approval application, or PMA, or PMA supplement. Further, any modification to our plasma system may have an impact on the cryoprecipitation system, which may similarly require approval of a new 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 submissions 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, we are redesigning the illuminators used in the platelet and plasma systems and may need to further redesign the illuminator. We will need to obtain regulatory approval of any future redesign of the illuminator before it can be commercialized. Generating data from the new illuminator may be time consuming, expensive or unsuccessful. In addition, in order to address the entire market in the U.S., customers will need to change their operating practices to conform to our product specifications or we will need to obtain approval for additional configurations of the platelet system, as discussed in greater detail above under "*Risks Related to Our Business and Industry—Our platelet and plasma products and product candidates are not compatible with some collection, production and storage methods or combinations thereof*." Should we decide not to pursue or otherwise fail to obtain FDA and foreign regulatory approvals of any new configurations, our ability to generate product revenue from sales of the platelet system may be impaired and our growth prospects may be materially and adversely affected.

In addition, if the FDA or other regulatory or accrediting body were to mandate safety interventions, including the option of pathogen reduction technology, when we had not received approval for all operational configurations, the market to which we could sell our products may be limited until we obtain such approvals, if ever, or may be permanently impaired if competing options are more broadly available.

For those products sold in the EU, we must notify our Notified Body if significant changes are made to the products or if there are substantial changes to our quality assurance systems affecting those products. If a significant change is made to products which have been CE Marked on the basis of CE Certificates of Conformities delivered on the basis of the MDD, we may no longer be able to rely on our CE Certificates of Conformities delivered on the basis of the MDD and may need to obtain CE Certificates of Conformity on the basis of the MDR. Obtaining certification can be a time-consuming process, and delays in obtaining required future clearances or approvals would adversely affect our ability to introduce new or enhanced products in a timely manner, which in turn would harm our future growth.

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, among other things, limiting the kinds of financial arrangements we may have with hospitals, 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 EU, the control of unlawful marketing activities is a matter of national law and regulations in each of the EU Member States. There are a variety of organizations and entities within EU Member States which monitor perceived unlawful marketing activities. We could face civil, criminal and administrative sanctions if it is determined that we have breached our obligations in any EU Member State in respect of our marketing activities. 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, state and local healthcare regulatory laws, and equivalent foreign laws, and equivalent third country 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, blood centers, physicians, other healthcare providers, and our customers are subject to scrutiny under these laws. Violations of these laws can subject us to significant 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, or equivalent foreign programs, additional reporting requirements and/or oversight if we become subject to a corporate integrity agreement or similar agreement to resolve allegations of non-compliance with these laws, 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 offering, paying, soliciting, or receiving any remuneration, directly or indirectly, overtly or covertly, in cash or in kind, in exchange for or to induce, the referral of an individual for, 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, including the civil False Claims Act, which can be enforced by private citizens on behalf of the government, through civil whistleblower or qui tam actions, and the federal civil monetary penalties law, that prohibit, among other things, knowingly presenting, or causing to be presented, claims for payment or approval from Medicare, Medicaid or other federal payors that are false or fraudulent, or knowingly making a false statement to improperly avoid, decrease or conceal an obligation to pay money to the federal government, and which may apply to entities that provide coding and billing advice to customer;

- the federal Health Insurance Portability and Accountability Act of 1996, as amended, or HIPAA, which created federal criminal laws that prohibit, among other things, executing a scheme to defraud any healthcare benefit program, including private payors, or making materially false statements in connection with the delivery of, or payment for, healthcare benefits, items or services relating to healthcare matters;
- HIPAA, as amended by the Health Information Technology for Economic and Clinical Health Act of 2009, or HITECH, and their respective implementing regulations, which impose requirements on covered entities, including certain healthcare providers, health plans and healthcare clearinghouses as well as their business associates and their subcontractors that create, receive, maintain or transmit individually identifiable health information for or on behalf of a covered entity, relating to the privacy, security and transmission of individually identifiable health information, 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 or local 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 and local 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.

In addition, there has been a trend of increased U.S. federal, state and local regulation of payments and transfers of value provided to healthcare professionals or entities. The Physician Payments Sunshine Act, imposes annual reporting requirements on device manufacturers for which payment is available under Medicare, Medicaid, or the Children's Health Insurance Program, with specific exceptions, to track and annually report to the Centers for Medicare & Medicaid Services, or CMS, for payments and other transfers of value provided by them, directly or indirectly, to physicians (defined to include doctors, dentists, optometrists, podiatrists and chiropractors), other healthcare professionals (such as physician assistants and nurse practitioners) and teaching hospitals, as well as ownership and investment interests held by physicians and their family members. 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.

We are also subject to domestic and foreign laws and regulations covering data privacy and the protection of health-related and other personal information. Domestic privacy and data security laws are complex and changing rapidly. Many states have enacted laws regulating the online collection, use and disclosure of personal information and requiring that companies implement reasonable data security measures. Laws in all states and U.S. territories also require businesses to notify affected individuals, governmental entities and/or credit reporting agencies of certain security breaches affecting personal information. These laws are not consistent, and compliance with them in the event of a widespread data breach is complex and costly.

In the U.S., the California Consumer Privacy Act of 2018, or CCPA, gives California residents expanded rights related to their personal information, including the right to access and delete their personal information, and receive details about how their personal information is used and shared. These create an additional burden on us, as do the restrictions on "sales" of personal information that allow Californians to opt-out of certain sharing of their personal information. The CCPA prohibits discrimination against individuals who exercise their privacy rights, provides for civil penalties for violations and creates a private right of action for data breaches that is expected to increase data breach litigation. Similarly, the California Privacy Rights Act, or CPRA, when it becomes effective on January 1, 2023, will restrict use of certain categories of sensitive personal information; further restrict the use of cross-contextual advertising techniques; establish restrictions on the retention of personal information; expand the types of data breaches subject to the private right of action; and establish the California Privacy Protection Agency to implement and enforce the new law, as well as impose administrative fines. Other states have also enacted data privacy laws. For example, Virginia passed the Consumer Data Protection Act, and Colorado passed the Colorado Privacy Act, both of which differ from the CPRA and become effective in 2023. If we become subject to new data privacy laws, at the state level, the risk of enforcement action against us could increase because we may become subject to additional obligations, and the number of individuals or entities that can initiate actions against us may increase (including individuals, via a private right of action, and state actors).

In the EU, the General Data Protection Regulation, or GDPR, which is wide-ranging in scope, imposes detailed requirements relating to the control over personal data by individuals to whom the personal data relates, the information that we must provide to the individuals, the documentation we must maintain, the security and confidentiality of the personal data, data breach notification and the use of third-party processors in connection with the processing of personal data. The GDPR also imposes strict rules on the transfer of personal data

out of the EU and authorizes the imposition of large penalties for noncompliance, including the potential for fines of up to €20 million or 4% of the annual global revenues of the non-compliant company, whichever is greater.

Further, the exit of the United Kingdom, or UK, from the EU, often referred to as Brexit, has created uncertainty with regard to data protection regulation in the UK. Specifically, the UK exited the EU on January 1, 2020, subject to a transition period that ended December 31, 2020. The UK has implemented legislation similar to the GDPR, the UK GDPR, including the UK Data Protection Act, which provides for fines of up to the greater of 17.5 million British Pounds or 4% of a company's worldwide turnover, whichever is higher. Additionally, the relationship between the UK and the EU in relation to certain aspects of data protection law remains unclear following Brexit, including with respect to regulation of data transfers between EU Member States and the UK. On June 28, 2021, the European Commission announced a decision of "adequacy" concluding that the UK ensures an equivalent level of data protection to the GDPR, which provides some relief regarding the legality of continued personal data flows from the European Economic Area, or EEA, to the UK. Some uncertainty remains, however, as this adequacy determination must be renewed after four years and may be modified or revoked in the interim. We cannot fully predict how the Data Protection Act, the UK GDPR, and other UK data protection laws or regulations may develop in the medium to longer term nor the effects of divergent laws and guidance regarding how data transfers to and from the UK will be regulated.

Certain jurisdictions have enacted data localization laws and cross-border personal data transfer laws, which could make it more difficult to transfer information across jurisdictions (such as transferring or receiving personal data that originates in the EEA). Recent legal developments in Europe have created complexity and compliance uncertainty regarding certain transfers of personal data from the EEA. For example, on July 16, 2020, the Court of Justice of the European Union, or CJEU, invalidated the EU-U.S. Privacy Shield Framework (the "Privacy Shield") under which personal data could be transferred from the EEA to United States entities who had self-certified under the Privacy Shield scheme. While the CJEU upheld the adequacy of the standard contractual clauses ("SCCs") (a standard form of contract approved by the European Commission as an adequate personal data transfer mechanism, and potential alternative to the Privacy Shield), it made clear that reliance on them alone may not necessarily be sufficient in all circumstances. Use of SCCs must now be assessed on a case-by-case basis taking into account the legal regime applicable in the destination country, in particular applicable surveillance laws and rights of individuals. On June 4, 2021, the European Commission published a decision adopting an updated set of SCCs designed to address issues identified by the CJEU. The revised SCCs must be used for relevant new data transfers from September 27, 2021; and existing standard contractual clauses arrangements must be migrated to the revised clauses by December 27, 2022. The new SCCs apply only to the transfer of personal data outside of the EEA and not the UK. The UK is not subject to the European Commission's new standard contractual clauses but has published its own transfer mechanism, the International Data Transfer Agreement ("IDTA"), which enables transfers from the UK. We will be required to implement these new safeguards when conducting restricted data transfers under the GDPR and the UK. GDPR and doing so will require significant effort and cost. In addition, additional measures may be required even when relying on standard contractual clauses or the IDTA, where the laws of the importer's country do not offer an adequate level of protection, such as the United States.

The CCPA, CPRA and similar laws in other states, GDPR and other international privacy laws have increased our responsibility and potential liability in relation to personal data that we process compared to prior law, including in clinical trials and employee data, and we may be required to put in place additional mechanisms to ensure compliance with these laws, which could divert management's attention and increase our cost of doing business. However, despite our ongoing efforts to bring our practices into compliance with the GDPR and the UK GDPR, we may not be successful either due to various factors within our control or other factors outside our control. It is also possible that local courts and data protection authorities may have different interpretations of applicable law, leading to potential inconsistencies in application of these laws. If we are unable to implement sufficient safeguards to ensure that our transfers of personal information from the EEA are lawful, we will face increased exposure to regulatory actions, substantial fines, and injunctions against processing personal information from the EEA.

Complying with our obligations under applicable privacy laws, regulations, amendments to or re-interpretations of existing laws and regulations, and contractual or other requirements relating to privacy, data protection, data transfers, data localization, or information security may require us to make changes to our services to enable us or our customers to meet new legal requirements, incur substantial operational costs, modify our data practices and policies, and restrict our business operations. Any failure or alleged failure (including as a result of deficiencies in our policies, procedures or measures relating to privacy, data security, marketing or communications) by us to comply with laws, regulations, policies, legal or contractual obligations, industry standards or regulatory guidance relating to privacy or data security, may result in governmental investigations and enforcement actions, litigation, fines and penalties or adverse publicity. In addition, new regulations, legislative actions or changes in interpretation of existing laws or regulations regarding data privacy and security (together with applicable industry standards) may increase our costs of doing business.

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, distributors or joint venture partners 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, distributors or joint venture partners 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.

To enforce compliance with the healthcare regulatory laws, federal and state enforcement bodies have increased their scrutiny of interactions between healthcare companies and healthcare providers, which have led to a number of investigations, prosecutions, convictions and settlements in the healthcare industry. Any such investigation or settlement could increase our costs or otherwise have an adverse effect on our business. In addition, most of these laws apply to not only the actions taken by us, but also actions taken by our distributors and other third-party agents, and healthcare providers with whom we interact. 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.

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

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

Federal and state governments in the U.S. have 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 Patient Protection and Affordable Care Act, or ACA, continues to significantly impact the health care industry. Among other things, the ACA:

- established a Patient-Centered Outcomes Research Institute to oversee and identify priorities in comparative clinical effectiveness research in an effort to coordinate and develop such research; and
- implemented 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.

There have been executive, judicial and Congressional challenges to numerous provisions of the ACA. For example, legislation enacted in 2017, informally titled the Tax Cuts and Jobs Act of 2017, or the Tax Act, included a provision repealing, effective January 1, 2019, the tax-based shared responsibility payment imposed by the ACA on certain individuals who fail to maintain qualifying health coverage for all or part of a year that is commonly referred to as the "individual mandate". On June 17, 2021, the U.S. Supreme Court dismissed a challenge on procedural grounds that argued the ACA is unconstitutional in its entirety because the "individual mandate" was repealed by Congress. Thus, the ACA will remain in effect in its current form. Further, prior to the U.S. Supreme Court ruling, on January 28, 2021, President Biden issued an executive order that initiated a special enrollment period for purposes of obtaining health insurance coverage through the ACA marketplace, which began on February 15, 2021, and remained open through August 15, 2021. The executive order also instructed certain governmental agencies to review and reconsider their existing policies and rules that limit access to healthcare, including among others, reexamining Medicaid demonstration projects and waiver programs that include work requirements, and policies that create unnecessary barriers to obtaining access to health insurance coverage through Medicaid or the ACA. It is possible that the ACA will be subject to judicial or Congressional challenges in the future. It is unclear how any such challenges and the healthcare reform efforts of the Biden administration will impact ACA and our business. The implementation of new health care legislation could result in significant changes to the health care system, which could have a material adverse effect on our business, results of operations, financial condition and growth prospects.

In addition, other legislative changes have been proposed and adopted since the ACA 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, due to subsequent legislative amendments to the statute, will stay in effect through 2030, unless additional congressional action is taken. However, COVID-19 relief support legislation suspended the 2% Medicare sequester from May 1, 2020 through March 31, 2022. Under current legislation the actual reduction in Medicare payments will vary from 1% in 2022 to up to 3% in the final fiscal year of this sequester. 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. In addition, Congress is considering additional health reform measures.

More recently, there has been heightened governmental scrutiny in the U.S. to control the rising cost of healthcare. For example, such scrutiny has resulted in several recent presidential executive orders, congressional inquiries and federal and state legislative activity designed to, among other things, bring more transparency to pricing and reform government program reimbursement methodologies for healthcare products. State legislatures are also increasingly passing legislation and implementing regulations designed to control the cost of healthcare, including price or patient reimbursement constraints, discounts, restrictions on certain product access and marketing cost disclosure and transparency measures.

We cannot predict the likelihood, nature, or extent of health reform initiatives that may arise from future legislation or administrative action. 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.

The changes to the regulatory system implemented in the EU by the MDR include stricter requirements for clinical evidence and pre-market assessment of safety and performance, new classifications to indicate risk levels, requirements for third party testing by Notified Bodies, additional requirements for the quality management system, traceability of products and transparency as well a refined responsibility of economic operators. We are also required to provide clinical data in the form of a clinical evaluation report. Fulfilment of the obligations imposed by the MDR may cause us to incur substantial costs. We may be unable to fulfil these obligations, or our Notified Body, where applicable, may consider that we have not adequately demonstrated compliance with our related obligations to merit a CE Certificate of Conformity on the basis of the MDR.

Moreover, in the EU some countries may require the completion of additional studies that compare the cost-effectiveness of a particular medical device candidate to currently available therapies. This Health Technology Assessment, or HTA process, which is currently governed by the national laws of the individual EU Member States, is the procedure according to which the assessment of the public health impact, therapeutic impact and the economic and societal impact of use of a given medical device in the national healthcare systems of the individual country is conducted. The outcome of HTA regarding specific medical device will often influence the pricing and reimbursement status granted to these products by the competent authorities of individual EU Member States. On January 31, 2018, the European Commission adopted a proposal for a regulation on health technologies assessment. The proposed regulation is intended to boost cooperation among EU Member States in assessing health technologies, including new medical devices, and providing the basis for cooperation at EU level for joint clinical assessments in these areas. In December 2021 the HTA Regulation was adopted and entered into force on January 11, 2022. It will apply from 2025 onward.

Risks Related to Government Contracts

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

We anticipate that a significant portion of the funding for the development of the red blood cell system in the United States will come from our agreement with BARDA. The agreement, including its subsequent modifications, provide for reimbursement of certain expenses incurred by us for up to approximately $246.5 million to support the development of the red blood cell system. However, our agreement with BARDA only reimburses certain specified development and clinical activities that have been authorized by BARDA pursuant to the base period and certain options of the agreement and the potential exercise of subsequent option periods. To date, BARDA has exercised approximately $149.5 million under the base period of the agreement and associated options. Accordingly, our ability to receive any of the unexercised $97.0 million in additional funding provided for under the BARDA agreement is dependent on BARDA exercising additional options under the agreement, which it may do or not do at its sole discretion. In addition, BARDA is entitled to terminate our BARDA agreement for convenience at any time, in whole or in part, and is not required to provide continued funding beyond reimbursement of amounts currently incurred and obligated by us as a result of contract performance. In addition, activities covered under the base period and exercised options may ultimately take longer than is allowed or cost more than is covered by the BARDA contract. Exercised and unexercised options under the BARDA contract will likely require a longer performance period to complete than is remaining on our agreement; if we are unable to secure additional funding or allow for additional time for completion, we would have to bear the cost to complete the activities or terminate the activities before completion. In addition, should there be a temporary funding shortfall with any of the activities contemplated, we may need to cease, delay or defer completion of the activities until the funding shortfall is resolved, if ever. We have hired and maintain staffing, as well as having entered into agreements with third parties to perform activities associated with the BARDA contract. Should we be unable to fully utilize the personnel or third parties as planned, either because of BARDA funding or time limitations, or other reasons, we may be forced to bear costs that we had anticipated would be covered under the contract. Moreover, the continuation of our BARDA agreement depends in large part on our ability to meet development milestones previously agreed to with BARDA and on our compliance with certain operating procedures and protocols. BARDA may suspend or terminate the agreement should we fail to achieve key milestones, or fail to comply with the operating

procedures and processes approved by BARDA and its audit agency. There can be no assurance that we will be able to achieve these milestones or continue to comply with these procedures and protocols. The uncertainty regarding the duration of the COVID-19 pandemic, and its impact on participating blood centers, hospitals and their patients, severe weather or other natural disaster impacts to sites enrolling our clinical trials may all negatively impact our ability to complete our clinical trials. Our ability to meet the expectations of BARDA under our contract is largely dependent on our ability to attract, hire and retain personnel with competencies that are in short supply. In addition, in many instances we must identify third-party suppliers, negotiate terms acceptable to us and BARDA and ensure ongoing compliance by these suppliers with the obligations covered by our BARDA agreement. If we are unable to provide adequate supplier oversight or if suppliers are unable to comply with the requirements of the agreement, our ability to meet the anticipated milestones may be impaired.

There can also be no assurance that our BARDA agreement will not be terminated, that our BARDA agreement will be extended for existing exercised options or through the exercise of subsequent option periods, that any such extensions would be on terms favorable to us, or that we will otherwise obtain the funding that we anticipate to obtain under our agreement with BARDA. In addition, access to federal contracts is subject to the authorization of funds and approval of our research plans by various organizations within the federal government, including the U.S. Congress. The general economic environment and uncertainty associated with the COVID-19 pandemic, coupled with tight federal budgets, has led to a general decline in the amount available for government funding. Moreover, changes in government budgets and agendas may result in a decreased and deprioritized emphasis on supporting the development of pathogen reduction technology. While BARDA has provided funding for and has indicated a potential for future funding for many activities associated with combating COVID-19, the availability and focus for any BARDA funding will likely be finite and may require us to compete with other technologies, both similar and disparate. Furthermore, funding limitations may require certain activities to slow or be deferred which may be impractical to do. In addition, if we are unable to generate sufficient prerequisite Phase 3 clinical data, our agreement with BARDA will be severely limited in scope or could be terminated altogether, and our ability to complete the development activities required for licensure in the U.S. may require additional capital beyond which we currently have. If our BARDA agreement is terminated or suspended, if there is any reduction or delay in funding under our BARDA agreement, or if BARDA determines not to exercise some or all of the options provided for under the agreement, our revenues and cash flows would be significantly and negatively impacted and we may be forced to seek alternative sources of funding, which may not be available on non-dilutive terms, terms favorable to us or at all. If alternative sources of funding are not available, or if we determine that the cost of alternative available capital is too high, we may be forced to suspend or terminate development activities related to the red blood cell system in the U.S. Furthermore, should we be unable to deploy personnel or derive a benefit from fixed study costs or generate data from clinical sites and studies reimbursed by BARDA, our cash flows would be negatively impacted, or we may have to initiate furloughs and layoffs which would likely prove disruptive to our management and operations. This in turn would impair our ability to complete ongoing studies or commence new studies.

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

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

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

- audit and object to any BARDA agreement-related costs and fees on grounds that they are not allowable under the Federal Acquisition Regulation, or FAR, and require us to reimburse all such costs and fees;
- suspend or prevent us for a set period of time from receiving new contracts or grants or extending our existing agreement based on violations or suspected violations of laws or regulations;
- claim nonexclusive, nontransferable rights to product manufactured and intellectual property developed under the BARDA agreement and may, under certain circumstances involving public health and safety, license such inventions to third parties without our consent;
- cancel, terminate or suspend our BARDA agreement based on violations or suspected violations of laws or regulations;
- terminate our BARDA agreement in whole or in part for the convenience of the government for any reason or no reason, including if funds become unavailable to the U.S. Department of Health and Human Services' Office of the Assistant Secretary for Preparedness and Response;

- reduce the scope and value of our BARDA agreement;
- decline to exercise an option to continue the BARDA agreement;
- direct the course of the development of the red blood cell system in a manner not chosen by us;
- require us to perform the option periods provided for under the BARDA agreement even if doing so may cause us to forego or delay the pursuit of other red blood cell program opportunities with greater commercial potential;
- take actions that result in a longer development timeline than expected;
- limit the government's financial liability to amounts appropriated by the U.S. Congress on a fiscal-year basis, thereby leaving some uncertainty about the future availability of funding for the red blood cell program even after it has been funded for an initial period; and
- change certain terms and conditions in our BARDA agreement.

Generally, government contracts, including our agreement with BARDA, contain provisions permitting unilateral termination or modification, in whole or in part, at the U.S. government's convenience. Termination-for-convenience provisions generally enable us to recover only our costs incurred or committed (plus a portion of the agreed fee) and settlement expenses on the work completed prior to termination. Except for the amount of services received by the government, termination-for-default provisions do not permit recovery of fees. In addition, in the event of termination or upon expiration of our BARDA agreement, the U.S. government may dispute wind-down and termination costs and may question prior expenses under the contract and deny payment of those expenses. Should we choose to challenge the U.S. government for denying certain payments under our BARDA agreement, such a challenge could subject us to substantial additional expenses that we may or may not recover. Further, if our BARDA agreement is terminated for convenience, or if we default by failing to perform in accordance with the contract schedule and terms, a significant negative impact on our cash flows and operations could result.

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

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

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

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

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

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

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

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

In addition, as a U.S. government contractor, we are required to comply with applicable laws, regulations and standards relating to our accounting practices and are subject to periodic audits and reviews. As part of any such audit or review, the U.S. government may review the adequacy of, and our compliance with, our internal control systems and policies, including those relating to our purchasing, property, estimating, compensation and management information systems. Based on the results of its audits, the U.S. government may adjust our agreement-related costs and fees, including allocated indirect costs. This adjustment could impact the amount of revenues reported on a historic basis and could impact our cash flows under the contract prospectively. In addition, in the event that the government determines that certain costs and fees were unallowable or determines that the allocated indirect cost rate was higher than the actual indirect cost rate, the government would be entitled to recoup any overpayment from us as a result. In addition, if an audit or review uncovers any improper or illegal activity, we may be subject to civil and criminal penalties and administrative sanctions, including termination of our agreements, forfeiture of profits, suspension of payments, fines and suspension or prohibition from doing business with the U.S. government. We could also suffer serious harm to our reputation if allegations of impropriety were made against us, which could cause our stock price to decline. In addition, under U.S. government purchasing regulations, some of our costs may not be reimbursable or allowed under our contracts. Further, as a U.S. government contractor, we are subject to an increased risk of investigations, criminal prosecution, civil fraud, whistleblower lawsuits and other legal actions and liabilities as compared to private sector commercial companies.

Risks Related to Our Reliance on Third Parties

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 adversely affect our financial condition and results of operations. In addition, failure by our distributors to provide an accurate forecast impacts our ability to predict the timing of product 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. We have a finite number of illuminators that can be produced under the current approved configuration before a redesigned and approved illuminator is available. 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.

Currently, a fairly concentrated number of distributors contribute a meaningful portion of our product 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 the past, we have experienced weaker than expected growth due to declining performance by certain of our distributors. Periodically, we transition certain territories to new distribution partners or our direct sales force where we believe we can improve performance relative to the distributor. Because new distribution partners or our direct sales force may have limited experience marketing and selling our products in certain territories, or at all, we cannot be certain that they will perform better than the predecessor distributor. In certain cases, our distributors hold the regulatory approval to sell INTERCEPT for their particular geography. Termination, loss of exclusivity or transitioning from these distributors may 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 revenue will be adversely impacted with the loss or transition of one or more of these distributors. If we choose to terminate 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 or that the distributor will honor its outstanding commitments to us. In addition, terminated distributors may own illuminators placed at customer sites and may necessitate us to repurchase those devices or require end-user customers to purchase new devices from us. Additionally, we may need terminated distributors to cooperate with us or a new distributor in transitioning sub-distributor relationships and contracts, hospital contracts, public tenders, or regulatory certificates or licenses held in their name. These factors may be disruptive for our customers and our reputation may be damaged as a result. Our distribution partners may have more established relationships with potential end user customers than a new distributor or we may have in particular territory, which could adversely impact our ability to successfully commercialize our products in these territories. In addition, it may take longer for us to be paid if payment timing and terms in these new arrangements are less favorable to us than those in our existing distributor arrangements. As we service end-user accounts directly rather than through distributors, we incur additional expense, our working capital is negatively impacted due to longer periods from cash collection from direct sales customers when compared to the timing of cash collection from our former distribution partners and we may be exposed to additional complexity including local statutory and tax compliance. Current or transitioning distributors may irreparably harm relationships with local existing and prospective customers and our standing with the blood banking community in general. In the event that we are unable to find alternative distributors or mobilize our own sales efforts in the territories in which a particular distributor operates, customer supply, our reputation and our operating results may be adversely affected. In addition, in territories where new distributors are responsible for servicing end-user accounts, there will be a period of transition in order to properly qualify and train these new distributors, which may disrupt the operations of our customers and adversely impact our reputation and operating results. In certain cases where a terminated distributor holds title to illuminators placed in the field, we may choose to buy back the illuminators from the distributor to ensure continuity of service to those customers. If this were to occur, our recognizable product revenue would be negatively impacted.

In February 2021, we entered into an Equity Joint Venture Contract with Shandong Zhongbaokang Medical Implements Co., Ltd, or ZBK, to establish Cerus Zhongbaokang (Shandong) Biomedical Co., LTD., or the JV, for the purpose of developing, obtaining regulatory approval for, and eventual manufacturing and commercialization of the INTERCEPT blood transfusion for platelets and red blood cells in the People's Republic of China. We own 51% of equity in the JV and consolidate the JV. The JV will need to obtain regulatory approval for the INTERCEPT Blood System for Platelets and Red Blood Cells before it can begin commercializing in China. In order to obtain that regulatory approval, the JV may need to run additional clinical studies in China. We cannot assure you the JV will be successful in meeting the endpoint, once defined, or that it will ever receive regulatory approval.

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. For example, Fresenius is our sole supplier for the manufacture of finished disposable kits for the platelet and plasma systems. We also rely on other third-party suppliers for other components and products that are currently our sole qualified suppliers for such components and products. In the event Fresenius or any of our other sole qualified suppliers refuses or is unable to continue operating under our supply agreements with them, 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 may also encounter unforeseen manufacturing difficulties which, at a minimum, may lead to higher than anticipated costs, scrap rates, or delays in manufacturing products. In addition, our product supply chain requires us to purchase certain components in minimum quantities or make last time purchases of obsolete components and may result in a production cycle of more than one year. Significant disruptions to any of the steps in our supply chain process may result in longer productions cycles which could lead to inefficient use of cash or may impair our ability to supply customers with product. Moreover, 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 gross margins will be negatively impacted.

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. In addition, we may need to identify, validate and qualify additional manufacturing capacity with existing or new suppliers. Further, customer demand for our platelet kits is likely to fully utilize the production capacity of our third-party manufacturer(s). Under the terms of our new 2022 Agreement, Fresenius will expand manufacturing of the components and disposable sets to multiple production facilities, following qualification and licensure of such additional facilities. If Fresenius experiences any delays in the qualification and licensure for its new production facilities, then our ability to continue to grow the platelet business will be impaired and our supply and mix of platelet kits or plasma kits will be adversely impacted. Even a temporary failure to supply adequate numbers of INTERCEPT Blood System components may cause an irreparable loss of customer goodwill and potentially irreversible loss of momentum in the marketplace. Although we are actively evaluating alternate suppliers and working with suppliers to make the capital investments to operationalize additional sites within our existing supplier's networks for certain components and finished kits, we do not have qualified additional sites or suppliers or capacity beyond those on which we currently rely, and we understand that Fresenius relies substantially on sole suppliers of certain materials for our products. In addition, suppliers from whom our contract manufacturers source components and raw materials may cease production or supply of those components to our contract

manufacturers. Identification and qualification of alternate suppliers is time consuming and costly, and there can be no assurance that we will be able to demonstrate equivalency of alternate components or suppliers or that we will receive regulatory approval in the U.S. or other jurisdictions. If we conclude that supply of the INTERCEPT Blood System or components from suppliers 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.

We have purchased a last time build of our current model illuminator, which is being phased out of manufacture due to obsolescence of certain components. As a result, we will not be able to continue manufacturing the current model illuminator. We are currently redesigning the illuminator which is expected to take more than twelve months to complete and obtain regulatory approval. Until such time as we obtain approval for the redesigned illuminator, if ever, the demand for illuminators may be higher than the remaining number of illuminators in inventory, resulting in possible customer allocations or loss of sales. We understand that components used in the current model illuminator are no longer commercially available beyond what we have stockpiled or to which we have access under final buy transactions or may become unavailable in the current specifications in the near-term. As component become unavailable or obsolete, we may be required to identify and qualify replacement components for the current model illuminator and in doing so, we may be required to conduct additional studies, which could include clinical trials to demonstrate equivalency or validate any required design or component changes. We anticipate that we will need to continue investing in subsequent versions of the illuminator to enhance functionality and manage obsolescence. 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, increase production for existing customers or sign up new customers may be negatively impacted. 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.

We recently signed an agreement with a supplier to produce the new redesigned illuminator. We must transfer over the design documentation and validate our new supplier, as well as secure components for the new redesigned illuminator. Some on the new components require long order lead times and may require that we procure the components in advance of receiving regulatory approval in order to satisfy demand for our products. Until we are able to validate our new supplier, obtain regulatory approvals and sell our newly designed illuminator, sales of illuminators will be limited to the quantity of the current model illuminator that we have on hand. Any failure to, or delays in, receiving regulatory approvals for the redesigned illuminator, or increased costs associated with mitigating any such delays, could materially and adversely affect our business, financial condition, results of operations and growth prospects and impair our sales and ability to penetrate new markets.

To meet the growing demand for our products, we are likely to invest in manufacturing capacity at existing or alternative manufacturing sites with existing and alternative suppliers, which could be costly and disruptive to our business. In the event that alternate manufacturers or alternate manufacturing sites are identified and qualified, we will need to transfer know-how relevant to the manufacture of the INTERCEPT Blood System to such alternate manufacturers and manufacturing sites; however, certain of our supplier's materials, manufacturing processes and methods are proprietary to them, which will impair our ability to establish alternate sources of supply, even if we are required to do so as a condition of regulatory approval. We may be unable to establish alternate suppliers without having to redesign certain elements of the platelet and plasma systems. Such redesign may be costly, time consuming and require further regulatory review and approvals. We may be unable to identify, select, and qualify such manufacturers or those third parties able to provide support for development and testing activities on a timely basis or enter into contracts with them on reasonable terms, if at all.

Moreover, the inclusion of components manufactured by new suppliers or by alternate sites within our current network of 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. Furthermore, we do not have experience working with partners that are producing our products in multiple sites globally. Should we need to oversee our manufacturers producing components or finished goods for our products in multiple global plants, we may be unsuccessful in providing an adequate level of oversight, may be unable to manage the complexity of such operations, including quality, incur additional costs in managing the global supply chain including capital investments in those plants or become less efficient with our use of cash and working capital.

Raw materials, components or finished product may not meet specifications or may be subject to other nonconformities. In the past, non-conformities in certain component lots have caused delays in manufacturing of INTERCEPT disposable kits. Similarly, we have

experienced non-conformities and out of specification results in certain component manufacturing needed for clinical use, commercial sale and regulatory submissions. Non-conformities can increase our expenses and reduce gross margins or result in delayed regulatory submissions or clinical trials. Any quality failure in manufacturing by our suppliers may result in a significant write down and impact to our reported gross margins. Should non-conformities occur in the future, we may be unable to manufacture products to support our red blood cell clinical trials, or to meet customer demand for our commercial products, which would result in delays for our clinical programs, or lost sales for our commercial products, 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.

In addition, we may not receive timely or accurate demand information from distributors or direct customers, or may not accurately forecast demand ourselves for the INTERCEPT Blood System. Should actual demand for our products exceed our own forecasts or forecasts that customers provide, we may be unable to fulfill such orders timely, if at all. Should we be unable to fulfill demand, particularly if mandated by a public health authority or as included in the Final Guidance Document for the U.S., our reputation and business prospects may be impaired.

Further, certain distributors and customers require, and potential future distributors or customers may require, product with a minimum shelf life. If customers requiring minimum shelf-lives order smaller quantities or do not purchase product as we anticipate, or at all, we may have elevated inventory levels with relatively short shelf-lives which may lead to increased write-offs and inefficient use of our cash. Should we choose not to fulfill smaller orders with minimum shelf lives, our product sales may be harmed. We will need to destroy or consume outdated inventory in product demonstration activities, which may in turn lead to elevated product demonstration costs and/or reduced gross margins. In order to meet minimum shelf-life requirements, we may need to manufacture sufficient product to meet estimated 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. Our platelet and plasma systems' disposable kits have 18 to 24 months shelf lives from the date of manufacture. Should we change or modify any of our product configurations or components, such future configurations of our products may not achieve the same shelf life that existing products have. 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. We have entered into certain public tenders or may enter into commercial contracts with customers, that 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 penalty fees, permanent harm to our customer relations or loss of customers. In addition, certain large national prospective customers, like those in the UK or Japan, may choose to convert all of their operations to INTERCEPT. Should we or our suppliers encounter any manufacturing issues or if we and our suppliers are not able to build more manufacturing capacity, we may not be able to satisfy all of the global demand or may have to allocate available product to certain customers which may force customers to adopt competing products, which could permanently impact our ability to convert those customers to INTERCEPT users and may negatively impact our customers operations and consequently, our competitive position and reputation. 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.

Until we sell sufficient INTERCEPT Blood System for Cryoprecipitation kits to blood center affiliate organizations, expand the number of manufacturing partners producing IFC for us, or more of our manufacturing partners for IFC receive approval of their BLAs, our IFC sales will be limited. Additionally, because IFC are products derived from our INTERCEPT Blood System for plasma, any supply disruptions or failures that could impact our plasma system will have a negative direct impact on the production of IFC. We currently have no experience with customer expectations regarding turnover or inventory levels of IFC held at either our blood center manufacturing partners or at the hospitals themselves. Our IFC product has a shelf life of five days from thaw before it expires. To mitigate product expiration, should hospitals require that we use a consigned inventory model whereby unused product at the hospital at expiration is replaced with fresh product at reduced or no cost to the hospital, we may need to keep additional inventory or manufacture IFC above levels generating an economic return, which could adversely affect our results of operations and financial condition.

Obsolescence or shortage of raw materials, key components of and accessories to the INTERCEPT Blood System, may impact our ability to supply our customers, may negatively impact the operational costs of our customers and may increase the prices at which we sell our products, resulting in slower than anticipated growth or negative future financial performance.

The manufacture, supply and availability of key components of, and accessories to, our products are dependent upon a limited number of third parties and the commercial adoption and success of our products is dependent upon the continued availability of these components or accessories. For example, our customers rely on continued availability of third-party sets, supplied plastics, saline and reagents for processing, storing and manufacturing blood components. If the blood product industry experiences shortages of these components or accessories, or if manufacturers cease production of these components or accessories, the availability and use of our products may be impaired.

With respect to the manufacture of our products, our third-party manufacturers source components and raw materials for the manufacture of the INTERCEPT processing sets. Certain of these components are no longer commercially available, are nearing end-of-life or are available only from a limited number of suppliers. We and our third-party manufacturers do not have guaranteed supply contracts with all of the raw material or component suppliers for our products, which magnify the risk of shortage and obsolescence and decreases our manufacturers' ability to negotiate pricing with their suppliers. For example, a solvent used in the manufacture of the plastic beads for the compound adsorption devices used for our products is no longer available. Accordingly, we purchased all remaining existing material. We will need to qualify plastic beads produced with a new solvent prior to consuming available inventory levels. If we are unable to use all of the raw material produced during the final production run, or if the final material produces suboptimal results, we may require customers to modify their operating practices, or run out of material before an alternate material can be qualified. Moreover, we may be required to impair or write-off the value of any unused last-time-buy raw materials or components. Customers may object to changes in operating practices or changes to the instructions for use, and a potential negative impact on their operations as a result of the use of this material, could impair our reputation or customer acceptance of our products. Any shortage or obsolescence of raw materials, components or accessories or our inability to control costs associated with raw materials, components or accessories, could increase our costs to manufacture our products. Further, if any supplier to our third-party manufacturers is unwilling or unable to provide high quality raw materials in required quantities and at acceptable prices, our manufacturers may be unable to find alternative sources or may fail to find alternative suppliers at commercially acceptable prices, on satisfactory terms, in a timely manner, or at all. Furthermore, we do not yet know whether or not certain components used by blood center operators or used in the production of INTERCEPT will comply with the new standards under the MDR. Failure to comply with the new standards timely may result in a disruption to blood center operations or the manufacture of the INTERCEPT Blood System. If any of these events were to occur, our product quality, competitive position, reputation and business could suffer, we could experience cancellations of customer orders, refusal by customers to accept deliveries or a reduction in our prices and margins to the detriment of our financial performance and results of operations.

Risks Related to Our Financial Condition and Capital Requirements

We expect to continue to generate losses and we may never achieve a profitable level of operations.

Our cost of product sold, research and development and selling, general and administrative expenses have resulted in substantial losses since our inception. While our net losses are narrowing, at our expected and guided sales levels of the platelet, plasma and cryoprecipitation systems, and of IFC, our costs to manufacture, distribute, market, sell, support the systems and develop new products are likely to continue to be in excess of our product revenue. We expect to incur additional research and development costs associated with the development of different configurations of existing product candidates and products and our illuminator, development of new products, planning, enrolling and completing ongoing clinical and non-clinical studies, including the post-approval studies or registry studies we are and may be required to conduct in connection with the approvals of the platelet system, pursuing potential regulatory approvals in other geographies where we do not currently sell our platelet and plasma systems, planning and conducting *in vitro* studies and clinical development of our red blood cell system in Europe and the U.S., and completing activities to support a potential CE Certificate of Conformity and the CE Marking for our red blood cell system in the EU. 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 addition, we may be required to reduce the sales price for our products in order to make our products economically attractive to our customers and to governmental and private payors, or to compete favorably with other blood safety interventions or other pathogen reduction technologies, which may reduce or altogether eliminate any gross profit on sales.

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.

Until we are able to generate a sufficient amount of product revenue or limit expenses or capital investments and generate positive net cash flows from operations, which we may never do, meeting our long-term capital requirements is in large part reliant on continued access to funds under our BARDA agreement and the public and private equity and debt capital markets, as well as on collaborative arrangements with partners, augmented by cash generated from operations and interest income earned on the investment of our cash balances. While we believe that our available cash and cash equivalents and short-term investments, as well as cash received from product sales and under our agreement with BARDA, will be sufficient to meet our working capital requirements for at least the next 12 months, if we are unable to generate sufficient product revenue, or access sufficient funds under our BARDA agreement or the public and private equity and debt capital markets, we may be unable to execute successfully on our operating plan. 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. In addition, while our stated goal is to achieve profitability in the future, actual results may be different than our forecasted operating plan and may require that we make certain trade-offs to potentially achieve profitability. Such trade-offs may negatively impact our commercial potential or result in deferrals in 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 Credit, Security and Guaranty Agreement (Term Loan), or the Term Loan Credit Agreement, and our

Credit, Security and Guaranty Agreement (Revolving Loan), or the Revolving Loan Credit Agreement, both with MidCap Financial Trust, or MidCap, 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, financial performance covenants and repayment provisions that reduce cash resources and limit future access to capital markets. Should interest rates continue to increase, the rates that we are obligated to pay under our Credit Agreements may increase, potentially leading to higher interest expense. 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, political change, and other factors, including uncertainty associated with the COVID-19 pandemic, 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. As a result of stimulus programs put in place over the past two years, the U.S. and many countries are currently experiencing an inflationary environment. In addition, the U.S. Federal Reserve has raised, and may again raise, interest rates, in response to concerns about inflation, which in turn has negatively impacted equity values, including the value of our common stock. Furthermore, our suppliers may raise prices in an inflationary environment, costs to transport our products may increase, availability timeliness of shipping. If we are unable to raise additional capital when needed, 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 if additional studies are necessary for regulatory approval or certifications in the EU, which would increase our costs and potentially delay the approval. We may need to obtain additional funding to conduct additional randomized controlled clinical trials for existing or new products, particularly if we are unable to access any additional portions of the funding contemplated by our BARDA agreement, and we may choose to defer such activities until we can obtain sufficient additional funding or, at such time, our existing operations provide sufficient cash flow to conduct these trials.

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

As of June 30, 2022, our total indebtedness under our Term Loan Credit Agreement and Revolving Loan Credit Agreement was approximately $69.7 million. All of our current and future assets, except for intellectual and certain investments in subsidiaries and affiliates, are secured, are secured for our borrowings under the Term Loan Credit Agreement and Revolving Loan Credit Agreement. The Term Loan Credit Agreement and Revolving Loan Credit Agreement require 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 Term Loan Credit Agreement or the Revolving Loan Credit 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 Term Loan Credit Agreement or the Revolving Loan Credit Agreement. If we are unable to repay those amounts, the lenders under the Term Loan Credit Agreement or the Revolving Loan Credit 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 or certain other covenants or if we default on any portion of our outstanding borrowings, the lenders can also impose an exit fee of a percentage of the amount borrowed pursuant to the Term Loan Credit Agreement.

The proposed discontinuation or replacement of the London Inter-Bank Offered Rate, or LIBOR, may adversely affect interest rates on our current or future indebtedness and may otherwise adversely affect our financial condition and results of operations.

In July 2017, the Chief Executive of the UK Financial Conduct Authority, or FCA, which regulates LIBOR, announced that the FCA intends to phase out the use of LIBOR. In addition, the U.S. Federal Reserve, in conjunction with the Alternative Reference Rates Committee, a steering committee comprised of large U.S. financial institutions, is considering replacing U.S. dollar LIBOR with the Secured Overnight Financing Rate, or SOFR, a new index calculated by short-term repurchase agreements, backed by Treasury securities. Although there have been certain issuances utilizing SOFR, it is unknown whether this or any other alternative reference rate will attain market acceptance as a replacement for LIBOR. The one-month U.S. dollar LIBOR is used as a benchmark rate in our Term Loan Credit Agreement and Revolving Loan Credit Agreement. The FCA had indicated that the one-month U.S. dollar LIBOR reference rate will phase out as of June 30, 2023. There remains uncertainty regarding the future utilization of LIBOR and the nature of any replacement rate, and any potential effects of the transition away from LIBOR on us are not yet known with certainty. The transition process may involve, among other things, increased volatility and illiquidity in markets for instruments that currently rely on LIBOR and may result in increased borrowing costs and interest rates, the effectiveness of related transactions such as hedges, uncertainty under applicable documentation, including our Term Loan Credit Agreement and Revolving Loan Credit Agreement, or difficult and costly

processes to amend such documentation. As a result, our ability to refinance our Term Loan Credit Agreement, Revolving Loan Credit Agreement or other indebtedness or to hedge our exposure to floating rate instruments may be impaired, which could adversely affect our business, financial condition and results of operations.

Risks Related to Managing Our Growth and Other Risks

We operate a complex global commercial organization, with limited experience in many countries. We have limited resources and experience complying with regulatory, legal, tax and political complexities as we expand into new and increasingly broad geographies. We may be distracted by expansion into new geographies where we do not have experience and we may be unsuccessful in monetizing such opportunities for the benefit of our organization at large.

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 will need to maintain and may need to increase our competence and size in a number of functions, including sales, deployment and product support, marketing, regulatory, inventory and logistics, customer service, credit and collections, risk management, and quality assurance systems in order to successfully support our commercialization activities in all of the jurisdictions we currently sell and market, or anticipate selling and marketing, our products. Many of these competencies require compliance with U.S., EU, South American, Asian and local standards and practices, including regulatory, legal and tax requirements, 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. Currently, we and third-parties we work with are experiencing an extremely tight labor market exacerbating our ability to attract and retain talent. 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 product revenue that we recognize from such a territory, which would adversely affect our results of operations and could adversely affect our financial condition. Furthermore, we may choose to seek alternative ways to sell or treat blood components with our products. These may include new business models, which may include selling kits to blood centers, performing inactivation ourselves, staffing blood centers or selling services or other business model changes. We have no experience with these types of business models, or the regulatory requirements or licenses needed to pursue such new business models. We cannot assure you that we will pursue such business models or if we do, that we will be successful. For example, in early 2021, we formed a joint venture with a Chinese entity with the intent to develop and commercialize blood transfusion products to enhance blood safety in the Peoples Republic of China. Our involvement in the joint venture may be a distraction for our management and impair our ability to successfully and timely manage our other operations. Additionally, the operations of the joint venture may require future capital infusion from us and we may never see a return from our investment in the joint venture.

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

Sales of our products are dependent on purchasing decisions of and/or reimbursement from government health administration authorities, distribution partners and other organizations. As a result of adverse conditions affecting the global economy and credit and financial markets, including the COVID-19 pandemic, disruptions due to political instability or terrorist attacks, economies and currencies largely affected 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, and of which could adversely affect our business, financial condition, results of operations and growth prospects.

In the past, a meaningful amount of our product revenue has come from sales to distributors for the Russian, other CIS countries, as well as Middle Eastern markets. While we believe that all patients wanting access to INTERCEPT-treated blood components should have access, Russia's ongoing war against Ukraine and the elevated U.S. and EU sanctions imposed against Russia has made servicing our distributor in Russia more difficult. Furthermore, because of the severe devaluation of the Ruble in the currency markets, our products have become more costly for the Russian market. Should the situation persist or worsen, including sanctions in response to the war, we may be unable to service our Russian distributor. Weakness and/or instability in worldwide oil demand and/or prices, civil, political and economic disturbances any potential spillover effect may have a negative impact on markets that we service.

Risks associated with our operations outside of the United States could adversely affect our business.

We have operations and conduct business outside the United States and we plan to expand these activities. Consequently, we are, and will continue to be, subject to risks related to operating in foreign countries, which include:

- complying with diverse and unfamiliar foreign laws or regulatory requirements or unexpected changes to those laws or requirements;
- complying with other laws and regulatory requirements to which our business activities abroad are subject, such as the U.S. Foreign Corrupt Practices Act and anti-corruption laws, and similar laws with a significant anti-corruption intent in foreign countries (as discussed in greater detail above under "*Risks Related to Regulatory Approval and Oversight, and Other Legal Compliance Matters—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*" and "*Risks Related to Our Reliance on Third Parties—We rely on third parties to market, sell, distribute and maintain our products and to maintain customer relationships in certain countries*");
- differing payor reimbursement regimes, governmental payors and price controls;
- changes in the political or economic condition of a specific country or region;
- fluctuations in the value of foreign currency versus the U.S. dollar;
- adverse tax consequences, including changes in applicable tax laws and regulations;
- liabilities for activities of, or related to, our international operations and those of our agents, distributors and joint venture partners;
- tariffs, trade protection measures, import or export licensing requirements, trade embargoes, and sanctions (including those administered by the Office of Foreign Assets Control of the U.S. Department of the Treasury), and other trade barriers;
- economic weakness, including inflation, or political or economic instability in particular economies and markets outside the U.S.;
- difficulties in attracting and retaining qualified personnel; and
- cultural differences in the conduct of business.

For example, product sales of the INTERCEPT Blood System sold in many countries outside of the U.S. are typically invoiced to customers in Euros. In addition, we purchase finished INTERCEPT disposable kits for our platelet and plasma systems and incur certain operating expenses in Euros and other foreign currencies. Our exposure to foreign exchange rate volatility is a direct result of our product sales, cash collection and cash payments for expenses to support our international operations. Significant fluctuations in the volatility of foreign currencies relative to the U.S. 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 and other currencies we transact in, our product revenues and expenses denominated in Euros or other foreign currencies are translated into U.S. dollars at a lower/higher value than they would be in an otherwise constant currency exchange rate environment. Currently we do not have a formal hedging program to mitigate the effects of foreign currency volatility. As our commercial operations grow globally, our operations are exposed to more currencies and as a result our exposure to foreign exchange risk will continue to grow.

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

Finally, following the result of a referendum in 2016, the UK left the EU on January 31, 2020, commonly referred to as "Brexit." We may face new regulatory costs and challenges as a result of Brexit that could have a material adverse effect on our operations as the UK determines which EU laws to replace or replicate. Altered regulations could add time and expense to the process by which our product candidates receive regulatory approval in the EU. Given the lack of comparable precedent, it is unclear what financial, regulatory, trade and legal implications the withdrawal of the UK from the EU will ultimately have and how such withdrawal will affect us.

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. Labor shortages of qualified personnel is expected to persist for the foreseeable future and has required that we broaden our searches and change the way we operate. If we are unable to attract, retain and motivate quality individuals, our business, financial condition, ability to perform under our BARDA agreement, or results of operations and growth prospects could be adversely affected. Even if we are able to identify and hire qualified personnel commensurate with our growth objectives and opportunities, the process of integrating new employees is time consuming, costly and distracting to existing employees and management. Such disruptions may have an adverse impact on our operations, our ability to service existing markets and customers, or our ability to comply with regulations and laws.

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.

Significant disruptions of information technology systems or actual or alleged 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 include those that are used directly by our operations and those used by critical service providers and suppliers, including our manufacturing partners. As use of information technology systems has increased, deliberate attacks, attempts to gain unauthorized access to computer systems and networks, and unintentional actions or inactions that expose us to security vulnerabilities and incidents have increased in frequency and sophistication. Our and our supplier's information technology, systems and networks are potentially vulnerable to breakdown, ransomware, supply chain attacks, malicious intrusion and computer viruses which may result in the impairment of production and key business processes or loss of data or information. We and our suppliers are also potentially vulnerable to data security breaches-whether by (a) intentional or accidental actions or inactions or (b) employees or others-which may expose sensitive data to unauthorized persons. For example, we have in the past and may in the future be subject to "phishing" attacks in which third parties send emails purporting to be from reputable sources. Phishing attacks may attempt to obtain personal information, infiltrate our systems to initiate wire transfers or otherwise obtain proprietary or confidential information. Although we have not experienced any losses as a result of such attacks or any other breaches of data security, such 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.

We may be subject to contractual, regulatory, or legal requirements that obligate us to use industry-standard or reasonable security measures to safeguard personal information. A security breach could lead to claims by our customers or other relevant stakeholders that we have failed to comply with such legal or contractual obligations. As a result, we could be subject to legal action or our customers could end their relationships with us. There can be no assurance that the limitations of liability in our contracts would be enforceable or adequate or would otherwise protect us from liabilities or damages, and in some cases our customer agreements do not limit our remediation costs or liability with respect to data breaches.

Litigation resulting from security incidents may adversely affect our business. Actual or alleged unauthorized access to our platform, systems, networks, or physical facilities, or those of our vendors, could result in litigation with our customers or other relevant stakeholders. These proceedings could force us to spend money in defense or settlement, divert management's time and attention, increase our costs of doing business, or adversely affect our reputation. We could be required to fundamentally change our business activities and practices or modify our products and/or platform capabilities in response to such litigation, which could have an adverse

effect on our business. If a security breach were to occur, and the confidentiality, integrity, or availability of personal information was disrupted, we could incur significant liability, or our platform, systems, or networks may be perceived as less desirable, which could negatively affect our business and damage our reputation.

We know that certain of our suppliers have been successfully attacked by certain malware aimed at extracting a ransom. Should such ransomware breaches occur in the future, production may be impacted, information exfiltrated or other records and information compromised or lost. Breaches and other inappropriate access can be difficult to detect and any delay in identifying them could increase their harm. While we have implemented security measures designed to protect our data security and information technology systems, such measures may not prevent such events. Notifications and follow-up actions related to a security breach of one of our suppliers could impact our reputation, cause us to incur significant costs, including legal expenses and remediation costs.

Any such breaches of security and inappropriate access could disrupt our operations, harm our reputation or otherwise have a material adverse effect on our business, financial condition and results of operations. Further, the costs to respond to a security breach and/or to mitigate any security vulnerabilities that may be identified could be significant, our efforts to address these problems may not be successful, and these problems could result in interruptions, delays, cessation of service, negative publicity, loss of customer trust, less use of our products and services as well as other harms to our business and our competitive position. Remediation of any potential security breach may involve significant time, resources, and expenses, which may result in potential regulatory inquiries, litigation or other investigations, and can affect our financial and operational condition.

While we have attempted to limit our liability in our contracts, there can be no assurance that contractual limitations of liability are sufficient to protect us from liabilities, damages, or claims related to our data privacy and security obligations. We cannot be sure that our insurance coverage will be adequate or sufficient to protect us from or to mitigate liabilities arising out of our privacy and security practices, that such coverage will continue to be available on commercially reasonable terms or at all, or that such coverage will pay future claims.

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 (if any), and we cannot predict with certainty when, or whether, we will generate sufficient taxable income to use all of our NOL carryforwards. Under current law, U.S. federal net operating losses incurred in tax years beginning after December 31, 2017, may be carried forward indefinitely, but the deductibility of such federal net operating losses in tax years beginning after December 31, 2020, is limited to 80% of taxable income. It is uncertain if and to what extent various states will conform to federal tax laws. In general, under Sections 382 and 383 of the Internal Revenue Code of 1986, as amended, if a corporation undergoes an "ownership change," generally defined as a greater than 50% change (by value) in its equity ownership over a three-year period, the corporation's ability to use its pre-change 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 utilized to reduce future income tax liabilities. In addition, at the state level, there may be periods during which the use of net operating loss carryforwards is suspended or otherwise limited, which could accelerate or permanently increase state taxes owed. As a result, if we earn net taxable income, we may be unable to use all or a material portion of our net operating loss carryforwards and other tax attributes, which could potentially result in increased future tax liability to us and adversely affect our future cash flows.

Risks Related to Our Intellectual Property

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 an expired U.S. patent issued to a third-party that covers methods to remove psoralen compounds from blood products. We have reviewed the patent and believe there exist substantial questions concerning its validity. We cannot be certain, however, that a court would hold the patent to be invalid or not infringed by our platelet or plasma systems. In this regard, whether or not we have infringed 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 have infringed any valid claim of this patent, we may, among other things, be required to pay damages. Our patents expire at various dates between 2022 and 2038. In addition, we have a license from Fresenius to U.S. and foreign patents relating to the INTERCEPT Blood System, which expire at various dates between 2022 and 2024. Due to the extensive time required for development, testing and regulatory review of our potential products, our patents may expire or remain in existence for only a short period following commercialization. This would reduce or eliminate any advantage of the patents.

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

Our patents do not cover all of the countries in which we are selling, and planning to sell, our products. We will not be able to prevent potential competitors from using our technology in countries where we do not have patent coverage. Further, the laws of some foreign countries may not protect intellectual property rights to the same extent as the laws of the U.S., including the CIS countries, China and other jurisdictions where we are currently expanding or seeking to expand our commercialization efforts through distributors or otherwise. For example, we recently formed a joint venture with the intent to develop and commercialize blood transfusion products to enhance blood safety in the Peoples Republic of China. The prosecution of intellectual property infringement and trade secret theft in China is more difficult and unpredictable than in the United States, and we may also have limited legal recourse in the event our intellectual property rights are infringed. In any event, our inability to adequately enforce or protect our intellectual property rights to INTERCEPT in China and other foreign jurisdictions where we are currently expanding or seeking to expand our commercialization efforts could adversely impact our potential commercial success and harm our business.

In certain countries, including EU Member States, China and India, 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 the INTERCEPT Blood System to a third-party, which could materially diminish the value of such patents. This could adversely impact our potential product revenue opportunities.

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

General Risk Factors

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. For example, with respect our joint venture formed with the intent to develop and commercialize blood transfusion products to enhance blood safety in the Peoples Republic of China, we had no prior experience designing and maintaining effective internal control over financial reporting for joint ventures or for economic entities in China. Failure to adequately maintain an effective internal control structure over the joint venture's financial results may result in significant deficiencies or material weaknesses in our internal control over financial reporting. 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. Should our internal controls be deemed ineffective, our ability to obtain additional financing, or obtain additional financing on favorable terms, could be materially and adversely affected which, in turn, could materially and adversely affect our business, our financial condition and the value of our common stock. If we are unable to assert that our internal control over financial reporting is effective in the future, or if our independent registered public accounting firm is unable to express an opinion or expresses an adverse opinion on the effectiveness of our internal controls in the future, investor confidence in the accuracy and completeness of our financial reports could be further eroded, which would have a material adverse effect on the price of our common stock.

Provisions of our charter documents, our 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. 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

Not applicable.

ITEM 6. EXHIBITS

Exhibit Number	Description of Exhibit
3.1 (1)	Amended and Restated Certificate of Incorporation of Cerus Corporation.
3.2 (1)	Certificate of Amendment to the Amended and Restated Certificate of Incorporation of Cerus Corporation.
3.3 (4)	Certificate of Amendment to the Amended and Restated Certificate of Incorporation of Cerus Corporation.
3.4 (5)	Certificate of Amendment to the Amended and Restated Certificate of Incorporation of Cerus Corporation.
3.5 (2)	Amended and Restated Bylaws of Cerus Corporation.
4.1 (3)	Specimen Stock Certificate (see Exhibit 4.2 to Form S-1 Registration Statement filed with the SEC on January 8, 1997).
10.1	Amended and Restated Non-Employee Director Compensation Policy, effective February 17, 2022.
10.2†	Second Amended and Restated Supply and Manufacturing Agreement, by and between Cerus Corporation and Fresenius Kabi Deutschland GmbH, effective January 1, 2022.
10.3	Amended and Restated 2008 Equity Incentive Plan, effective June 1, 2022.
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 (6)	Certification of the Principal Executive Officer and Principal Financial Officer pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.
101.INS	Inline XBRL Instance Document - the instance document does not appear in the Interactive Data File because its XBRL tags are embedded within the Inline XBRL document.
101.SCH	Inline XBRL Taxonomy Extension Schema Document.
101.CAL	Inline XBRL Taxonomy Extension Calculation Linkbase Document.
101.DEF	Inline XBRL Taxonomy Extension Definition Linkbase Document.
101.LAB	Inline XBRL Taxonomy Extension Label Linkbase Document.
101.PRE	Inline XBRL Taxonomy Extension Presentation Linkbase Document.
104	Cover Page Interactive Data File (formatted as Inline XBRL and contained in Exhibit 101).

† Certain portions of this exhibit (indicated by "[***]") have been omitted as the Registrant has determined (i) the omitted information is not material and (ii) the omitted information would likely cause harm to the Registrant if publicly disclosed.

(1) Incorporated by reference to the like-described exhibit to the Registrant's Quarterly Report on Form 10-Q (File No. 000-21937), for the quarter ended September 30, 2012.
(2) Incorporated by reference to the like-described exhibit to the Registrant's Current Report on Form 8-K (File No. 000-21937), filed with the SEC on June 19, 2008.
(3) Incorporated by reference to the like-described exhibit to the Registrant's Registration Statement on Form S-1 (File No. 333-11341) and amendments thereto.
(4) Incorporated by reference to the like-described exhibit to the Registrant's Quarterly Report on Form 10-Q (File No. 000-21937), for the quarter ended June 30, 2014.
(5) 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, 2021.
(6) This certification accompanies the Form 10-Q to which it relates, is not deemed filed with the Securities and Exchange Commission, and is not incorporated by reference into any filing of the Registrant under the Securities Act of 1933, as amended, or the Securities Exchange Act of 1934, as amended (whether made before or after the date of the Form 10-Q), irrespective of any general incorporation language contained in such filing.

SIGNATURES

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

CERUS CORPORATION

Date: August 4, 2022

/s/ Kevin D. Green

Kevin D. Green
Vice President, Finance and Chief Financial Officer
(on behalf of registrant and as Principal Financial Officer)

Exhibit 10.1

Cerus Corporation
Amended and Restated Non-Employee Director Compensation Policy
Effective: January 1, 2012
Amended by Compensation Committee: February 13, 2014
Approved by Board of Directors: February 14, 2014
Amended by Board of Directors: April 19, 2017
Amended by Board of Directors: March 2, 2018
Amended by Board of Directors: March 27, 2020
Amended by Board of Directors: February 22, 2021
Amended by Board of Directors: February 17, 2022

Each member of the Board of Directors (the "***Board***") of Cerus Corporation ("***Cerus***") who is not also serving as an employee of Cerus or any of its affiliates (each such member, a "***Director***") will receive the compensation set forth in this Cerus Corporation Amended and Restated Non-Employee Director Compensation Policy (this "***Policy***") for his or her Board service, as applicable.

Annual Cash Compensation

The annual cash compensation set forth below is payable to each Director, as applicable, in equal quarterly installments, payable in advance during the first 30 days of each quarter in which the service will occur. If a Director joins the Board, or becomes Chairman of the Board or a Chairman or other member of any of the committees of the Board set forth below, in each case at a time other than effective as of the first day of the calendar year, each applicable element of the annual cash compensation set forth below will be pro-rated based on days served in the applicable calendar year, with the pro-rated amount paid for the first quarter in which the Director provides the service (payable not later than 30 days after the Director commences such service), and regular full quarterly amounts paid thereafter. The annual cash compensation is vested upon payment.

1. **Annual Cash Retainer:**
    a. Chairman of the Board: $80,000
    b. All other Directors: $45,000

2. **Committee Chair Service Fee:**
    a. Chairman of the Audit Committee: $26,000
    b. Chairman of the Compensation Committee: $15,000
    c. Chairman of the Nominating and Corporate Governance Committee: $10,000

3. **Committee Member (non-Chair) Service Fee:**

   a. Audit Committee: $13,000

   b. Compensation Committee: $8,000

   c. Nominating and Corporate Governance Committee: $6,000

Equity Compensation

The equity compensation set forth below will be granted under the Cerus Corporation Amended and Restated 2008 Equity Incentive Plan (the "***Plan***"). All stock options granted pursuant to this Policy will be non-statutory stock options, with an exercise price per share equal to 100% of the "Fair Market Value" (as defined in the Plan) of the underlying Cerus common stock on the date of grant, and a term of not more than ten (10) years from the date of grant. All equity awards granted pursuant to this Policy will be made automatically in accordance with the terms of this Policy and the Plan, without the need for any additional corporate action by the Board or the Compensation Committee of the Board. All equity awards granted pursuant to this Policy will become fully vested immediately prior to a "Change in Control" (as defined in the Plan), subject to the Director's "Continuous Service" (as defined in the Plan) through such time.

1. Annual Grant, All Directors: On the date of each of Cerus' Annual Meetings of Stockholders (each, an "***Annual Meeting***"), each Director will be granted the following equity awards, provided that such individual: (i) is a Director on such date, (ii) has been a member of the Board for at least twelve (12) months prior to the date of the applicable Annual Meeting and (iii) will be continuing as a Director immediately following such date:

(a) a stock option for the number of shares of Cerus common stock equal to (i) $100,000, divided by (ii) the Black-Scholes value of a stock option share, determined using the average daily closing sales price per share of Cerus common stock for the thirty (30) market trading days immediately prior to the grant date (the "***Average 30-Day Price***"), with the resulting number rounded down to the nearest whole share, with such stock option vesting on the later of (x) the first anniversary of the date of grant or (y) the day prior to the next Annual Meeting, subject to the Director's Continuous Service through the applicable vesting date; and

(b) a restricted stock unit award ("***RSU***") for the number of shares of Cerus common stock equal to (i) $100,000, divided by (ii) the Average 30-Day Price, with the resulting number rounded down to the nearest whole share, with 100% of the shares subject to such RSU vesting on the later of (x) the first anniversary of the date of grant or (y) the day prior to the next Annual Meeting, subject to the Director's Continuous Service through the applicable vesting date.

2. **Initial Grant.** On the date of the Director's initial election to the Board (or, if such date is not a market trading day, the first market trading day thereafter), the Director will be granted the following equity awards:

(a) a stock option for the number of shares of Cerus common stock equal to (i) $150,000, divided by (ii) the Black-Scholes value of a stock option share, determined using the average daily closing sales price per share of Cerus common stock for the thirty (30) market trading days immediately prior to the grant date (the "***Average 30-Day Price***"), with the resulting number rounded down to the nearest whole share, with such stock option vesting in three (3) equal annual installments following the date of grant, subject to the Director's Continuous Service through the applicable vesting date; and

(b) a restricted stock unit award ("***RSU***") for the number of shares of Cerus common stock equal to (i) $150,000, divided by (ii) the Average 30-Day Price, with the resulting number rounded down to the nearest whole share, with such RSU vesting in three (3) annual installments following the date of grant, subject to the Director's Continuous Service through the applicable vesting date, subject to the Director's Continuous Service through the applicable vesting date.

Exhibit 10.2

SECOND AMENDED AND RESTATED MANUFACTURING AND SUPPLY AGREEMENT

THIS SECOND AMENDED AND RESTATED MANUFACTURING AND SUPPLY AGREEMENT (this "Agreement") is entered into by and between **Fresenius Kabi AG**, **Fenwal France SAS**, and **Fenwal International, Inc.** (together with their Affiliates "Fresenius Kabi"), **Cerus Corporation**, a company organized under the laws of Delaware ("Cerus"), and solely for purposes of amending and restating the Original Supply Agreement (as defined below) **Fresenius Kabi Deutschland GmbH**, a company organized under the laws of Germany ("FK Deutschland"). Fresenius Kabi and Cerus are sometimes referred to herein as a "Party" and collectively as the "Parties." This Agreement shall be effective as of January 1, 2022 (the "Effective Date").

WHEREAS Cerus and FK Deutschland are parties to that certain Amended and Restated Manufacturing and Supply Agreement, effective as of July 1, 2015 (the "Original Supply Agreement");

WHEREAS Cerus desires to ensure continuity of supply and achieve acceptable cost of goods regarding the supply of Manufactured Products, as such term is defined in this Agreement;

WHEREAS Fresenius Kabi desires to supply Cerus with its requirements for Manufactured Products as set forth herein; and

WHEREAS the Parties now wish to further amend and restate the Original Supply Agreement and substitute Fresenius Kabi as supplier in place of FK Deutschland in the manner set forth in this Agreement;

NOW, THEREFORE, in consideration of the premises and covenants set forth herein and other good and valuable consideration, the receipt and sufficiency of which is hereby acknowledged, Fresenius Kabi and Cerus agree as follows:

Article 1
Definitions

In this Agreement, the following terms have the meanings specified or referred to in this Article 1 and shall be equally applicable to both the singular and plural forms. The words "including", "includes" and "include" shall be deemed to be followed by the phrase "without limitation", unless the context clearly dictates otherwise. Any agreement, schedule, attachment or exhibit referred to herein shall mean such agreement, schedule, attachment or exhibit as amended, restated, supplemented or modified from time to time to the extent permitted by the applicable provisions of this Agreement. Reference to any statute or regulation means such statute or regulation as amended at the time and from time to time and includes any successor statute or regulation. Unless

otherwise stated, references to recitals, articles, sections, paragraphs, schedules and exhibits shall be references to recitals, articles, sections, paragraphs, schedules and exhibits of this Agreement.

"AAA" shall have the meaning ascribed to it in Section 12.12.

"Additional Facility" shall have the meaning ascribed to it in Section 2.2(c).

"Affiliate" means, with respect to any Person, at the time in question, any other Person controlling, controlled by or under common control with such Person. For purposes of this definition, "control" shall mean (a) in the case of corporate entities, direct or indirect ownership of any of the stock or shares having the right to vote for the election of a majority of directors, (b) in the case of non-corporate entities, direct or indirect ownership of any of the equity interest with the power to direct the management and policies of such non-corporate entities.

[***]

"APAC Countries" means the following countries: Afghanistan, American Samoa, Australia, Bangladesh, Bhutan, Brunei, Cambodia, China, Cook Islands, East Timor, Federated States of Micronesia, Fiji, French Polynesia, Guam, Hong Kong, India, Indonesia, Japan, Kiribati, Laos, Macau, Malaysia, Maldives, Marshall Islands, Mongolia, Myanmar, Nauru, Nepal, New Caledonia, New Zealand, Niue, North Korea, Northern Mariana Islands, Pakistan, Palau, Papua New Guinea, Philippines, Samoa, Singapore, Solomon Islands, South Korea, Sri Lanka, Taiwan, Thailand, Timor-Leste, Tokelau, Tonga, Tuvalu, Vanuatu, Vietnam, Wallis and Futuna.

"Base Transfer Price" shall have the meaning ascribed to it in Section 4.1(a).

"Breach" shall have the meaning ascribed to it in Section 11.3(a).

"Business Continuity Plan" shall have the meaning ascribed to it in Section 2.1(c).

"Business Heads" shall have the meaning ascribed to it in Section 4.3(c).

[***]

[***]

"Cerus Assets" shall have the meaning ascribed to it in Section 4.3(e).

"Cerus Discounted Transfer Price" shall have the meaning ascribed to it in Section 4.1(b).

"Cerus Indemnified Parties" shall have the meaning ascribed to it in Section 11.1(a).

"Cerus-Supplied Materials" shall have the meaning ascribed to it in Section 5.1(a).

"Components" means all raw materials and sub-assemblies, such as plastics, containers (including without limitation "wet-filled" containers), tubing, cannulas and compound adsorption devices and Intersol Solution for the production of or use in connection with the Sets and RBC Sets.

"Confidential Information" shall have the meaning ascribed to it in Section 10.1.

"Conversion Loss Reduction Plan" shall have the meaning ascribed to it in Section 4.2(b).

"Cost of Goods" means Fresenius Kabi's fully burdened cost of manufacturing a New Product and shall be equal to the sum of the following costs to the extent reasonably and properly allocable to such New Product, in each case calculated in accordance with International Financial Reporting Standards (IFRS), consistently applied: **[***]**; provided, for purposes of clarification, that the allocation of the foregoing costs shall be made to generally reflect **[***]** and will not include **[***]**. Delivery costs, insurance, freight, import and export duties and taxes are not included in Cost of Goods.

"Current Good Manufacturing Practice" or "cGMP" means the then-current standards for the manufacture of pharmaceutical products, as applicable pursuant to (a) the FD&C Act (21 U.S.C. 321 et seq.); (b) relevant United States regulations in Title 21 of the United States Code of Federal Regulations (including Parts 11, 210, and 211); (c) EC Directive 2003/94 EC of October 8, 2003; (d) the EC Guide to Good Manufacturing Practice for Medicinal Intermediate Products; (e) International Conference on Harmonization (ICH) ICH Q7A Good Manufacturing Practice Guidance for Active Pharmaceutical Ingredients; (f) any Japanese laws, rules, guidelines, or regulations corresponding to the subject matter of the foregoing; and (g) all additional Regulatory Authority documents or regulations that replace, amend, modify, supplant or complement any of the foregoing

"Damages" shall have the meaning ascribed to it in Section 11.3(b).

"Device Master Record" shall include device specifications, production process specifications, quality assurance procedures and specifications (including acceptance criteria and quality assurance equipment to be used), and packaging and labeling specifications.

"Facility" and "Facilities" shall have the meanings ascribed to them in Section 2.2(c).

"Force Majeure Event" shall have the meaning ascribed to it in Section 12.5.

"Fresenius Kabi Elements" shall have the meaning ascribed to it in Section 11.1(a).

"Fresenius Kabi Firm Purchase Order" shall have the meaning ascribed to it in Section 2.4(b).

"Fresenius Kabi Indemnified Parties" shall have the meaning ascribed to it in Section 11.1(c).

"Funded Development Costs" shall have the meaning ascribed to it in Section 6.1(c).

"Funded Projects" means the projects set forth on Exhibit F.

"Future Products" shall have the meaning ascribed to it in Section 6.2.

"GSH" shall mean glutathione sodium salt, a tripeptide used to quench S-303 side reactions.

"IFUs" shall have the meaning ascribed to it in Section 4.2(b).

"Indemnifying Parties" shall have the meaning ascribed to it in Section 11.2(a).

"Initial Term" shall have the meaning ascribed to it in Section 7.1(a).

"INTERCEPT Illuminator" means a proprietary illumination device, including operating software and data management system, including source code for each, developed for use with Platelet Sets and Plasma Sets.

"Intersol Solution" means a proprietary platelet storage solution currently sold under the trademark "Intersol."

"Liabilities" shall have the meaning ascribed to it in Section 11.3(c).

"License Agreement" means the agreement entered between Fresenius Kabi (as successor-in interest to Baxter) and Cerus, effective February 2, 2005, governing the ownership of and licensed rights to certain patents, know-how and materials.

"Licensed Assets" means the Licensed Know-How, Licensed Materials and Licensed Patents, in each case as defined and set forth in the License Agreement.

"Manufactured Products" means Platelet Sets, Plasma Sets, RBC Sets, Components and any New Products.

"Manufacturing Services" shall have the meaning ascribed to it in Section 2.1(a).

"Negotiation Period" shall have the meaning ascribed to it in Section 4.1(e).

"New Products" means any Future Products or new products resulting from the Funded Projects.

"New Product Transfer Price" shall have the meaning ascribed to it in Section 4.1(c).

"Permitted Assignees" shall have the meaning ascribed to it in Section 12.2(a).

"Person" means an individual, corporation, limited liability company, partnership, sole proprietorship, joint venture, or other form of organization or governmental agency or authority.

"**[***]**" means, if applicable, the effective date of **[***]**.

"Phase 4 Project" means each of the designated Funded Projects set forth on Exhibit F under the title "Phase 4 Projects."

"Phase 4 Project Milestone" means the date on which annual production volume of Sets and RBC Sets is **[***]**.

"Plasma Disks" means sintered porous plastic adsorbent disks designed for the pathogen inactivation system for plasma.

"Plasma Sets" means disposable processing sets for inactivation of pathogens in plasma components of blood, containing S-59.

"Platelet Sets" means disposable processing sets for the inactivation of pathogens in platelet components of blood, containing S-59.

"Platelet Wafers" means sintered porous plastic adsorbent wafers designed for the pathogen inactivation system for platelets.

"Proceeding" shall have the meaning ascribed to it in Section 11.3(d).

"Production Disruption" shall have the meaning ascribed to it in Section 2.4(a).

"Product Specifications" means the specifications for the Platelet Sets, the Plasma Sets and RBC Sets (as described in Section 2.1(b)), and as modified from time to time pursuant to Section 2.2 and Article 6 of this Agreement. The Product Specifications for Components will be the applicable specifications for Components included within the Product Specifications mentioned above in this definition, or if such do not exist for any Component, then specifications to be developed by the Parties for such Component.

[***]

"Quality Agreement" means that certain quality agreement dated as of even date herewith.

"QSRs" shall have the meaning ascribed to it in Section 2.2(d).

"RBC Filter Set" means a disposable set for the sterile delivery of red blood cells, GSH and S-303 for the pathogen inactivation system for red blood cells.

"RBC Processing Set" means a disposable set for the mixing, incubation and storage of red blood cells for the pathogen inactivation system for red blood cells.

"RBC Sets" means disposable processing sets for the inactivation of pathogens in red blood cell components of blood, containing GSH, S-303, an RBC Filter Set and an RBC Processing Set.

"Regulatory Approval" means, for a particular country or regulatory jurisdiction, all approvals from the applicable Regulatory Authority required for the commercial marketing or sales of the Manufactured Products in such country, along with satisfaction of any related applicable regulatory requirements

"Regulatory Authority" means any regulatory authority or entity having the responsibility, jurisdiction, and authority to approve or regulate the manufacture, use, importation, packaging, labeling, marketing and sale of the Manufactured Products in any country or regulatory jurisdiction, including without limitation the United States and the European Union.

"Renewal Term" shall have the meaning ascribed to it in Section 7.1(a).

"S-303" shall mean the raw material S-303:2HCL powder used for the inactivation of pathogens.

"S-59" means the raw material amotosalen HCl, a component of Platelet Sets and Plasma Sets.

"Sets" means the Platelet Sets and the Plasma Sets.

"Steering Committee" shall have the meaning ascribed to it in Section 4.3.

"Supply Disruption" means any event the consequence of which is Fresenius Kabi is unable to fulfill Cerus' reasonable purchase orders for a period in excess of **[***]**, except to the extent that such disruption is due to Cerus' failure to deliver any Cerus-Supplied Material that is required for the manufacture of the applicable Manufactured Product.

"Term" shall have the meaning ascribed to it in Section 7.1(a).

"Territory" means all countries in the world, except the APAC Countries or elsewhere where local or regional manufacturing is needed to obtain product registrations or sales.

"Third Party Changes" shall have the meaning ascribed to it in Section 2.2(a).

"Transfer Price" shall have the meaning ascribed to it in Section 4.1(a).

"Unfunded Projects" shall have the meaning ascribed to it in Section 4.4(b).

"Warranty Period" shall have the meaning ascribed to it in Section 3.1(e).

"Work Order" means a written, signed order for the performance by Fresenius Kabi of mutually agreed services. A Work Order shall include a scope of work, a project budget and a payment schedule. All Work Orders shall be deemed to be incorporated into this Agreement and governed by its terms and conditions.

Article 2
Manufacturing and Supply

Section 2.1 Manufacturing Services.

(a) **General**. Fresenius Kabi will, during the term of this Agreement, manufacture Manufactured Products for Cerus on the terms set forth below all in accordance with the Product Specifications (collectively, the "Manufacturing Services") in a professional and efficient manner and in accordance with the terms and conditions of this Agreement and the Quality Agreement.

(b) **Product Specifications for Platelet and Plasma Sets**. As of the Effective Date, the Product Specifications for the Platelet Sets, Plasma Sets, and RBC Sets are listed on Exhibit A, Exhibit B, and Exhibit C, respectively, to this Agreement.

(c) **Business Continuity Plan.** On or prior to December 1st of each calendar year during the Term, Fresenius Kabi shall provide Cerus with a report on manufacturing capacity at each of the Facilities for the following **[***]** based on the "optimistic" and "base case" forecasts provided by Cerus pursuant to Section 2.4, and a business continuity plan setting forth its ability to provide Manufactured Products during the Term (collectively, the "Business Continuity Plan"). A mutually approved Business Continuity Plan effective as of the Effective Date is attached hereto as Exhibit H.

Section 2.2 Change Requests.

(a) **Product Specifications; Device Master Record**. In the event that Cerus requests any changes to a Product Specification (including, without limitation, the addition of new product codes or changes made to comply with any requirement, order or instructions by any Regulatory Authority), Fresenius Kabi will, subject to the review and approval process in accordance with the provisions of this Section 2.2(a) and Section 4.4(a), perform and complete such requests in a timely fashion. Fresenius Kabi will not unreasonably withhold or delay its approval to any requests of Cerus to change Product Specifications. In addition, Fresenius Kabi may from time-to-time request certain changes to a Product Specification by timely submitting such request to Cerus for review and approval. Fresenius Kabi will not implement any such change unless and until such change is approved by Cerus, in its sole discretion. Any changes to the Product Specifications or Device Master Record, whether initiated by Cerus or Fresenius Kabi, must be reviewed and approved under Fresenius Kabi and/or Cerus change control procedures. Fresenius Kabi will make no changes to the Device Master Record for the Manufactured Products without the prior written approval of Cerus. Notwithstanding the foregoing, the Parties acknowledge certain changes are caused by third-party suppliers ("Third Party Changes) and are thus outside the scope of Fresenius Kabi's control. Fresenius Kabi shall give Cerus at least **[***]** notice of any such Third Party Changes, provided such third party gave sufficient notice to Fresenius Kabi. If, due to circumstances beyond Fresenius Kabi's control, Fresenius Kabi is required to qualify a new third-party supplier, it will so notify Cerus and the Parties will confer on the determination of and terms

of agreement with such new third-party supplier. Except for such changes as may be contemplated by the Funded Projects set forth on Exhibit F, the terms of which are governed by Section 6.1, allocation of costs for any change described in this Section 2.2(a) is further described in Section 4.4(a).

(b) **[Reserved].**

(c) **Changes in Manufacturing Location.** The Fresenius Kabi facilities in La Châtre, France, San German, Puerto Rico, and Haina, Dominican Republic shall be the primary manufacturing sites and product development support centers for the Manufactured Products (each, a "Facility" and collectively, the "Facilities"). Fresenius Kabi will not make any change in its manufacturing location for Sets, RBC Sets or New Products without Cerus' prior written consent, which consent will not be unreasonably withheld or delayed, and, in any event, will not change its manufacturing location until the new location is fully-qualified and licensed with each applicable Party's regulatory body for the manufacture of the Manufactured Product for sale or clinical testing. Changes in manufacturing location include changes in Fresenius Kabi's manufacturing location for raw materials, components, subassemblies, or finished goods; changes in location or subcontractor for sterilization processes; and changes in chemical and physical facilities. In the event the Parties mutually agree in writing to expand the manufacturing sites and product development support centers for the Manufactured Products beyond the Facilities, Fresenius Kabi shall identify and qualify such additional Fresenius Kabi facility with ISO 13485 certification and an FDA establishment license for the manufacture of the applicable Manufactured Product, provided that such facility shall have low overhead and labor costs associated with the manufacture of goods (such facility, an "Additional Facility"). The transfer pricing for Manufactured Products manufactured at such Additional Facility shall be subject to mutual agreement by the Parties based on good faith discussions, taking into account Fresenius Kabi's costs and cost savings, the effects of any efficiencies realized as a result, any amortization of capital equipment costs incurred and contemplated by Section 4.4(c) hereof, and such other factors as may be reasonably relevant; provided, however, in no event shall such prices exceed those as set forth on Exhibit D unless otherwise agreed by the Parties. Allocation of costs for any such changes is further described in Section 4.4(c).

(d) **U.S. FDA Compliance.** Upon Cerus' written request, Fresenius Kabi agrees to review and modify, as may be necessary, and maintain its existing manufacturing facilities and quality systems to be compliant with FDA quality system requirements ("QSRs") and cGMP. In the event of a modification to meet QSRs, cGMP and standards applicable to the United States, Europe or APAC Countries (if applicable), Fresenius Kabi will review and modify its existing manufacturing facilities in agreement with Cerus. Allocation of costs for such changes is further described in Section 4.4(d).

(e) **Plastics.** Cerus understands that Fresenius Kabi may receive, from time-to-time, "Supplier Notice of Change" notifications from its suppliers for any of the formulations for the key plastics used in the Platelet and Plasma Sets manufactured by its suppliers. If either Party reasonably determines that any such change causes, or would reasonably be expected to cause, the Manufactured Products to fail to meet any regulatory requirements, the Parties shall discuss in good faith the need to procure alternative suppliers and/or solutions, as well as any extensions to planned production times and additional costs or pricing changes. Except for such changes as may be contemplated by the Funded Projects set forth on Exhibit F, the terms of which are governed by Section 6.1, allocation of costs for such changes is further described in Section 4.4(e).

(f) **Work Order.** In the event Cerus requires Fresenius Kabi to perform any work pursuant to this Section 2.2, the Parties shall enter into a Work Order for the performance by Fresenius Kabi of such mutually agreed services. Such services may include, but are not limited to, the conduct of annual stability studies and additional testing of Manufactured Products beyond the scope currently set forth in this Agreement and the Quality Agreement.

Section 2.3 Supply and Purchase Commitments.

(a) Subject to Cerus' supply of (a) Platelet Wafers, Plasma Disks and S-59 for the Sets and (b) S-303, GSH, RBC Filter Sets and RBC Processing Sets for the RBC Sets, during the Term of this Agreement, Fresenius Kabi shall supply Cerus with Manufactured Products within the delivery times required under Section 2.4. Cerus shall purchase Manufactured Products from Fresenius Kabi as set forth in Section 2.5.

(b) Cerus shall purchase the following:

(i) Except as set forth in this subsection "(i)", Cerus shall purchase **[***]** of its requirements for Sets for the Territory from Fresenius Kabi; provided, however, Cerus may purchase **[***]** of Sets from a third party to the extent necessary to maintain supply qualification of said third party; provided further, Cerus shall be permitted to purchase Sets from a qualified third party supplier as cover for commercial purposes in the event of and to the extent of (i) a Supply Disruption, or (ii) Fresenius Kabi's inability, due to capacity constraints (identified in accordance with the other terms and conditions of this Agreement), to satisfy **[***]** of Cerus' requirements for Sets.

(ii) Except as set forth in this subsection "(ii)" and subsection "(iii)" below, and subject to successful completion of the activities required by Items "15 and 23" of the Funded Projects list in Exhibit F and as developed and defined by the Parties pursuant to Article 6 below, Cerus shall purchase **[***]** of its requirements for RBC Sets for the Territory from Fresenius Kabi; provided, however, Cerus may purchase **[***]** of RBC Sets from a third party to the extent necessary to maintain supply qualification of said third party; provided further, Cerus shall be permitted to purchase RBC Sets from a qualified third party supplier as cover for commercial purposes in the event of and to the extent of (i) a Supply Disruption, or (ii) Fresenius Kabi's inability, due to

capacity constraints (identified in accordance with the other terms and conditions of this Agreement), to satisfy **[***]** of Cerus' requirements for RBC Sets.

(iii) Except as set forth in this subsection "(iii)", and subject to successful completion of the activities required by Items "15 and 23" of the Funded Projects as developed and defined by the Parties pursuant to Article 6 below, Cerus shall purchase **[***]** of its requirements for **[***]** for the Territory from Fresenius Kabi, except to the extent prohibited by existing contractual obligations; provided, however, Cerus may purchase **[***]** of **[***]** from a third party **[***]**; provided further, Cerus shall be permitted to purchase **[***]** from a qualified third party supplier as cover for commercial purposes in the event of and to the extent of (i) a Supply Disruption, or (ii) Fresenius Kabi's inability, due to capacity constraints (identified in accordance with the other terms and conditions of this Agreement), to satisfy **[***]** of Cerus' requirements for **[***]**. For clarity sake, it is understood by the Parties that Cerus currently has a contractual obligation to a third-party supplier for the manufacture and supply of at **[***]** of Cerus' annual total requirements for such **[***]** in the **[***]**, provided such requirements do not exceed such third-party supplier's production capacity, and in the case of the **[***]**, that Cerus has not implemented **[***]**. It is further understood by the Parties that Cerus is party to a development agreement for such **[***]** and, upon validation and approval of such **[***]**, the manufacture and supply of such **[***]** will be subject to certain purchase requirements currently being negotiated by Cerus and such potential third-party supplier. Any rights by Fresenius Kabi to manufacture, and obligations by Cerus to purchase, such **[***]** shall be subject to the rights and obligations with respect thereto to be set forth in the definitive manufacturing and supply agreement Cerus enters into with such third party supplier. It is further understood and agreed by the Parties that, in connection with any renewal rights Cerus may have with respect to extending the initial term of the applicable definitive agreements for the manufacture and supply of the **[***]**, Cerus shall **[***]**. Fresenius Kabi shall thereafter **[***]** and Cerus shall **[***]**; provided, however, that **[***]**.

(c) **San German facility.** In the event **[***]** between Fresenius Kabi and the Government of Puerto Rico Department of Economic Development and Commerce ("DEDC"), **[***]**, related to the San German facility that requires **[***]**, and **[***]** under this Agreement, **[***]**; provided however that **[***]**.

Section 2.4 Forecasts.

(a) In order to assist Fresenius Kabi in its production planning of Manufactured Products for Cerus, Cerus will provide to Fresenius Kabi during the Term of this Agreement a **[***]** forecast by product/article code on or prior to the **[***]**, of which the first **[***]** will constitute firm purchase orders for Platelet Sets, Plasma Sets and RBC Sets, and of which the first **[***]** will constitute firm purchase orders in the case of Components ordered separately (each a "Firm Purchase Order"). Fresenius Kabi will provide Cerus written confirmation of its acceptance

or rejection of the Firm Purchase Order no later than the **[***]** after receipt thereof and, upon acceptance, shall thereafter be obligated to produce the Manufactured Products set forth therein; provided, however, that Fresenius Kabi shall not be obligated to accept and may reject any Firm Purchase Order the volume for which **[***]**. In the event that Fresenius Kabi becomes aware of an event or circumstance that would adversely impact Fresenius Kabi's ability to manufacture and supply all or a portion of the Manufactured Products set forth in the Firm Purchase Order (a "Production Disruption"), Fresenius Kabi will provide notice (email acceptable) thereof, including the details describing the event or circumstance and Fresenius Kabi's proposed resolution, including the timing thereof, within **[***]** of becoming aware of such Production Disruption. Any Manufactured Products ordered pursuant to a Firm Purchase Order and not delivered as a result of a Production Disruption **[***]** Fresenius Kabi **[***]** such Firm Purchase Order **[***]** in one or more **[***]**. For the purposes of clarity and avoidance of doubt, Cerus acknowledges that **[***]** within **[***]** in accordance with accepted Firm Purchase Orders **[***]**, except to the extent **[***]**. With respect to the Sets, the **[***]** for the **[***]** constituting a Firm Purchase Order shall not be greater than **[***]** ordered, but in no event shall be greater than **[***]** on a **[***]** basis, without giving effect to any impact arising out of or resulting from **[***]**, for the applicable Set in the preceding **[***]** period unless otherwise agreed to in writing by a Steering Committee Member of both Parties. Cerus agrees that these forecasts will include consideration of obligations for supply of products to meet the forecasts of any third party distributors or other third parties. Additionally, during the third quarter of each calendar year, Cerus shall provide to Fresenius Kabi an "optimistic" volume forecast and a "base case" volume forecast, for the following **[***]**. "Optimistic" volume forecast shall be used for manufacturing capacity assessment and discussion of manufacturing capacity planning between the Parties based on such assessment and shall be taken into account in the Business Continuity Plan. Monthly meetings with Fresenius Kabi and Cerus representatives shall be held at a mutually agreeable time to discuss production planning and inventory management, including, but not limited to, volume forecasts provided pursuant to this Section 2.4, as well as Fresenius Kabi's demand forecasts for Cerus-Supplied Materials for the succeeding **[***]** period.

(b) In order to assist Cerus in its production planning of Cerus-Supplied Materials, Fresenius Kabi will provide to Cerus during the Term of this Agreement a **[***]** forecast by product code on or prior to the **[***]**, of which the first **[***]** will constitute firm purchase orders for Cerus-Supplied Materials (each a "Fresenius Kabi Firm Purchase Order"). Such Fresenius Kabi Firm Purchase Order shall contemplate (i) no less than **[***]** and no more **[***]** of safety stock of Plasma Disks and Platelet Wafers (not including any Plasma Disks or Platelet Wafers then in production for Sets) and (ii) no less than **[***]** and no more than **[***]** of safety stock of S-59 (not including any S-59 then in production for Sets), in each case based on future production demand of the corresponding Set. The safety stock requirements with respect to the RBC Sets and other Cerus-Supplied Materials shall be mutually agreed upon by the Parties, each acting in good faith. The **[***]** for the **[***]** constituting a Fresenius Kabi Firm Purchase Order shall **[***]** ordered in the preceding **[***]** period unless otherwise agreed to in writing by a Steering Committee Member of both Parties.

Section 2.5 Purchase Orders.

The Firm Purchase Orders in each rolling forecast described in Section 2.4 above will constitute a binding obligation on the part of Cerus to purchase such Manufactured Products regardless of whether Cerus has a need for such Manufactured Products at the time of delivery and such purchase obligation will not be relieved for longer than a **[***]** period, except on account of any Force Majeure Event or the unavailability of Cerus-Supplied Materials that may arise subsequent to the date the purchase order is placed. The terms and conditions of this Agreement will be controlling over any terms and conditions included in any purchase order form used in ordering Manufactured Product. Any term or condition of any purchase order, invoice, packing slip, quotation or other document delivered by either Party incident to the purchases hereunder that is in addition to, different from or contrary to the terms and conditions of this Agreement will be void, unless the Parties otherwise agree by a separate written agreement.

Section 2.6 Delivery; Shipment; Invoices.

(a) All Manufactured Products supplied under this Agreement will be delivered by Fresenius Kabi to Cerus' designated carrier at the Facility (FCA, Facility location, INCOTERMS 2020). Title and risk of loss passes to Cerus when the Manufactured Product has been received by Cerus' designated carrier at such designated location. Fresenius Kabi shall issue invoices at the time such Manufactured Products leave Fresenius Kabi's warehouse for delivery to Cerus, provided that Cerus shall pay said invoices within **[***]** days of release of such Manufactured Products by the Parties' quality departments in accordance with the Quality Agreement. Disputed invoices are to be resolved expeditiously and in good faith by the Parties. Fresenius Kabi shall cause to be delivered all Manufactured Products according to the Firm Purchase Orders made by Cerus pursuant to Section 2.4 of this Agreement.

(b) Fresenius Kabi shall include a packing list in each shipment of the Manufactured Products providing the following information: (1) Cerus purchase order number; (2) Fresenius Kabi Components Code; and (3) Quantity. Fresenius Kabi shall also mail a copy of each packing list to Cerus for each shipment at the time of shipment. Fresenius Kabi shall provide to Cerus a certificate of compliance for each lot of Manufactured Products shipped.

(c) All Manufactured Product shall have a shelf life at the time of release by Fresenius Kabi QA for receipt by Cerus' designated carrier pursuant to Section 2.6(a) above of not less than the maximum shelf life (as set forth in the applicable Product Specification) less **[***]** or, with respect to Manufactured Products reprocessed pursuant to Section 7.9 of the Quality Agreement, **[***]**.

(d) Within **[***]** of receipt of Product Release Records (as defined in the Quality Agreement between the Parties) for Manufactured Products, Cerus will complete a review to identify any variations from the Product Specifications referenced on the relevant exhibit to this Agreement. If Cerus delivers such notice of variation from Product Specifications within such **[***]** period, Cerus shall promptly make available to Fresenius Kabi for examination and testing, at the expense of Fresenius Kabi, the Manufactured Products in the rejected shipment. Cerus will

work with Fresenius Kabi to determine if the identified variations from Product Specifications can be clarified or resolved. If the parties are unable to agree on whether said Manufactured Products meet the Specifications, samples of the same shall be provided to an independent qualified third party acceptable to both Cerus and Fresenius Kabi for such evaluation. The decision of said third party shall be binding on both parties. In the event the Manufactured Product is found to not meet Specifications, Fresenius Kabi shall, at Fresenius Kabi's expense, either (i) credit Cerus for the amount of such non-conforming Manufacturing Products for which Cerus has previously paid Fresenius Kabi, or (ii) promptly provide replacement Manufactured Products that meet the Product Specifications.

Article 3
Warranty

Section 3.1 Warranty.

(a) Each Party represents and warrants to the other as follows:

(i) As of the Effective Date, all corporate action necessary for the authorization, execution and delivery of this Agreement by such Party and the performance of its obligations hereunder has been taken.

(ii) As of the Effective Date, the execution, delivery and anticipated performance of this Agreement do not violate or conflict with any law applicable to it, any provision of its charter or bylaws, any order or judgment of any court or other agency of government applicable to it or any of its assets or any contractual restriction or provision or agreement or instruction binding on or affecting it or any of its assets.

(iii) As of the Effective Date, its obligations hereunder constitute its legal, valid and binding obligations, enforceable in accordance with their respective terms (subject to applicable bankruptcy, reorganization, insolvency, moratorium or similar laws affecting creditors' rights generally and subject, as to enforceability, to equitable principles of general application, regardless of whether enforcement is sought in a proceeding in equity or at law).

(iv) To the knowledge of the Parties as of the Effective Date, no consents, waivers, approval or authorizations of any third party, other than the Regulatory Authorities in other countries in the Territory, are required for such Party to perform any of its obligations under this Agreement.

(b) Fresenius Kabi represents and warrants that, upon shipment and for a **[***]** from the date of production of each Manufactured Product (or for the shelf-life of the Manufactured Product, if such period is longer) (the "Warranty Period"), Manufactured Products will meet the then-current Product Specifications, and be free from defects in material, workmanship and title, provided Manufactured Products are stored according to label copy and are used according to label instructions; provided, however, for the avoidance of doubt, said warranty shall not apply to

failures caused by the design of the Products (except to the extent that such design was based on input from Fresenius Kabi) nor by Cerus-Supplied Materials.

(c) Subject to Section 2.2(d), Fresenius Kabi represents and warrants that its manufacturing facilities used to provide Manufactured Products hereunder meet the QSRs, cGMP and standards applicable as required to meet the Product Specifications.

Section 3.2 Disclaimer of Warranties. With respect to the subject matter of this Agreement, the warranties granted in Section 3.1 are exclusive and are offered in LIEU OF ALL IMPLIED OR STATUTORY WARRANTIES (INCLUDING WITHOUT LIMITATION, WARRANTIES AS TO MERCHANTABILITY OR FITNESS FOR A PARTICULAR PURPOSE, OR ARISING FROM COURSE OF DEALING OR USAGE OF TRADE) or any other express or implied warranties or representations.

Section 3.3 Remedies. If any item manufactured by Fresenius Kabi or its subcontractors shall prove defective in material and/or workmanship within the Warranty Period, Cerus shall notify Fresenius Kabi in writing of such defect or noncompliance as soon as reasonably practicable, but in any event within **[***]** of Cerus' discovery of such defect or noncompliance, and Fresenius Kabi shall replace said item. The Warranty Period for such replaced item shall be as set forth in Section 3.1(b) of this Agreement. Fresenius Kabi shall have no responsibility if (a) such item has been improperly stored by Cerus or used outside of label instruction by Cerus, its agents or customers or (b) the defect or noncompliance is due to an act or omission by Cerus or its third-party suppliers as relating to (i) with respect to the Sets, the Platelet Wafers, Plasma Disks, S-59 or INTERCEPT Illuminator devices, (ii) with respect to the RBC Sets, the RBC Filtering Sets, RBC Processing Set **[***]**, S-303 or GSH; or (iii) any other Cerus- Supplied Materials. The foregoing shall be Fresenius Kabi's sole and exclusive liability and Cerus' sole and exclusive remedy for any breach of contract action arising out of any such defect, except with respect to each Party's indemnification obligations as set forth in Article 11, provided that Fresenius Kabi shall remain responsible to carry out its obligations under the Quality Agreement.

Article 4
Payments; Audit; Steering Committee

Section 4.1 Compensation for Manufacturing Services.

(a) **Transfer Pricing for Sets**. The **[***]** transfer price at which the Sets will be invoiced to Cerus shall be determined based upon the total volume of Sets **[***]**, so long as **[***]** approved by the Parties. Notwithstanding the foregoing, in the event that the **[***]** of Sets purchased in **[***]** is (x) greater than the **[***]** of Sets set forth in the **[***]**, or (y) less than the **[***]** of Sets set forth in the **[***]** due to (i) a **[***]** for the applicable **[***]** as compared to the **[***]** of Sets set forth in the **[***]**, or (ii) the **[***]**, and in each case the differences resulting from "(x)" or "(y)" would result in a different pricing tier as set forth on Exhibit D (the "Adjusted Pricing Tier"), then, in the case of "(x)," Fresenius Kabi will issue a credit to Cerus in an amount equal to the aggregate amount paid by Cerus for the applicable **[***]** ("Actual Payments") less the amount Cerus would

have paid at such the Adjusted Pricing Tier ("Adjusted Payments"), and in the case of "(y)," Fresenius Kabi will issue an invoice for an amount equal to Cerus' Adjusted Payments less Cerus' Actual Payments and in the event Cerus has not paid such invoice within **[***]** of issuance, such failure shall be considered a breach of this Agreement. For purposes of clarity, any **[***]** shall be counted for purposes of calculating the applicable Transfer Price for the calendar year for which the shutdown, closure or disruption occurred and disregarded for purposes of calculating the applicable Transfer Price for the subsequent calendar year. The base transfer price by **[***]** is set forth on Exhibit D (the "Base Transfer Price"); provided however that the Base Transfer Price for Sets produced in San German, Puerto Rico shall be converted to US dollars at a mutually agreed exchange rate. Commencing **[***]**, and each **[***]** thereafter during the Term, each of the Base Transfer Price, New Product Transfer Price (defined below), and Project Surcharge (defined below) will be adjusted annually by Fresenius Kabi by an amount equal to the **[***]** based on a **[***]** to **[***]** timeframe (Base Transfer Price as adjusted, the "Transfer Price"). Notwithstanding the foregoing, for the period commencing on the Effective Date and through the remainder of **[***]**, the Base Transfer Price is the Transfer Price.

(b) **Transfer Pricing for Cerus-Supplied Materials**. Cerus shall provide Fresenius Kabi with the Cerus-Supplied Materials at **[***]** to Fresenius Kabi; provided, however, Cerus shall invoice and Fresenius Kabi shall reimburse Cerus for its costs as set forth on Exhibit I (**[***]** as described in Section 4.1(a) at the beginning of each new **[***]** of the Term, commencing **[***]**) as a result of **[***]** in excess of **[***]** percent (**[***]**%) of each shipment of Cerus-Supplied Materials provided to Fresenius Kabi, provided that such Cerus-Supplied Materials meet applicable product specifications upon delivery to Fresenius Kabi.

(c) **Transfer Pricing for New Manufactured Products**. The initial transfer price for the RBC Sets, or any Components or New Product to be manufactured and supplied by Fresenius Kabi that is not manufactured and supplied by Fresenius Kabi to Cerus as of the Effective Date, shall be negotiated in good faith by the Parties and shall be set at an amount that maintains the **[***]** then in effect for all Manufactured Products as shown in Exhibit D for that **[***]** and shall adjust for each subsequent **[***]** to a transfer price that maintains the **[***]** then in effect for all Manufactured Products as shown in Exhibit D for such subsequent **[***]** (the "New Product Transfer Price"); provided however, that the **[***]** shall be in accordance with **[***]**. Adjustments to the New Product Transfer Price of such product shall also be done in accordance with Sections 4.1(a). Further, the Parties shall negotiate in good faith **[***]** for such Components or New Products based on **[***]** consistent with the **[***]** set forth on Exhibit D. In order to verify the Cost of Goods comprising the New Product Transfer Price pursuant to this Section 4.1(c), Fresenius Kabi shall provide to Cerus a written report of the calculation of the Cost of Goods for the applicable product at least **[***]** days prior to the commencing manufacture of such Components or New Products, as applicable. Cerus shall have the right to cause an independent, certified public accounting firm selected from among the "Big 4" nationally recognized accounting firms, or such other firm of national standing that is reasonably acceptable to Fresenius Kabi to audit Fresenius Kabi's records relating to the Cost of Goods for such product to confirm the amount of the costs and expenses reflected in such report. The accounting firm shall be obligated to keep in strict confidence his findings also vis-à-vis Cerus and will inform Cerus and Fresenius Kabi

only about whether or not the calculation of the applicable New Product Transfer Price has been correct and the amount, if any, of the deviation from the charged New Product Transfer Price. **[***]** of such audit unless such audit discloses **[***]** by Fresenius Kabi of **[***]** percent (**[***]**%) or more, in which event **[***]** of such audit.

(d) **[Reserved]**

(e) **[Reserved]**

Section 4.2 Cost Calculations

(a) **Raw Material Cost Changes.** Notwithstanding the price changes set forth in Section 4.1(a), Cerus understands and acknowledges that Fresenius Kabi has supply agreements for raw materials or other components supplied by Fresenius Kabi, including key plastics, that are used in the Platelet and Plasma Sets. In the event that the cost of any such raw materials or other components procured from independent third party vendors increases by greater than **[***]** in a given **[***]** period during the Term (such cost increase, a "Extraordinary Charge"), Fresenius Kabi will promptly notify Cerus of the nature and amount of such Extraordinary Charge, including providing written evidence thereof as may be reasonably requested by Cerus. **[***]**; provided however, that **[***]** Cerus has had a reasonable opportunity to review the written evidence and had an opportunity to discuss with Fresenius Kabi, which review shall be concluded within **[***]** days after Fresenius Kabi has made such evidence available. Notwithstanding the foregoing, **[***]** shall require Cerus prior written approval (such approval not to be unreasonably withheld, conditioned or delayed) before Fresenius Kabi procures such raw material or other component. For purposes of clarity, **[***]**.

(b) **Conversion Loss.** Fresenius Kabi shall use commercially reasonable efforts to continually reduce conversion loss and rework for Manufactured Products and Cerus-Supplied Materials. For the purpose of this Agreement, "conversion loss" shall include losses due to quality control testing and scrap of excess or non-conforming Manufactured Products. The Parties will jointly prepare a development plan to reduce such conversion loss and rework for Manufactured Products and Cerus-Supplied Materials (the "Conversion Loss Reduction Plan").

(c) **Scrap.** Cerus agrees **[***]** of scrap charges for excess materials, such as obsolete labels and instructions for use ("IFUs") solely to the extent arising from changes in Manufactured Products Specifications. Fresenius Kabi will promptly notify Cerus of the nature and amount of such scrap charges and invoice Cerus accordingly.

(d) **Project Surcharge**. Fresenius Kabi shall **[***]** a project surcharge as shown in Exhibit D ("Project Surcharge") **[***]** to the Transfer Price. The Project Surcharge covers **[***]** of the **[***]** of the applicable projects identified on Exhibit D. In the event an identified project is completed, the applicable Project Surcharge shall **[***]** beginning **[***]** after the applicable project is completed.

Section 4.3 Steering Committee.

(a) The Parties shall establish a Joint Steering Committee comprised of an equal number of representatives from Fresenius Kabi and Cerus (the "Steering Committee"), which members shall initially be the individuals identified on Exhibit E. The Steering Committee shall meet at least twice per calendar year and shall have primary responsibility for providing oversight with respect to: (i) execution of the Business Continuity Plan; (ii) the overall stability and long-term viability of Fresenius Kabi's La Châtre facility for purposes of enabling Cerus to evaluate its rights and obligations under **[***]**; (iii) **[***]** upon termination or expiration of Cerus' contractual commitments as described in Section 2.3(b); and (iv) the preparation of detailed project plans, including scope, roles and responsibilities, prioritization and timelines with respect to the Funded Projects.

(b) In addition to the responsibilities set forth in Section 4.3(a), the Steering Committee shall meet at least twice per calendar year to perform the following tasks:

(i) Review and prioritize cost reduction initiatives, at which time, Cerus and Fresenius Kabi shall identify projects for implementation (if any), and estimate and allocate related costs (including, but not limited to, engineering time, operating and capital expenses), and risks and benefits.

(ii) Review and prioritize New Products and product improvements, and anticipated changes.

(c) In the event that the Steering Committee is unable to reach a decision on any matter after **[***]** business days, the decision will be escalated to the Chief Executive officer of Cerus and the designated member of the Management Board of Fresenius Kabi (together, the "Business Heads"), who will have an additional **[***]** business days to reach a mutually agreeable decision. If the Business Heads are unable in good faith to reach resolution, the Parties shall submit the issue to an independent third party jointly selected by the parties for resolutions. The parties shall jointly bear the costs, if any, of such third party.

(d) For the avoidance of doubt, and subject to Section 2.2, (i) Fresenius Kabi shall be able, without Cerus' consent (or Steering Committee involvement), to implement any projects or other process improvements that do not affect product specifications or registrations, provided that such projects or process improvements do not result in an increase in pricing, and (ii) Cerus shall not unreasonably withhold or delay its consent to initiate any projects or other process improvements that affect product registrations, provided that such projects or process improvements shall not be implemented without Cerus' consent and approval until any required Regulatory Approvals are obtained.

(e) For the avoidance of doubt, and in accordance with Sections 2.2, 6.2 and 6.3, Cerus shall be able, without Fresenius Kabi consent (or Steering Committee involvement), to implement any projects or other process improvements, provided such projects or process improvements do not

result in any costs, investments or expenses for Fresenius Kabi. In the event that such projects or process improvements would result in a cost, investment or expense for Fresenius Kabi, the Parties shall negotiate in good faith any adjustment to pricing that may result from such projects or process improvements, and Fresenius Kabi shall not unreasonably withhold or delay its consent to any such projects or process improvements.

Section 4.4 Change Requests; Capital Expenditures.

(a) **Product Specifications.** Except for such changes as may be contemplated by the Funded Projects set forth on Exhibit F, the terms of which are governed by Section 6.1, in the event of any change in Product Specifications under Section 2.2(a), Fresenius Kabi will not be required to perform any work with respect to such change until the Parties reach written agreement on the scope of the additional work, the roles and responsibilities of the Parties with respect to the execution of such change, the allocation of expenses and the change in Transfer Price.

(b) **Product Development; Product Improvements; Prototypes.** Except as to the Funded Projects set forth on Exhibit F, the terms of which are governed by Section 6.1, at Cerus' request, Fresenius Kabi will provide cost estimates for projected development work, including any development work related to any Future Products (the "Unfunded Projects"). Cerus will reimburse Fresenius Kabi on a time and material basis for pre-approved out-of-pocket expenses, engineering trials, prototype manufacturing for research and development (including costs of making changes or conducting activities described under Section 2.2(b)) and/or clinical trials, FTE support and materials) incurred in connection with such Unfunded Projects.

(c) **Manufacturing Location.** Fresenius Kabi will bear any and all costs of relocating and revalidating manufacturing equipment and facilities unless such relocation and validation is expressly requested by Cerus. Except as otherwise provided herein, any costs involved with any change in manufacturing relocation will not be included in the Transfer Price and will not increase the Transfer Price to Cerus over the Transfer Price that was then in effect.

(d) **Compliance with U.S. FDA QSRs and cGMP.** The costs of maintaining (as to the Facility) and establishing (as to an Additional Facility) compliance with QSRs, cGMP and other regulatory standards for a Class III medical device pursuant to Section 2.2(d) will be borne by Fresenius Kabi.

(e) **Plastics.** Cerus understands that significant testing costs may be required for the qualification and submission of potential changes described in Section 2.2(e). Except as contemplated by the Funded Projects set forth on Exhibit F, Cerus agrees to fully fund any qualification and validation work required specifically for use of plastics in the Manufactured Products. Fresenius Kabi will fund the generic qualification and validation work that would be required for material changes required for use of such plastics in Fresenius Kabi products.

(f) **Capital Expenditures.** Except as provided in Sections 4.4(c) and 4.4(d), and except for

(i) any cost of relocating manufacturing facilities, (ii) identifying and qualifying an Additional Facility as contemplated by Section 2.2(c), (iii) providing sufficient capacity for Manufactured Products to Cerus, and/or (iv) any costs contemplated by the Funded Projects, each of which will be Fresenius Kabi's financial responsibility, any capital expenditure required exclusively to meet the changes requested by Regulatory Authorities will be paid for directly by Cerus. Except as provided in Section 6.5, any such capital assets paid for by Cerus ("Cerus Assets") shall be purchased in Cerus' name and be owned by Cerus. Fresenius Kabi shall be liable for all risk of damage to or loss of such Cerus Assets while in the possession or control of Fresenius Kabi, ordinary wear and tear excepted. Fresenius Kabi shall tag all such Cerus Assets in its possession or control with appropriate indicators that they are owned by Cerus, and shall ensure that no third party acquires any security interest in the Cerus Assets while they are in the possession or control of Fresenius Kabi. All Cerus Assets in the possession or control of Fresenius Kabi shall be returned to Cerus upon the termination of this Agreement, unless otherwise agreed to by the Parties.

Section 4.5 Payment; Late Payment Charges. Cerus will pay any purchase price or payment for services due hereunder in Euros in the event Euros are the local currency of the manufacturing site or site of performance of services, and in U.S. Dollars in all other cases, unless the Parties otherwise agree in writing. Such payments shall be made within **[***]** days of release of such Manufactured Products by the Parties' quality departments in accordance with the Quality Agreement by check or wire transfer to a bank account designated in writing by Fresenius Kabi. Undisputed invoices not timely paid will be subject to a late payment charge of **[***]** percent (**[***]**%) per month, or the highest amount permitted by law, if lower.

Article 5
Cerus-Supplied Materials; Illuminators

Section 5.1 Cerus-Supplied Materials.

(a) Cerus shall have full management and control of the supply chain for certain Components ("Cerus-Supplied Materials"), including, but not limited to, specifications, qualification, change control, purchasing of certain raw materials, production planning and facility expansion, and OEM relationships with third party suppliers. Cerus shall have the right to enter directly into contractual arrangements with such third party suppliers for said purposes. Any agreement with third party suppliers designated as such by Cerus (as of the Effective Date, **[***]**, Powdersize, LLC, a Lonza Company, Porex Corporation, Purolite LLC, Laboratorios Grifols, S.A., **[***]**, Baxter Oncology GmbH, **[***]**) shall provide for the release of Cerus-Supplied Materials according to Cerus specifications. Cerus shall have the responsibility to resolve technical issues with third party suppliers related to the supply of Cerus-Supplied Materials. The Parties acknowledge that Cerus has had, and agree that Cerus shall continue to have, full management and control of the supply chain for S-59, including, but not limited to, specifications, qualification, change control, purchasing and development studies. For all Components manufactured by Fresenius Kabi, the responsibilities set forth in in this Section 5.1(a) with respect to the management and control of the supply chain for such Components shall be borne by Fresenius Kabi. This Section supersedes Section 15(d) of the Commercialization Agreement.

(b) Cerus agrees to provide to Fresenius Kabi Cerus-Supplied Materials at a level of inventory of **[***]** of Plasma Disks and Platelet Wafers (not including any Plasma Disks or Platelet Wafers then in production for Sets) and **[***]** of S-59 (not including any S-59 then in production for Sets), in each case based on third party supplier lead times and **[***]** forecasts provided by Cerus.

(c) Once released, Fresenius Kabi shall arrange for shipment of any Cerus-Supplied Materials from the applicable third party manufacturer's facilities to Fresenius Kabi's receiving facility. Fresenius Kabi shall be the importer of records for import of any Cerus-Supplied Materials and for tax purposes. As such, Fresenius Kabi shall be responsible for preparing and filing documentation, and paying related fees, as required by applicable laws, rules and regulations, to import such goods. Fresenius Kabi will notify Cerus upon (i) receipt of each shipment of Cerus-Supplied Materials; and (ii) upon completion of acceptance testing for such Cerus-Supplied Materials, as applicable. Title to Cerus-Supplied Materials shall remain with Cerus at all times, including upon receipt by Fresenius Kabi of such Cerus-Supplied Materials from the applicable third party manufacturer's facilities. Subject to Section 4.1(b), Cerus shall remain responsible for risk of loss related to the Cerus-Supplied Materials and shall carry appropriate levels of insurance coverage for the Cerus-Supplied Materials at all times.

Section 5.2 [Reserved].

Section 5.3 Illuminators. Cerus shall take full management and control of the supply chain for INTERCEPT Illuminator devices, including, but not limited to, OEM relationships, inventory, obsolescence planning and change control, and Cerus shall have the right to enter directly into contractual arrangements with third party suppliers for the supply and manufacturing of such devices. Cerus shall continue to have the responsibility for field service, resolving technical issues with third party suppliers related to the supply and manufacturing of INTERCEPT Illuminator devices. This Section supersedes Section 15(e) of the Commercialization Agreement.

Section 5.4 Inspection of physical inventory. By the **[***]**, Fresenius Kabi will provide Cerus with a **[***]** inventory reconciliation clearly indicating per type of Cerus Supplied Material; quantity at **[***]**, total quantity delivered **[***]**, total quantity consumed **[***]** and total quantity remaining **[***]**. During the Term, and no more than twice a year or for cause, Cerus shall have the right to conduct a physical inspection and reconciliation of Cerus owned Manufactured Products and inventory, at the Facility and during normal business hours, in order to ascertain or verify the number and description of Manufactured Products held by Fresenius or in the process of being manufactured. Cerus shall endeavor to give Fresenius Kabi at least **[***]** days' notice prior to arrival for such physical inspection, but in any event shall give Fresenius Kabi no less than **[***]** business days' notice prior to arrival for such physical inspection. Any such physical inspection must be conducted in a manner so as not to unreasonably disrupt Fresenius Kabi's normal business operations. Fresenius shall use commercially reasonable efforts to cooperate with Cerus in the inventory inspection.

Article 6
Funded Projects; Future Products

Section 6.1 Funded Projects.

(a) Pursuant to the terms of the Original Supply Agreement, the Parties undertook the development of the Funded Projects set forth in Exhibit F and Section 6.1(d) below. Each Party shall use its commercially reasonable efforts to successfully complete the remaining Funded Projects, including obtaining the necessary product registrations and Regulatory Approvals. In the event that it is no longer viable for an outstanding Funded Projects to be completed, the Parties shall discuss in good faith amending Exhibit F to either amend the scope of or terminate such Funded Project.

(b) Each Party has appointed one or more contact persons to serve as project manager for the Funded Projects, which persons shall continue to manage all aspects of the collaboration, including development, validation and regulatory status and timelines, and means to reduce costs and increase efficiencies of both Parties. Cerus shall be responsible for developing the specifications and project codes for any New Products resulting from the Funded Projects, subject to Fresenius Kabi's review and approval, which shall not be unreasonably withheld or delayed. Fresenius Kabi shall be responsible for managing meetings and taking meeting minutes to document the progress of the Funded Projects, which minutes shall be jointly reviewed and approved.

(c) Pursuant to the terms of the Original Supply Agreement, Fresenius Kabi agreed to fully fund the Funded Projects, including, but not limited to, any facility costs, capital expenditures, labor and equipment costs, material costs, costs associated with producing prototype, clinical and registration lots, costs associated with any required manufacturing validation studies, and costs associated with design verification studies related to the physical products, such as biocompatibility, stability, aging, packaging, distribution, functionality, and integrity studies, in each case to the extent reasonably attributable to such Funded Projects (the "Funded Development Costs"), which may be depreciated by Fresenius Kabi. In furtherance of the foregoing, Cerus contributed €3.1 million towards the Funded Development Costs. For the avoidance of doubt, nothing in this Agreement including this Section 6.1 shall require Fresenius Kabi to pay or reimburse any costs of or expenses incurred by Cerus in relation to Funded Projects for in vitro or clinical verification and validation studies of the products for their intended use of ex vivo treatment of blood components intended for transfusion or for any samples of Manufactured Products provided to Cerus' customers.

(d) It is understood and agreed by the Parties that the Phase 4 Projects will be initiated upon achievement of the Phase 4 Project Milestone. Notwithstanding the foregoing, Fresenius Kabi agrees to complete and provide to Cerus a feasibility assessment and project plan with respect to each of the Phase 4 Projects upon reasonable request by Cerus.

Section 6.2 Future Products.

(a) Upon mutual agreement, the Parties may collaborate on the development of new products not contemplated by the Funded Projects set forth on Exhibit F ("Future Products"). Each Party agrees to use its commercially reasonable efforts to successfully complete any development and validation work required to obtain the necessary product registrations and Regulatory Approvals with respect to such Future Products.

(b) Each Party shall appoint one or more contact persons to serve as project manager for any Future Product under development, which persons shall manage all aspects of the collaboration, including development, validation and regulatory status and timelines, and means to reduce costs and increase efficiencies of both Parties. Cerus shall be responsible for developing the specifications and project codes for such Future Products, subject to Fresenius Kabi's review and approval, which shall not be unreasonably withheld or delayed. Fresenius Kabi shall be responsible for managing meetings and taking meeting minutes to document the progress of such Future Products, which minutes shall be jointly reviewed and approved.

Section 6.3 Projects; Product Development; Product Improvements; Prototypes.

Upon mutual agreement, the Parties may undertake new projects, product development, product improvement or prototype work ("Projects"). Each Project shall be evidenced by a mutually agreed upon written Work Order or project statement of work, which shall include, at a minimum, a description of the work to be performed by both parties; responsibilities for costs and expenses incurred by both Parties; completion milestones and criteria; and other terms mutually agreed upon by the Parties. No Work Order or project statement of work shall become binding upon either Party, unless and until the applicable Work Order or project statement of work, as applicable, is signed by a duly authorized representative of both Parties. Upon written acceptance of a new Work Order or statement of work in accordance with this Section, such new Work Order or statement of work, as applicable, shall be deemed incorporated into this Agreement. All requirements of this Agreement shall apply to such Work Order or project statement of work. Notwithstanding anything to the contrary, any Project, New Product or Funded Project (or portion thereof) involving costs, expenses and/or investments (individually or in the aggregate) greater than **[***]** must be mutually agreed upon and shall be subject to Fresenius Kabi board pre-approval.

Section 6.4 New Fresenius Kabi Product Development. The Parties agree to collaborate, to the extent commercially reasonable for both Parties given existing internal priorities, on the qualification and validation of **[***]**. Subject to mutual agreement at the time Cerus is preparing to make its initial FDA submission **[***]**, Cerus shall seek to include the **[***]** as part of such submission, provided that **[***]** has received FDA clearance prior to such submission. If Cerus in its discretion is unable to include the **[***]** in its initial submission because such inclusion would cause an unreasonable delay in the submission, Cerus shall include the **[***]** as part of a follow-up FDA submission for **[***]** as soon as reasonably possible provided that **[***]** has received FDA clearance. Fresenius Kabi shall **[***]** by Cerus resulting

from or attributed to the inclusion of the **[***]** as part of Cerus' FDA submission, provided that **[***]** are agreed upon in writing by the parties in advance. Fresenius Kabi may audit Cerus' records relating to **[***]**. For purposes of clarity, Cerus shall have no obligation to include the **[***]** in its FDA submission unless and until the Parties reach agreement on **[***]**.

Section 6.5 [***] CAPEX.

(a) The Parties agree to purchase and install (i) a second E-beam machine in Fresenius Kabi's LaChatre, France manufacturing facility, including related infrastructure (the "Second E-beam"), (ii) a third E-beam machine and S-59 filling capability in Fresenius Kabi's San German, Puerto Rico manufacturing facility, including related infrastructure (the "Third E-beam" and together with the Second E-beam, the "New E-beams") and (iii) an automatic bag welding machine plus wafer in mesh machine at Fresenius Kabi's Haina, Dominican Republic manufacturing facility (the "Bag Welding/Mesh Project" and together with the New E-beams, the "CAPEX Projects"). With respect to the CAPEX Projects, Cerus and Fresenius Kabi shall **[***]**. Notwithstanding any of the foregoing, (a) Cerus will be responsible for all registration costs related to or arising from the CAPEX Projects, including without limitation, any necessary studies or samples for registrations, and (b) Fresenius Kabi will be responsible for all validation and qualification costs related to or arising from the CAPEX Projects.

(b) All capital assets paid for by Cerus and/or Fresenius Kabi pursuant to this Section 6.5 shall be purchased in **[***]** by, and under the sole control of, Fresenius Kabi ("Fresenius Kabi Assets"). Fresenius Kabi shall be permitted to **[***]**. Payment of any CAPEX Projects costs, investments, and expenses by Cerus pursuant to this Section 6.5 is due within **[***]** of Fresenius Kabi giving written notice to Cerus of the incurrence of such costs, investments, and expenses, including providing written evidence thereof as may be reasonably requested by Cerus.

Article 7
Term; Termination

Section 7.1 Term.

(a) The term of this Agreement shall be from the Effective Date of execution through December 31, 2031, unless earlier terminated pursuant to Section 7.2 (the "Initial Term"). In the case this Agreement continues after [***], the Parties agree to negotiate in good faith any necessary commercial modifications for production of Sets at the other Facilities. Upon expiration of the Initial Term, the term of this Agreement will automatically renew for additional successive two (2) year periods (each, a "Renewal Term" and together with the Initial Term, the "Term") unless (i) either Party provides written notice of non-renewal (A) with respect to the Initial Term, at least two (2) years prior to the expiration of the Initial Term, and (B) with respect to any Renewal Term, at least one (1) year prior to the expiration of such Renewal Term, or (ii) such Renewal Term is earlier terminated pursuant to the terms of this Agreement or applicable law or regulation. If the Initial Term or any Renewal Term is renewed for any Renewal Term(s) pursuant to this Section

7.1, the terms and conditions of this Agreement during each such Renewal Term will be the same as the terms in effect immediately prior to such renewal. In the event that either Party provides timely notice of its intent not to renew this Agreement, then, unless earlier terminated in accordance with its terms, this Agreement terminates upon the expiration of the Initial Term or the then-current Renewal Term, as applicable.

(b) Notwithstanding the termination provisions set forth in Section 7.1(a) or termination pursuant to Section 7.2, in the event that Cerus is materially impeded from manufacturing, or having third parties manufacture Manufactured Products due to Fresenius Kabi's patents, know-how or materials, such as plastics, seals, connectors and sterilization, that have been excluded from the licenses to Cerus under the License Agreement, Fresenius Kabi will either (a) continue to supply to Cerus the specific items whose manufacture is impeded by such excluded rights for so long as Cerus requires such items, or (b) expand the license under the License Agreement so as to eliminate such impediment.

(c) Notwithstanding any other provision hereof, it shall be a Fresenius Kabi obligation to have furnished to Cerus all information to be provided under this Agreement and the Licensed Materials to be provided under the License Agreement (as such term is defined in the License Agreement) concurrent with any notice of termination of this Agreement delivered by Fresenius Kabi, or in the event of termination by Cerus, within thirty (30) days of delivery of notice of termination by Cerus. This provision is not intended to relieve Fresenius Kabi from any obligation stated herein or in the License Agreement to furnish to Cerus information and Licensed Materials sooner than such time.

Section 7.2 **Termination**. This Agreement may be terminated as follows:

(a) by Fresenius Kabi and Cerus upon their mutual agreement;

(b) by Fresenius Kabi or Cerus upon a material breach of this Agreement by the other Party, provided, however, that the Party allegedly in breach shall be entitled to written notice of such breach and thirty (30) days to cure such breach (or such longer period as may be necessary if such Party has commenced curing such breach and is diligently proceeding to cure such breach) before the Agreement may be terminated; and

(c) by Fresenius Kabi or Cerus with written notice to take effect immediately upon receipt thereof by the other Party in the event that the Party receiving notice has filed for bankruptcy or is adjudged insolvent or has made an assignment for the benefit of creditors, or a receiver is appointed for its business or a voluntary or involuntary petition of bankruptcy is filed, or proceedings for the reorganization of the Party are instituted.

(d) by Cerus upon **[***]**, such termination effective as of **[***]**.

Section 7.3 **Survival.** The following provisions of this Agreement will survive any expiration or earlier termination of this Agreement: Sections 2.5, 2.6, 3.1, 3.2, 3.3, 4.2(c), 4.4, 4.5, 7.1, 7.3, 8.1, 8.2, and Articles 9, 10, 11 and 12.

Article 8
Quality

Section 8.1 **Manufacturing Quality.** Fresenius Kabi shall perform the obligations in accordance with the Quality Agreement. All Manufactured Products shall be subjected to quality control inspections by Fresenius Kabi in accordance with Fresenius Kabi's quality control standards and system and by Cerus to ensure adherence to the obligations set forth in the Quality Agreement.

Section 8.2 **Adverse Information**. Each Party will promptly notify the other Party following receipt of any information, including but not limited to any problems regarding the Manufactured Products or any information regarding any threatened or pending action that might affect the production or marketing of the Manufactured Products. Cerus, as holder of the regulatory approvals and marketing authorization for the Manufactured Products, shall be solely responsible to make a timely report of such matter as necessary to any Regulatory Authority or take other action that it deems to be appropriate or required under applicable law or regulation. Cerus shall determine the plan setting forth the appropriate actions for addressing any problems report with respect to any Manufactured Products and Fresenius Kabi will provide its full cooperation and attention with respect to carrying out such plan.

Article 9
Additional Covenants

Section 9.1. **Acquisition of Residual Inventory.** Upon the expiration or termination of this Agreement, Cerus shall purchase all existing inventory of Manufactured Products and Components, which shall include any or all work-in-process or raw materials to the extent specifically identified for Cerus. Notwithstanding the foregoing, Cerus shall have no obligation to purchase any such inventory to the extent that it exceeds Cerus' forecasted requirements for the applicable **[***]** or **[***]** period after such expiration or termination or fails to meet the applicable Product Specifications or the shelf-life requirement set forth in Section 2.6(c), with the exception of any inventory specifically requested by Cerus to be held, unless otherwise agreed in writing by the Parties.

Section 9.2 **Technology Transfer and Technical Assistance.** Subject to the terms and conditions of the License Agreement, in the event of (a) **[***]**; (b) Fresenius Kabi's election to terminate this Agreement or (c) a Supply Disruption, Fresenius Kabi shall promptly transfer to Cerus all technical information pertaining to the manufacturing and quality testing of the Manufactured Products (including without limitation, Bills of Materials, SOPs for manufacturing quality assurance and quality control, design history files and batch records, and including HUD, CER, etc. documents, technical reports and regulatory submissions) and provide to Cerus technical

experts to assist, consult and cooperate with technical personnel of Cerus or its manufacturing sublicensee in the design, production, inspection and maintenance of the Manufactured Products; provided, however, that any technical information transferred in connection with a Supply Disruption shall only be used for the limited purpose of meeting Cerus' supply requirements for the duration of such Supply Disruption and any agreement with a qualified third party supplier having access to such technical information shall have a limitation on the use of such technical information consistent herewith. Cerus may make requests for technical assistance during the Term of this Agreement, however, not to exceed two such requests a calendar year and one such request for each manufacturing change Fresenius Kabi may introduce. Cerus has the rights to use such information provided by Fresenius Kabi in accordance with the terms of the License Agreement. Cerus shall pay the reasonable traveling, living and other related expenses of such technicians of Fresenius Kabi as agreed between the Parties, and Cerus shall pay for such services on an hourly rate (excluding travel time) equal to $ **[***]** (US) per day per person. Fresenius Kabi shall arrange at the request of Cerus for the visit of Cerus' technical personnel to the offices or plants or any other facilities of Fresenius Kabi for the study of manufacturing processes, practices, testing shipment and know-how used by Fresenius Kabi in the manufacture of the Manufactured Products as provided for under the License Agreement. In no event will Fresenius Kabi technicians be expected to meet or travel for Cerus to a country for which the U.S. Department of State has issued a travel advisory recommending U.S. citizens leave or avoid traveling to such country at that time.

Section 9.3 **Compliance with Laws**. Each Party will comply with all applicable laws, rules, ordinances and regulations of any governmental entity or Regulatory Authority governing the Manufacturing Services to be provided hereunder, including but not limited to the laws on fair competition, anti-money laundering/terrorism financing and anti-bribery and corruption and data protection laws (for the purposes of this section, the "Applicable Laws"). No Party will take any action in violation of any applicable law, rule, ordinance or regulation that could result in liability being imposed on the other Party.

Fresenius Kabi will comply at all times with then current ISO standards and then current Good Manufacturing Practices (cGMP) and maintain related certification, subject to Section 2.2(d). Neither Party nor its directors, employees, agents or representatives have, directly or indirectly, provided or paid and will not provide or pay commissions, payments, kickbacks, lavish or extensive entertainment or gift, or other inducements of more than minimal value to any provider organization, customer, employee or agent of the other Party, or other persons in connection with this Agreement. Neither Party has, directly or indirectly, provided or paid and neither Party will provide or pay any monies or other items of value in violation of, or which may cause either Party or their respective affiliates to be in violation of the U.S. Foreign Corrupt Practices Act of 1977, as amended (including the anti-bribery provision thereof) or any similar laws. No officer, director, employee, agent or representative of a Party is or shall be an official of the government of any country or political subdivision thereof or regulating agency, and no part of the purchase price, fees or charges hereunder have accrued or shall accrue, in whatever form, for the benefit of any such official.

In case of a court's final adjudication of a material breach of the provisions of any Applicable Laws by either Party, the other Party shall be entitled to terminate this Agreement for cause by written notice with immediate effect. Each Party shall fully cooperate with, and provide conclusive documentation to, the other Party, any of its affiliated companies or any auditor acting on its behalf in case the other Party or such affiliated company or auditor initiates the conduct of a review of compliance with Applicable Laws, in particular the measures taken and implemented by the other Party to ensure such compliance.

Section 9.4 **Relationship of the Parties**. Fresenius Kabi shall and will remain at all times an independent contractor of Cerus in the performance of all Manufacturing Services hereunder. In all matters relating to this Agreement, each Party hereto will be solely responsible for the acts of its employees and agents, and employees or agents of one Party shall not be considered employees or agents of the other Party. No Party will have any right, power or authority to create any obligation, express or implied, on behalf of any other Party nor shall either Party act or represent or hold itself out as having authority to act as an agent or partner of the other Party, or in any way bind or commit the other Party to any obligations. Nothing in this Agreement is intended to create or constitute a joint venture, partnership, agency, trust or other association of any kind between the parties or persons referred to herein.

Section 9.5 **Purchase of Equipment.** Upon termination of Fresenius Kabi's obligations under this Agreement and as long as Fresenius Kabi has no obligations for Manufactured Products to either Cerus or its successors or assigns, Cerus may elect to purchase any equipment, instruments, tools, ties and molds dedicated to the manufacturing of the Manufactured Products at a price to be negotiated by the Parties in good faith.

Section 9.6 **Milestone Payment.** The Parties acknowledge that Cerus made a one-time, lump sum payment of €5.5 million to Fresenius Kabi in August 2019.

Section 9.7 **[***]**

Section 9.8 **Amendment to License Agreement.** Effective as of July 1, 2015, the license granted by the License Agreement was converted to a royalty-free license. For purposes of clarity, no royalties will be assessed with respect to Net Sales of Products (in each case, as defined in the License Agreement) occurring on or after the Effective Date.

Article 10
Confidentiality

Section 10.1 **Confidential Information.** All information and materials containing information provided by any Party to another relating to this Agreement, including but not limited to customer requirements, lists, preferences and methods of operation, the technology, any know-how, data, process, or technique of any Party relating to such Party's products, and any research project, work-in-process, future development, scientific, engineering, or manufacturing information, know-how, designs, drawings, management information reports and other

computer-generated reports, financial information, pricing policies and details, details of contracts, operational methods, plans or strategies, business acquisition plans, and the business affairs of such Party, whether in oral, graphic or written form, as the case may be, are and shall be treated as confidential ("Confidential Information"). Among other things, Confidential Information shall include confidential or proprietary information or materials of third parties and the Parties' respective Affiliates, that are in the possession of one of the Parties and provided pursuant to this Agreement.

Section 10.2 Obligations. Except as expressly authorized by prior written consent of the disclosing Party, the receiving Party shall:

(a) limit access to any Confidential Information of the disclosing Party received by it to its, its Affiliates', sublicensees' and distributors' employees, agents, representatives, and consultants who have a need-to-know in connection with this Agreement and the rights and obligations of the Parties hereunder, and who are under appropriate non-use and non-disclosure restrictions which are at least as restrictive as those set forth herein;

(b) safeguard all Confidential Information of the disclosing Party received using a reasonable degree of care, but not less than that degree of care used by the receiving Party in safeguarding its own confidential information or material; and

(c) use the Confidential Information of the disclosing Party only for the purposes and in connection with the performance of such Party's obligations set forth in this Agreement.

Section 10.3 Exceptions to Confidentiality. Notwithstanding Section 10.2, the Parties' obligations of confidentiality and non-use shall not apply to any particular information or materials that the receiving Party can demonstrate:

(a) was, at the time of disclosure to it, in the public domain;

(b) after disclosure to it, is published or otherwise becomes part of the public domain through no fault of the receiving Party;

(c) was received after disclosure to it from a third party who had a lawful right to disclose such information or materials to it;

(d) was required to be disclosed to any regulatory body having jurisdiction over the receiving Party or any of its respective Affiliates, sublicensees or customers;

(e) that disclosure is necessary by reason of applicable legal, accounting or regulatory requirements beyond the reasonable control of the receiving Party; or

(f) is subsequently developed by the receiving Party independently of the information received from the disclosing Party.

In the case of any disclosure pursuant to Sections 10.3(d) or 10.3(e), to the extent practical, the receiving Party shall notify the disclosing Party in advance of the required disclosure and shall use commercially reasonable efforts to assist the disclosing Party in obtaining a protective order, if available, covering such disclosure. If such a protective order is obtained, such information and materials shall continue to be deemed to be Confidential Information.

Notwithstanding Section 10.2, the receiving Party shall have the right to disclose Confidential Information of the disclosing Party to the receiving Party's attorneys, accountants, actual or potential sources of financing, and actual or potential investors or acquirers under appropriate non-use and non-disclosure restrictions which are at least as restrictive as those set forth herein.

Section 10.4 Use of Certain Information. No Party shall, without the appropriate Party's prior written consent, use the names, service marks or trademarks of another Party as trademarks or use such names, service marks or trademarks to suggest any affiliation, sponsorship, endorsement or recommendation. All employees, agents, representatives and consultants of each Party and its Affiliates and sublicensees shall be required to comply with the terms of this Section 10, and each Party, as applicable, shall be responsible for any breach thereof and the performance or non-performance of each such party.

Section 10.5 No Publicity. Except as required by law, no Party shall originate any news release or other public announcement relating to this Agreement or the terms hereof without the prior written approval of the other Party; provided, however that any Party to this Agreement may provide public information concerning this transaction to the extent necessary or appropriate to comply with applicable securities laws and/or customary corporate communications processes.

Section 10.6 Equitable Remedies. Each Party acknowledges that if it, its Affiliates or their respective employees, agents, representatives, or consultants breach (or attempt to breach) the obligations set forth in this Article 10, the other Party will suffer immediate and irreparable harm, it being acknowledged that legal remedies are inadequate. Accordingly, if a court of competent jurisdiction should find that any such Party has breached (or attempted to breach) any such obligations, such Party shall not oppose the entry of an appropriate order compelling performance by such Party and restraining it from any further breaches (or attempted breaches).

Article 11
Indemnification; Insurance; Liability Limitation

Section 11.1 Indemnification.

(a) **Intellectual Property Indemnification by Fresenius Kabi**. Fresenius Kabi will, indemnify, defend and hold harmless Cerus and its Affiliates, and their respective officers, directors, agents, and employees (collectively, with respect to Cerus, the "Cerus Indemnified Parties") from and against any Damages arising out of or relating to any claim from any third party that Fresenius Kabi's plastics, subassemblies, such as bags, tubing and connectors, or manufacturing or packaging processes for the Manufactured Products (the "Fresenius Kabi Elements"), infringe, misappropriate or violate any patent, copyright, trade secret, confidential information or other intellectual property of any third party.

(b) **Exceptions to Fresenius Kabi Intellectual Property Indemnification**. Fresenius Kabi shall have no indemnification obligations under Section 11.1(a) with respect to any infringement relating to:

(i) Cerus' direction, without Fresenius Kabi's approval, to any Person to use the Manufactured Products in a manner contrary to the instructions for use of such Manufactured Product and the infringement is caused by such contrary use; or

(ii) the combination, incorporation or use of any Manufactured Products by Cerus with Cerus' or any third party's product(s), or the use of such combined or incorporated Manufactured Products by Cerus' customers, if such infringement would not have existed but for such combination or incorporation of the Manufactured Products by Cerus with or into any such Cerus product or any other third party product, or the use of such combined or incorporated product by Cerus' customers, except for combinations, incorporations or use specified in the instructions for use of such Manufactured Products.

(c) **Intellectual Property Indemnification by Cerus**. Cerus will indemnify, defend and hold harmless Fresenius Kabi and its Affiliates, and their respective officers, directors, agents, and employees (collectively, with respect to Fresenius Kabi, the "Fresenius Kabi Indemnified Parties") from and against any Damages arising out of or relating to any claim from any third party that any Cerus-Supplied Materials or Manufactured Product infringes, misappropriates or violates any patent, copyright, trademark, trade secret, confidential information or other intellectual property right of any third party; provided that the indemnification obligation set forth in this Section 11.1(c) shall not apply to the extent that such Damages arise out of or relate to (i) a Fresenius Kabi Element or (ii) the Licensed Assets, or (iii) a Manufactured Product that is not in conformity with the Product Specifications and such infringement, misappropriation or violation would not have existed but for the difference between the specifications and the Product Specifications.

(d) **Other Indemnification by Fresenius Kabi**. Fresenius Kabi will indemnify, defend and hold harmless the Cerus Indemnified Parties from and against any Damages arising out of or relating to any claim from any third party that (x) defective Manufactured Product, (y) negligence or willful misconduct of Fresenius Kabi, or (z) acts or omissions of Fresenius Kabi that would constitute a Breach, have created Liabilities to the third party; provided, however, for the avoidance of doubt, Fresenius Kabi shall have no obligation to indemnify Cerus for any Liabilities caused by (i) the design of the Products (except to the extent that such design was based on input from Fresenius Kabi), (ii) Cerus-Supplied Materials, or (iii) any claim encompassed within Cerus' obligation to indemnify pursuant to Section 11(e) below.

(e) **Other Indemnification by Cerus**. Cerus will indemnify, defend and hold harmless the Fresenius Kabi Indemnified Parties from and against any Damages arising out of or relating to any claim from any third party (other than claims of infringement of patent, copyright, trademark, trade secret, confidential information or other intellectual property right) that Cerus' or its distributors', resellers' or Affiliates' sale, offer for sale, import, manufacture, use or distribution of Manufactured Products, or use of such Manufactured Products by customers of Cerus, has created Liabilities to the third party; except to the extent the claim is encompassed within Fresenius Kabi's obligation to indemnify pursuant to Section 11.1(d), above.

Section 11.2 Procedure for Indemnification - Third Party Claims.

(a) Promptly after receipt by an Indemnified Party of notice of the commencement of any Proceeding against it, the Indemnified Party shall notify the other Parties obligated to indemnify such Indemnified Party (the "Indemnifying Party") of the commencement of the claim.

(b) If any Proceeding referred to in Section 11.2(a) is brought against an Indemnified Party and it gives notice to the Indemnifying Party of the commencement of the Proceeding, the Indemnifying Party shall, upon written notice given within thirty (30) days after the Indemnified Party's notice is given, be entitled to assume the defense of the Proceeding. If the Indemnifying Party elects to assume the defense of a Proceeding, the Indemnified Party shall turn the Proceeding over to the Indemnifying Party, who shall, at its own expense, assume the defense of the Proceeding and the Indemnified Party shall have the right (but not the obligation) to participate, at its own expense, in the defense thereof by counsel of its own choice, and shall cooperate with and assist the Indemnifying Party in connection with the defense or contest, but the Indemnifying Party shall retain control thereof and have final authority to determine all matters in connection therewith. Notwithstanding the foregoing, (i) the Indemnifying Party shall have the right to control the defense, litigation and settlement of the action only if the Indemnifying Party has agreed in writing to be responsible for all costs, expenses, judgments and liabilities connected with the claim, (ii) the Indemnifying Party shall not enter into any settlement of any Proceeding unless such settlement is contingent upon obtaining a general release in form and substance acceptable to the Indemnified Party releasing the Indemnified Party from all Liabilities in such Proceeding, and (iii) the Indemnifying Party shall not enter into any settlement of any Proceeding if such settlement grants any injunctive or equitable relief unless the Indemnified Party has consented in writing to such settlement.

Section 11.3 Definitions.

(a) As used herein, a "Breach" shall mean a breach of a covenant, obligation or other provision of this Agreement, and such breach will be deemed to have occurred if there is or has been one or more misstatements or inaccuracies in, or one or more failures to perform or comply with, any representation, warranty, covenant, obligation or other provision of this Agreement.

(b) As used herein, "Damages" shall mean all Liabilities, obligations, losses, damages, deficiencies, assessments, judgments, costs, expenses (including, without limitation, reasonable attorneys' fees and costs and expenses incurred in investigating, preparing, defending against or prosecuting any Proceeding).

(c) As used herein, "Liabilities" means any debts, obligations, duties or liabilities of any nature, whether known or unknown, and whether accrued, contingent or otherwise.

(d) As used herein, "Proceeding" means any third-party action, arbitration, audit, hearing, investigation, litigation or suit (whether civil, criminal, administrative, investigative or informal) commenced, brought, conducted or heard by or before, or otherwise involving, any governmental body or arbitrator.

Section 11.4 Fresenius Kabi Insurance. Fresenius Kabi shall carry appropriate levels of insurance coverage consistent with its commercially reasonable business practices.

Section 11.5 Cerus Insurance. Cerus shall carry appropriate levels of insurance coverage consistent with its commercially reasonable business practices.

Section 11.6 Limitation on Liability. NEITHER PARTY WILL BE LIABLE FOR LOST PROFITS, LOSS OF BUSINESS OR OTHER CONSEQUENTIAL, SPECIAL, INDIRECT OR PUNITIVE DAMAGES, REGARDLESS OF WHETHER SUCH PARTY SHALL BE ADVISED, SHALL HAVE OTHER REASON TO KNOW, OR IN FACT SHALL KNOW OF THE FOREGOING. Except with respect to a breach of a Party's confidentiality obligation hereunder or a Party's indemnification obligation under Section 11.1(a), 11.1(c), 11.1(d)(x) ([***]), 11.1(d)(y) ([***]), or 11.1(e), in no event shall any Party be liable for direct damages regardless of whether such Party shall be advised, shall have other reason to know, or in fact shall know of the foregoing, in excess of the [***] period preceding the claim, in the aggregate under the Agreement.

Article 12
Miscellaneous

Section 12.1 Governing Law. This Agreement shall be governed by and construed in accordance with the laws of the State of Delaware.

Section 12.2 Assignment and Delegation.

(a) **No Assignments Except as Permitted**. No Party may assign any of its rights under this Agreement other than assignments to a Permitted Assignee, except with the prior written consent of the other Party. That Party shall not unreasonably withhold its consent. "Permitted Assignees" include an Affiliate of the assigning Party and a third party to whom the assigning Party transfers substantially all of the products, business and services to which this Agreement relates and who assumes all obligations of the assigning party under this Agreement and has the capability to perform such obligations. All other assignments of rights are prohibited under this subsection, whether they are voluntary or involuntary, by merger, consolidation, dissolution, operation of law, or any other manner. For purposes of this Section, (i) a "change of control" is deemed an assignment of rights; and (ii) "merger" refers to any merger in which a Party participates, regardless of whether it is the surviving or disappearing corporation.

(b) **No Delegations**. No Party may delegate any performance under this Agreement.

(c) **Ramifications of Purported Assignment or Delegation**. Any purported assignment of rights or delegation of performance in violation of this Section is void.

Section 12.3 Successors and Assigns. This Agreement inures to the benefit of, and is binding upon, the successors and assigns of the Parties hereto.

Section 12.4 Entire Agreement; Amendments. This Agreement contains the entire understanding of the Parties with regard to the subject matter contained herein and thereon, and supersede all prior agreements or understandings between Cerus and Fresenius Kabi with respect to the subject matter of the Original Supply Agreement; provided however that any Work Orders or side letters entered into under the Original Supply Agreement shall survive and remain in effect. For purposes of clarity, except as stated in Sections 5.1 and 5.3 of this Agreement, this Agreement does not supersede the Commercialization Agreement, the Restructuring Agreement entered between the Parties as of February 2, 2005, or the Concurrent Agreement (as defined in the Restructuring Agreement). For further clarity, except as stated in Section 9.8 of this Agreement, this Agreement does not supersede or amend the terms of the License Agreement, which governs the terms of any intellectual property applicable to the rights and obligations of the Parties hereunder. This Agreement will not be amended, modified or supplemented except by a written instrument signed by an authorized representative of each of the Parties.

Section 12.5 Force Majeure. Neither Party will be deemed in default if delayed or prevented from performing its obligations under this Agreement, in whole or in part, due to an act of God, fire, flood, explosion, pandemic, epidemic, civil disorder, strike, lockout or other labor trouble, material shortages of utilities, equipment, materials or facilities, delay in transportation, breakdown or accident, riot, war, terrorist attack or other cause beyond its control (a "Force

Majeure Event"); provided that it shall resume full performance of this Agreement as soon as practicable following the conclusion of the Force Majeure Event.

Section 12.6 Interpretation; No Strict Construction. Article titles and headings to Sections herein are inserted for convenience of reference only and are not intended to be a part of or to affect the meaning or interpretation of this Agreement. The language used in this Agreement shall be deemed to be the language chosen by the Parties hereto to express their mutual intent, and no rule of strict construction shall be applied against any Party hereto.

Section 12.7 Partial Invalidity. If any provision of this Agreement, or the application thereof, is held by a court of competent jurisdiction to be invalid, void or unenforceable, the remainder of the provisions of this Agreement will in no way be effected, impaired or invalidated, and to the extent permitted by applicable law, any such provision will be restricted in applicability or reformed to the minimum extent required for such provision to be enforceable.

Section 12.8 No Third Party Beneficiary. This Agreement will not confer any rights or remedies on any person other than the Parties hereto and their respective successors and permitted assigns.

Section 12.9 Counterparts. This Agreement may be executed in one or more counterparts (and by facsimile), all of which shall be considered one and the same agreement, and shall become effective when one or more counterparts have been signed by each of the Parties and delivered to the other parties.

Section 12.10 Notices. Wherever under this Agreement one Party is required or permitted to give written notice to the other, such notice will be deemed given if made in accordance with the terms of the License Agreement.

Section 12.11 Nonwaiver. No alleged waiver, modification or amendment to this Agreement shall be effective against either Party hereto, unless in writing, signed by the Party against which such waiver, modification or amendment is asserted, and referring specifically to the provision hereof alleged to be waived, modified or amended. The failure or delay of either Party to insist upon the other Party's strict performance of the provisions in this Agreement or to exercise in any respect any right, power, privilege, or remedy provided for under this Agreement shall not operate as a waiver or relinquishment thereof, nor shall any single or partial exercise of any right, power, privilege or remedy preclude other or further exercise thereof, or the exercise of any other right, power, privilege, or remedy; provided, however, that the obligations and duties of either Party with respect to the performance of any term or condition in this Agreement shall continue in full force and effect. The execution of this Agreement by the Parties does not constitute or evidence any waiver of any right, or remedy either Party may have against the other Party under the Original Supply Agreement.

Section 12.12 Alternative Dispute Resolution. The Parties will attempt to settle any claim or controversy arising out of this Agreement through good faith negotiations and in the spirit

of mutual cooperation. Any issues that cannot be resolved will be referred to a senior management representative from each of the Parties who has the authority to resolve the dispute. In the event such senior management representatives cannot resolve the dispute, the dispute will be submitted to binding arbitration for resolution. Any such proceedings shall be conducted at the place of the principal office of the respondent in accordance with Commercial Arbitration Rules of the American Arbitration Association ("AAA"). Any such proceedings shall be conducted at the place of the principal office of the respondent in accordance with the Commercial Arbitration Rules of the AAA. Any such dispute or controversy shall be arbitrated before a single arbitrator selected in accordance with the rules of the AAA. The arbitrator's decision shall be final and binding upon the parties. The parties shall be entitled to full discovery in any such arbitration. Each party shall bear one half of the cost of such arbitration, unless the arbitrator otherwise allocates such costs. Judgment on the award rendered by the arbitrator(s) may be entered in any court having jurisdiction thereof. Nothing in this Section will prevent either Party from resorting to judicial process if injunctive relief from a court is necessary to prevent serious and irreparable injury to one Party or to others.

Section 12.13 Joint and Several Liability. Fresenius Kabi's obligations and liability under this Agreement shall be joint and several, including without limitation, with respect to each such party's indemnification obligations under Article 11.

Section 12.14 Availability of Injunction. Fresenius Kabi and Cerus agree that any breach, or threatened breach, of this Agreement by one Party could cause irreparable damage to the other Party. The Parties agree that, in the event of such breach, or threatened breach, the Parties shall have, in addition to any and all remedies of law, the right to an injunction, specific performance as well as all other equitable relief to prevent the violation of any obligations hereunder without the necessity of any proof of actual damages or the posting of a bond or other security. The Parties further agree that any action pursuant to this Section can and shall be brought in the state or federal courts located in Chicago, Illinois or San Francisco, California. The Parties hereby consent to the jurisdiction of such state or federal courts over such disputes and hereby waive and agree not to raise any and all defenses to the exercise of jurisdiction by such state or federal courts, including without limitation, personal jurisdiction, improper venue and forum non conveniens.

Section 12.15 Fresenius Kabi Deutschland. FK Deutschland hereby consents to the amendment and restatement of the Original Supply Agreement and as of the Effective Date, Fresenius Kabi (not FK Deutschland) shall be obligated to provide the Manufactured Products to Cerus.

[Signature Page to Follow]

Exhibit 10.2

IN WITNESS WHEREOF, the Parties have caused this Agreement to be executed by their duly authorized representatives as of the last date set forth below.

FENWAL INTERNATIONAL, INC.

By: /s/ Yamilett Odiott

Name: Yamilett Odiott

Title: Plant Manager

By: /s/ Scott Day

Name: Scott Day

Title: VP & Chief Counsel, Legal & IP

FENWAL FRANCE SAS

By: /s/ Olivier Symoneaux

Name: Olivier Symoneaux

Title: Plant Manager La Chatre

By: /s/ Georgi Jekov

Name: Georgi Jekov

Title: Senior Vice President Global Operations Disposables, Fresenius Kabi MedTech

FRESENIUS KABI DEUTSCHLAND GMBH

By: /s/ Stefan Vogt

Name: Stefan Vogt

Title:

By: /s/ Jens Schaake

Name: ppa. Jens Schaake

Title: Senior Vice President CoE Global Procurement

FRESENIUS KABI AG

By: /s/ Christian Hauer

Name: Dr. Christian Hauer

Title: President Fresenius Kabi MedTech

By: /s/ Kristina Nelkner

Name: ppa Kristina Nelkner

Title: Vice President HR / EHS & OHS

CERUS CORPORATION

By: /s/ William M. Greenman

Name: William M. Greenman

Title: President and CEO

EXHIBIT A

Product Specifications
Platelet Sets

[***]

EXHIBIT B

Product Specifications
Plasma Sets

[***]

EXHIBIT C

Product Specifications
RBC Sets

[***]

Exhibit C

EXHIBIT D

Transfer Price*

[***]

EXHIBIT E

Steering Committee Members

Fresenius Kabi Members		Cerus Members	
[***]	[***]	[***]	[***]
[***]	[***]	[***]	[***]
[***]	[***]	[***]	[***]
[***]	[***]	[***]	[***]

Exhibit F

SECOND AMENDED AND RESTATED MANUFACTURING AND SUPPLY AGREEMENT (FRESENIUS KABI – CERUS)

EXHIBIT F

Funded Projects

[***]

EXHIBIT G

[***]

[attached]

EXHIBIT H

Business Continuity Plan

[attached]

EXHIBIT I

Cerus-Supplied Materials Cost

[***]

CERUS CORPORATION
AMENDED AND RESTATED 2008 EQUITY INCENTIVE PLAN

APPROVED BY THE BOARD OF DIRECTORS ON: APRIL 19, 2017
APPROVED BY STOCKHOLDERS ON: JUNE 7, 2017
AMENDED AND RESTATED BY THE BOARD OF DIRECTORS ON: APRIL 19, 2019
AMENDED AND RESTATED BY THE BOARD OF DIRECTORS ON: MAY 23, 2019
APPROVED BY STOCKHOLDERS ON: JUNE 5, 2019
AMENDED AND RESTATED BY THE BOARD OF DIRECTORS ON: APRIL 11, 2020
APPROVED BY STOCKHOLDERS ON: JUNE 3, 2020
AMENDED AND RESTATED BY THE BOARD OF DIRECTORS ON: MARCH 26, 2021
APPROVED BY STOCKHOLDERS ON: JUNE 2, 2021
AMENDED AND RESTATED BY THE BOARD OF DIRECTORS ON: MARCH 25, 2022 APPROVED BY STOCKHOLDERS ON: JUNE 1, 2022
TERMINATION DATE: APRIL 21, 2026

1. GENERAL.

(a) Successor and Continuation of Prior Plans. The Plan is intended as the successor to and continuation of the Cerus Corporation 1999 Equity Incentive Plan, as amended, and the Cerus Corporation 1998 Non-Officer Stock Option Plan (the "***Prior Plans***"). Following the Effective Date, no additional stock awards shall be granted under the Prior Plans. Any shares remaining available for future awards under the Prior Plans as of the Effective Date (the "***Prior Plans Available Reserve***") shall become available for issuance pursuant to Awards granted hereunder. From and after the Effective Date, all outstanding stock awards granted under either of the Prior Plans (each, a "***Prior Plan Award***") shall remain subject to the terms of the applicable Prior Plan, and from and after June 7, 2017, all outstanding stock awards granted under the Cerus Corporation Inducement Plan (the "***Inducement Plan***") (each, an "***Inducement Plan Award***") shall remain subject to the terms of the Inducement Plan; *provided, however*, that (i) any shares subject to any outstanding Prior Plan Award that, on or after the Effective Date, expires or terminates for any reason prior to exercise or settlement and (ii) any shares subject to any outstanding Inducement Plan Award as of April 13, 2017 that, on or after June 7, 2017, expires or terminates for any reason prior to exercise or settlement (collectively, the "***Returning Shares***") shall become available for issuance pursuant to Awards granted hereunder. All Awards granted on or after the Effective Date of this Plan shall be subject to the terms of this Plan.

(b) Eligible Award Recipients. The persons eligible to receive Awards are Employees, Directors and Consultants.

(c) Available Awards. The Plan provides for the grant of the following Awards: (i) Incentive Stock Options, (ii) Nonstatutory Stock Options, (iii) Restricted Stock Awards, (iv) Restricted Stock Unit Awards, (v) Stock Appreciation Rights, (vi) Performance Stock Awards, (vii) Performance Cash Awards, and (viii) Other Stock Awards.

(d) General Purpose. The Company, by means of the Plan, seeks to secure and retain the services of the group of persons eligible to receive Awards as set forth in Section 1(b), to provide incentives for such persons to exert maximum efforts for the success of the Company and any Affiliate and to provide a means by which such eligible recipients may be given an opportunity to benefit from increases in value of the Common Stock through the granting of Stock Awards.

(e) Section 162(m) Transition Relief. Notwithstanding anything in the Plan to the contrary, any provision in the Plan that refers to "performance-based compensation" under Section 162(m) of the Code will only apply to

any Award that is intended to qualify, and is eligible to qualify, as "performance-based compensation" under Section 162(m) of the Code pursuant to the transition relief provided by the Tax Cuts and Jobs Act (the "***TCJA***") for remuneration provided pursuant to a written binding contract which was in effect on November 2, 2017 and which is not modified in any material respect on or after such date, as determined by the Board, in its sole discretion, in accordance with the TCJA and any applicable guidance, rulings or regulations issued by the U.S. Department of the Treasury, the Internal Revenue Service or any other governmental authority.

2. ADMINISTRATION.

(a) Administration by Board. The Board shall administer the Plan unless and until the Board delegates administration of the Plan to a Committee or Committees, as provided in Section 2(c).

(b) Powers of Board. The Board shall have the power, subject to, and within the limitations of, the express provisions of the Plan:

(i) To determine from time to time (A) which of the persons eligible under the Plan shall be granted Awards; (B) when and how each Award shall be granted; (C) what type or combination of types of Award shall be granted; (D) the provisions of each Award granted (which need not be identical), including the time or times when a person shall be permitted to receive cash or Common Stock pursuant to a Stock Award; and (E) the number of shares of Common Stock with respect to which a Stock Award shall be granted to each such person.

(ii) To construe and interpret the Plan and Awards, and to establish, amend and revoke rules and regulations for the Plan's administration. The Board, in the exercise of this power, may correct any defect, omission or inconsistency in the Plan or in any Stock Award Agreement or in the written terms of a Performance Cash Award, in a manner and to the extent it shall deem necessary or expedient to make the Plan or Award fully effective.

(iii) To settle all controversies regarding the Plan and Awards.

(iv) To accelerate the time at which a Stock Award may first be exercised or the time during which an Award or any part thereof will vest in accordance with the Plan, notwithstanding the provisions in the Award stating the time at which it may first be exercised or the time during which it will vest.

(v) To suspend or terminate the Plan at any time. Suspension or termination of the Plan shall not impair rights and obligations under any Stock Award granted while the Plan is in effect except with the written consent of the affected Participant.

(vi) To amend the Plan in any respect the Board deems necessary or advisable, including, without limitation, relating to Incentive Stock Options and certain nonqualified deferred compensation under Section 409A of the Code and to bring the Plan and/or Stock Awards into compliance therewith, subject to the limitations, if any, of applicable law. However, except as provided in Section 9(a) relating to Capitalization Adjustments, stockholder approval shall be required for any amendment of the Plan that either (A) materially increases the number of shares of Common Stock available for issuance under the Plan, (B) materially expands the class of individuals eligible to receive Awards under the Plan, (C) materially increases the benefits accruing to Participants under the Plan or materially reduces the price at which shares of Common Stock may be issued or purchased under the Plan, (D) materially extends the term of the Plan, or (E) expands the types of Awards available for issuance under the Plan, but only to the extent required by applicable law or listing requirements. Except as provided above, rights under any Award granted before amendment of the Plan shall not be impaired by any amendment of the Plan unless (1) the Company requests the consent of the affected Participant, and (2) such Participant consents in writing.

(vii) To submit any amendment to the Plan for stockholder approval, including, but not limited to, amendments to the Plan intended to satisfy the requirements of (A) Section 162(m) of the Code and the

regulations thereunder regarding the exclusion of performance-based compensation from the limit on corporate deductibility of compensation paid to Covered Employees, (B) Section 422 of the Code regarding "incentive stock options" or (C) Rule 16b-3.

(viii) To approve forms of Award Agreements for use under the Plan and to amend the terms of any one or more Awards, including, but not limited to, amendments to provide terms more favorable to the Participant than previously provided in the Award Agreement, subject to any specified limits in the Plan that are not subject to Board discretion; *provided however,* that the Participant's rights under any Award shall not be impaired by any such amendment unless (A) the Company requests the consent of the affected Participant, and (B) such Participant consents in writing. Notwithstanding the foregoing, subject to the limitations of applicable law, if any, and without the affected Participant's consent, the Board may amend the terms of any one or more Awards if necessary to maintain the qualified status of the Award as an Incentive Stock Option or to bring the Award into compliance with Section 409A of the Code and Department of Treasury regulations and other interpretive guidance issued thereunder, including without limitation any such regulations or other guidance that may be issued or amended after the Effective Date.

(ix) Generally, to exercise such powers and to perform such acts as the Board deems necessary or expedient to promote the best interests of the Company and that are not in conflict with the provisions of the Plan or Awards.

(x) To adopt such procedures and sub-plans as are necessary or appropriate to permit participation in the Plan by Employees, Directors or Consultants who are foreign nationals or employed outside the United States.

(c) Delegation to Committee.

(i) General. The Board may delegate some or all of the administration of the Plan to a Committee or Committees. If administration of the Plan is delegated to a Committee, the Committee shall have, in connection with the administration of the Plan, the powers theretofore possessed by the Board that have been delegated to the Committee, including the power to delegate to a subcommittee of the Committee any of the administrative powers the Committee is authorized to exercise (and references in this Plan to the Board shall thereafter be to the Committee or subcommittee), subject, however, to such resolutions, not inconsistent with the provisions of the Plan, as may be adopted from time to time by the Board. The Board may retain the authority to concurrently administer the Plan with the Committee and may, at any time, revest in the Board some or all of the powers previously delegated to the Committee, Committees, subcommittee or subcommittees.

(ii) Section 162(m) and Rule 16b-3 Compliance. In the sole discretion of the Board, the Committee may consist solely of two (2) or more Outside Directors, in accordance with Section 162(m) of the Code, or solely of two (2) or more Non-Employee Directors, in accordance with Rule 16b-3. In addition, the Board or the Committee, in its sole discretion, may (A) delegate to a Committee which need not consist of Outside Directors the authority to grant Awards to eligible persons who are either (1) not then Covered Employees and are not expected to be Covered Employees at the time of recognition of income resulting from such Stock Award, or (2) not persons with respect to whom the Company wishes to comply with Section 162(m) of the Code, or (B) delegate to a Committee which need not consist of Non-Employee Directors the authority to grant Stock Awards to eligible persons who are not then subject to Section 16 of the Exchange Act.

(d) Delegation to an Officer. The Board may delegate to one (1) or more Officers the authority to do one or both of the following (i) designate Employees who are not Officers to be recipients of Options (and, to the extent permitted by applicable law, other Stock Awards) and the terms thereof, and (ii) determine the number of shares of Common Stock to be subject to such Stock Awards granted to such Employees; *provided, however*, that the Board resolutions regarding such delegation shall specify the total number of shares of Common Stock that may be subject to the Stock Awards granted by such Officer and that such Officer may not grant a Stock Award

to himself or herself. Notwithstanding anything to the contrary in this Section 2(d), the Board may not delegate to an Officer authority to determine the Fair Market Value pursuant to Section 13(x)(ii) below.

(e) Effect of Board's Decision. All determinations, interpretations and constructions made by the Board in good faith shall not be subject to review by any person and shall be final, binding and conclusive on all persons.

(f) Cancellation and Re-Grant of Stock Awards. Neither the Board nor any Committee shall have the authority to: (i) effect the reduction of the exercise price of any outstanding Option or Stock Appreciation Rights under the Plan (other than pursuant to Section 9 relating to adjustments upon changes in stock), or (ii) cancel any outstanding Options or Stock Appreciation Rights with an exercise price that is greater than the Fair Market Value on the date of cancellation in exchange for the grant in substitution therefore of cash or new Stock Awards under the Plan with an exercise price that is less than the original exercise price of the Options or Stock Appreciation Rights, unless the stockholders of the Company have approved such an action within twelve (12) months prior to such an event.

(g) Minimum Vesting Requirements. No Award granted on or after June 5, 2019 may vest (or, if applicable, be exercisable) until at least 12 months following the date of grant of the Award; *provided, however*, that shares of Common Stock up to 5% of the Share Reserve (as defined in Section 3(a)) may be issued pursuant to Awards granted on or after June 5, 2019 that do not meet such vesting (and, if applicable, exercisability) requirements.

(h) Dividends and Dividend Equivalents. Dividends or dividend equivalents may be paid or credited, as applicable, with respect to any shares of Common Stock subject to an Award, as determined by the Board and contained in the applicable Award Agreement; *provided, however*, that (i) no dividends or dividend equivalents may be paid with respect to any such shares before the date such shares have vested under the terms of such Award Agreement, (ii) any dividends or dividend equivalents that are credited with respect to any such shares will be subject to all of the terms and conditions applicable to such shares under the terms of such Award Agreement (including, but not limited to, any vesting conditions), and (iii) any dividends or dividend equivalents that are credited with respect to any such shares will be forfeited to the Company on the date, if any, such shares are forfeited to or repurchased by the Company due to a failure to meet any vesting conditions under the terms of such Award Agreement.

3. Shares Subject to the Plan.

(a) Share Reserve. Subject to the provisions of Section 9(a) relating to Capitalization Adjustments, the aggregate number of shares of Common Stock that may be issued pursuant to Stock Awards from and after the Effective Date shall not exceed 67,897,190 shares (the "***Share Reserve***"), which number includes the Prior Plans Available Reserve and the Returning Shares, if any, as such shares become available from time to time. For clarity, the Share Reserve is a limitation in the number of shares of the Common Stock that may be issued pursuant to the Plan and does not limit the granting of Stock Awards except as provided in Section 7(a). Shares may be issued in connection with a merger or acquisition as permitted by NASD Rule 4350(i)(1)(A)(iii) or, if applicable, NYSE Listed Company Manual Section 303A.08, or AMEX Company Guide Section 711 and such issuance shall not reduce the number of shares available for issuance under the Plan. Furthermore, if a Stock Award (i) expires or otherwise terminates without all of the shares covered by such Stock Award having been issued or (ii) is settled in cash (*i.e.*, the holder of the Stock Award receives cash rather than stock), such expiration, termination or settlement shall not reduce (or otherwise offset) the number of shares of Common Stock that may be issued pursuant to the Plan.

(b) Fungible Share Counting.

(i) Subject to Section 3(c), the number of shares of Common Stock available for issuance under the Plan shall be reduced by: (A) one (1) share for each share of Common Stock issued pursuant to an Appreciation

Award granted under the Plan; (B) one and sixty-one hundredths (1.61) shares for each share of Common Stock issued pursuant to a Full Value Award granted under the Plan prior to June 5, 2019; (C) one and fifty-five hundredths (1.55) shares for each share of Common Stock issued pursuant to a Full Value Award granted under the Plan on or after June 5, 2019 and prior to June 3, 2020; (D) one and seven hundredths (1.07) shares for each share of Common Stock issued pursuant to a Full Value Award granted under the Plan on or after June 3, 2020 and prior to June 2, 2021; (E) one and fifty-two hundredths (1.52) shares for each share of Common Stock issued pursuant to a Full Value Award granted under the Plan on or after June 2, 2021 and prior to June 1, 2022; and (F) one and thirty-nine hundredths (1.39) shares for each share of Common Stock issued pursuant to a Full Value Award granted under the Plan on or after June 1, 2022.

(ii) Subject to Section 3(c), the number of shares of Common Stock available for issuance under the Plan shall be increased by: (A) one (1) share for each Returning Share or share of Common Stock that again becomes available for issuance under the Plan pursuant to Section 3(c)(i), in each case that is subject to an Appreciation Award; (B) one and sixty-one hundredths (1.61) shares for each Returning Share or share of Common Stock that again becomes available for issuance under the Plan pursuant to Section 3(c)(i), in each case that is subject to a Full Value Award that returns to the Plan prior to June 5, 2019; (C) one and fifty-five hundredths (1.55) shares for each Returning Share or share of Common Stock that again becomes available for issuance under the Plan pursuant to Section 3(c)(i), in each case that is subject to a Full Value Award that returns to the Plan on or after June 5, 2019 and prior to June 3, 2020; (D) one and seven hundredths (1.07) shares for each Returning Share or share of Common Stock that again becomes available for issuance under the Plan pursuant to Section 3(c)(i), in each case that is subject to a Full Value Award that returns to the Plan on or after June 3, 2020 and prior to June 2, 2021; (E) one and fifty-two hundredths (1.52) shares for each Returning Share or share of Common Stock that again becomes available for issuance under the Plan pursuant to Section 3(c)(i), in each case that is subject to a Full Value Award that returns to the Plan on or after June 2, 2021 and prior to June 1, 2022; and (F) one and thirty-nine hundredths (1.39) shares for each Returning Share or share of Common Stock that again becomes available for issuance under the Plan pursuant to Section 3(c)(i), in each case that is subject to a Full Value Award that returns to the Plan on or after June 1, 2022.

(c) Reversion of Shares to the Share Reserve.

(i) Shares Available For Subsequent Issuance. If any shares of Common Stock issued pursuant to a Stock Award are forfeited back to the Company because of the failure to meet a contingency or condition required to vest such shares in the Participant, then the shares which are forfeited shall revert to and again become available for issuance under the Plan. Notwithstanding the provisions of this Section 3(c)(i), any such shares shall not be subsequently issued pursuant to the exercise of Incentive Stock Options.

(ii) Shares Not Available For Subsequent Issuance. The following shares of Common Stock shall not become available again for issuance under the Plan: (A) any shares that are reacquired or withheld (or not issued) by the Company to satisfy the exercise, strike or purchase price of a Stock Award, a Prior Plan Award or an Inducement Plan Award (including any shares subject to such award that are not delivered because such award is exercised through a reduction of shares subject to such award (i.e., "net exercised")); (B) any shares that are reacquired or withheld (or not issued) by the Company to satisfy a tax withholding obligation in connection with a Stock Award, a Prior Plan Award or an Inducement Plan Award; (C) any shares repurchased by the Company on the open market with the proceeds of the exercise, strike or purchase price of a Stock Award, a Prior Plan Award or an Inducement Plan Award; and (D) in the event that a Stock Appreciation Right granted under the Plan or a stock appreciation right granted under either of the Prior Plans or the Inducement Plan is settled in shares of Common Stock, the gross number of shares of Common Stock subject to such award.

(d) Incentive Stock Option Limit. Notwithstanding anything to the contrary in this Section 3(d), subject to the provisions of Section 9(a) relating to Capitalization Adjustments, the aggregate maximum number of shares of Common Stock that may be issued pursuant to the exercise of Incentive Stock Options shall be the Share Reserve.

(e) Section 162(m) Limitation on Annual Grants. Subject to the provisions of Section 9(a) relating to Capitalization Adjustments, at such time as the Company may be subject to the applicable provisions of Section 162(m) of the Code, no Employee shall be eligible to be granted during any calendar year Stock Awards whose value is determined by reference to an increase over an exercise or strike price of at least one hundred percent (100%) of the Fair Market Value on the date the Stock Award is granted (that is, Options or Stock Appreciation Rights) covering more than eight hundred thousand (800,000) shares of Common Stock.

(f) Source of Shares. The stock issuable under the Plan shall be shares of authorized but unissued or reacquired Common Stock, including shares repurchased by the Company on the market or otherwise.

4. ELIGIBILITY.

(a) Eligibility for Specific Stock Awards. Incentive Stock Options may be granted only to employees of the Company or a parent corporation or subsidiary corporation (as such terms are defined in Sections 424(e) and (f) of the Code). Stock Awards other than Incentive Stock Options may be granted to Employees, Directors and Consultants.

(b) Ten Percent Stockholders. A Ten Percent Stockholder shall not be granted an Incentive Stock Option unless the exercise price of such Option is at least one hundred ten percent (110%) of the Fair Market Value on the date of grant and the Option is not exercisable after the expiration of five (5) years from the date of grant.

(c) Consultants. A Consultant shall be eligible for the grant of a Stock Award only if, at the time of grant, a Form S-8 Registration Statement under the Securities Act ("***Form S-8***") is available to register either the offer or the sale of the Company's securities to such Consultant because of the nature of the services that the Consultant is providing to the Company, because the Consultant is a natural person, or because of any other rule governing the use of Form S-8.

5. OPTION PROVISIONS.

Each Option shall be in such form and shall contain such terms and conditions as the Board shall deem appropriate. All Options shall be separately designated Incentive Stock Options or Nonstatutory Stock Options at the time of grant, and, if certificates are issued, a separate certificate or certificates shall be issued for shares of Common Stock purchased on exercise of each type of Option. If an Option is not specifically designated as an Incentive Stock Option, then the Option shall be a Nonstatutory Stock Option. The provisions of separate Options need not be identical; *provided, however*, that each Option Agreement shall include (through incorporation of provisions hereof by reference in the Option Agreement or otherwise) the substance of each of the following provisions:

(a) Term. Subject to the provisions of Section 4(b) regarding Ten Percent Stockholders, no Option shall be exercisable after the expiration of ten (10) years from the date of its grant or such shorter period specified in the Option Agreement.

(b) Exercise Price. Subject to the provisions of Section 4(b) regarding Ten Percent Stockholders, the exercise price of each Option shall be not less than one hundred percent (100%) of the Fair Market Value of the Common Stock subject to the Option on the date the Option is granted. Notwithstanding the foregoing, an Option may be granted with an exercise price lower than one hundred percent (100%) of the Fair Market Value of the Common Stock subject to the Option if such Option is granted pursuant to an assumption of or substitution for another option in a manner consistent with the provisions of Section 424(a) of the Code (whether or not such options are Incentive Stock Options).

(c) Consideration. The purchase price of Common Stock acquired pursuant to the exercise of an Option shall be paid, to the extent permitted by applicable law and as determined by the Board in its sole discretion, by

any combination of the methods of payment set forth below. The Board shall have the authority to grant Options that do not permit all of the following methods of payment (or otherwise restrict the ability to use certain methods) and to grant Options that require the consent of the Company to utilize a particular method of payment. The methods of payment permitted by this Section 5(c) are:

(i) by cash, check, bank draft or money order payable to the Company;

(ii) pursuant to a program developed under Regulation T as promulgated by the Federal Reserve Board that, prior to the issuance of the stock subject to the Option, results in either the receipt of cash (or check) by the Company or the receipt of irrevocable instructions to pay the aggregate exercise price to the Company from the sales proceeds;

(iii) by delivery to the Company (either by actual delivery or attestation) of shares of Common Stock;

(iv) by a "net exercise" arrangement pursuant to which the Company will reduce the number of shares of Common Stock issued upon exercise by the largest whole number of shares with a Fair Market Value that does not exceed the aggregate exercise price; *provided, however*, that the Company shall accept a cash or other payment from the Participant to the extent of any remaining balance of the aggregate exercise price not satisfied by such reduction in the number of whole shares to be issued; *provided, further,* that shares of Common Stock will no longer be outstanding under an Option and will not be exercisable thereafter to the extent that (A) shares are used to pay the exercise price pursuant to the "net exercise," (B) shares are delivered to the Participant as a result of such exercise, and (C) shares are withheld to satisfy tax withholding obligations; or

(v) in any other form of legal consideration that may be acceptable to the Board.

(d) Transferability of Options. The Board may, in its sole discretion, impose such limitations on the transferability of Options as the Board shall determine. In the absence of such a determination by the Board to the contrary, the following restrictions on the transferability of Options shall apply:

(i) Restrictions on Transfer. An Option shall not be transferable except by will or by the laws of descent and distribution and shall be exercisable during the lifetime of the Optionholder only by the Optionholder; *provided, however*, that the Board may, in its sole discretion, permit transfer of the Option in a manner consistent with applicable tax and securities laws upon the Optionholder's request.

(ii) Domestic Relations Orders. Notwithstanding the foregoing, an Option may be transferred pursuant to a domestic relations order, *provided, however*, that an Incentive Stock Option may be deemed to be a Nonqualified Stock Option as a result of such transfer.

(iii) Beneficiary Designation. Notwithstanding the foregoing, the Optionholder may, by delivering written notice to the Company, in a form provided by or otherwise satisfactory to the Company, designate a third party who, in the event of the death of the Optionholder, shall thereafter be the beneficiary of an Option with the right to exercise the Option and receive the Common Stock or other consideration resulting from an Option exercise.

(e) Vesting Generally. The total number of shares of Common Stock subject to an Option may vest and therefore become exercisable in periodic installments that may or may not be equal. The Option may be subject to such other terms and conditions on the time or times when it may or may not be exercised (which may be based on the satisfaction of Performance Goals or other criteria) as the Board may deem appropriate. The vesting provisions of individual Options may vary. The provisions of this Section 5(e) are subject to Section 2(g) and any Option provisions governing the minimum number of shares of Common Stock as to which an Option may be exercised.

(f) Termination of Continuous Service. Except as otherwise provided in the applicable Option Agreement or other agreement between the Optionholder and the Company, in the event that an Optionholder's Continuous Service terminates (other than upon the Optionholder's death or Disability), the Optionholder may exercise his or her Option (to the extent that the Optionholder was entitled to exercise such Option as of the date of termination of Continuous Service) but only within such period of time ending on the earlier of (i) the date three (3) months following the termination of the Optionholder's Continuous Service (or such longer or shorter period specified in the Option Agreement), or (ii) the expiration of the term of the Option as set forth in the Option Agreement. If, after termination of Continuous Service, the Optionholder does not exercise his or her Option within the time specified herein or in the Option Agreement (as applicable), the Option shall terminate

(g) Extension of Termination Date. Unless otherwise provided in an Optionholder's Option Agreement, if the exercise of the Option following the termination of the Optionholder's Continuous Service would be prohibited at any time solely because the issuance of shares of Common Stock would violate the registration requirements under the Securities Act, then the Option shall terminate on the earlier of (i) the expiration of a period equal to the original post-termination exercise period applicable to such Award during which the exercise of the Option would not be in violation of such registration requirements, or (ii) the expiration of the term of the Option as set forth in the Option Agreement. In addition, unless otherwise provided in an Optionholder's Option Agreement, if the sale of the Common Stock received upon exercise of an Option following the termination of the Optionholder's Continuous Service would violate the Company's insider trading policy, then the Option shall terminate on the earlier of (i) the expiration of a period equal to the original post-termination exercise period applicable to such Award during which the exercise of the Option would not be in violation of the Company's insider trading policy, (ii) the 15th day of the third month after the date on which the Option would cease to be exercisable but for this Section 5(g), or such longer period as would not cause the Option to become subject to Section 409A(a)(1) of the Code; or (iii) the expiration of the term of the Option as set forth in the Option Agreement.

(h) Disability of Optionholder. In the event that an Optionholder's Continuous Service terminates as a result of the Optionholder's Disability, the Optionholder may exercise his or her Option (to the extent that the Optionholder was entitled to exercise such Option as of the date of termination of Continuous Service), but only within such period of time ending on the earlier of (i) the date twelve (12) months following such termination of Continuous Service (or such longer or shorter period specified in the Option Agreement), or (ii) the expiration of the term of the Option as set forth in the Option Agreement. If, after termination of Continuous Service, the Optionholder does not exercise his or her Option within the time specified herein or in the Option Agreement (as applicable), the Option shall terminate.

(i) Death of Optionholder. In the event that (i) an Optionholder's Continuous Service terminates as a result of the Optionholder's death, or (ii) the Optionholder dies within the period (if any) specified in the Option Agreement after the termination of the Optionholder's Continuous Service for a reason other than death, then the Option may be exercised (to the extent the Optionholder was entitled to exercise such Option as of the date of death) by the Optionholder's estate, by a person who acquired the right to exercise the Option by bequest or inheritance or by a person designated as the beneficiary of the Option upon the Optionholder's death, but only within the period ending on the earlier of (A) the date eighteen (18) months following the date of death (or such longer or shorter period specified in the Option Agreement), or (B) the expiration of the term of such Option as set forth in the Option Agreement. If, after the Optionholder's death, the Option is not exercised within the time specified herein or in the Option Agreement (as applicable), the Option shall terminate. If the Optionholder designates a third party beneficiary of the Option in accordance with Section 5(d)(iii), then upon the death of the Optionholder such designated beneficiary shall have the sole right to exercise the Option and receive the Common Stock or other consideration resulting from an Option exercise.

(j) Non-Exempt Employees. No Option granted to an Employee who is a non-exempt employee for purposes of the Fair Labor Standards Act shall be first exercisable for any shares of Common Stock until at least

six (6) months following the date of grant of the Option. The foregoing provision is intended to operate so that any income derived by a non-exempt employee in connection with the exercise or vesting of an Option will be exempt from his or her regular rate of pay.

6. Provisions of Stock Awards other than Options.

(a) Restricted Stock Awards. Each Restricted Stock Award Agreement shall be in such form and shall contain such terms and conditions as the Board shall deem appropriate. To the extent consistent with the Company's Bylaws, at the Board's election, shares of Common Stock may be (x) held in book entry form subject to the Company's instructions until any restrictions relating to the Restricted Stock Award lapse; or (y) evidenced by a certificate, which certificate shall be held in such form and manner as determined by the Board. The terms and conditions of Restricted Stock Award Agreements may change from time to time, and the terms and conditions of separate Restricted Stock Award Agreements need not be identical; *provided, however*, that each Restricted Stock Award Agreement shall include (through incorporation of provisions hereof by reference in the agreement or otherwise) the substance of each of the following provisions:

(i) Consideration. A Restricted Stock Award may be awarded in consideration for (A) past or future services actually or to be rendered to the Company or an Affiliate, or (B) any other form of legal consideration that may be acceptable to the Board in its sole discretion and permissible under applicable law.

(ii) Vesting. Subject to Section 2(g), shares of Common Stock awarded under the Restricted Stock Award Agreement may be subject to forfeiture to the Company in accordance with a vesting schedule to be determined by the Board.

(iii) Termination of Participant's Continuous Service. In the event a Participant's Continuous Service terminates, the Company may receive via a forfeiture condition, any or all of the shares of Common Stock held by the Participant that have not vested as of the date of termination of Continuous Service under the terms of the Restricted Stock Award Agreement.

(iv) Transferability. Rights to acquire shares of Common Stock under the Restricted Stock Award Agreement shall be transferable by the Participant only upon such terms and conditions as are set forth in the Restricted Stock Award Agreement, as the Board shall determine in its sole discretion, so long as Common Stock awarded under the Restricted Stock Award Agreement remains subject to the terms of the Restricted Stock Award Agreement.

(b) Restricted Stock Unit Awards. Each Restricted Stock Unit Award Agreement shall be in such form and shall contain such terms and conditions as the Board shall deem appropriate. The terms and conditions of Restricted Stock Unit Award Agreements may change from time to time, and the terms and conditions of separate Restricted Stock Unit Award Agreements need not be identical; *provided, however*, that each Restricted Stock Unit Award Agreement shall include (through incorporation of the provisions hereof by reference in the Agreement or otherwise) the substance of each of the following provisions:

(i) Consideration. At the time of grant of a Restricted Stock Unit Award, the Board will determine the consideration, if any, to be paid by the Participant upon delivery of each share of Common Stock subject to the Restricted Stock Unit Award. The consideration to be paid (if any) by the Participant for each share of Common Stock subject to a Restricted Stock Unit Award may be paid in any form of legal consideration that may be acceptable to the Board in its sole discretion and permissible under applicable law.

(ii) Vesting. Subject to Section 2(g), at the time of the grant of a Restricted Stock Unit Award, the Board may impose such restrictions or conditions to the vesting of the Restricted Stock Unit Award as it, in its sole discretion, deems appropriate.

(iii) Payment. A Restricted Stock Unit Award may be settled by the delivery of shares of Common Stock, their cash equivalent, any combination thereof or in any other form of consideration, as determined by the Board and contained in the Restricted Stock Unit Award Agreement.

(iv) Additional Restrictions. At the time of the grant of a Restricted Stock Unit Award, the Board, as it deems appropriate, may impose such restrictions or conditions that delay the delivery of the shares of Common Stock (or their cash equivalent) subject to a Restricted Stock Unit Award to a time after the vesting of such Restricted Stock Unit Award.

(v) Termination of Participant's Continuous Service. Except as otherwise provided in the applicable Restricted Stock Unit Award Agreement, such portion of the Restricted Stock Unit Award that has not vested will be forfeited upon the Participant's termination of Continuous Service.

(vi) Compliance with Section 409A of the Code. Notwithstanding anything to the contrary set forth herein, any Restricted Stock Unit Award granted under the Plan that is not exempt from the requirements of Section 409A of the Code shall contain such provisions so that such Restricted Stock Unit Award will comply with the requirements of Section 409A of the Code. Such restrictions, if any, shall be determined by the Board and contained in the Restricted Stock Unit Award Agreement evidencing such Restricted Stock Unit Award.

(c) Stock Appreciation Rights. Each Stock Appreciation Right Agreement shall be in such form and shall contain such terms and conditions as the Board shall deem appropriate. Stock Appreciation Rights may be granted as stand-alone Stock Awards or in tandem with other Stock Awards. The terms and conditions of Stock Appreciation Right Agreements may change from time to time, and the terms and conditions of separate Stock Appreciation Right Agreements need not be identical; *provided, however*, that each Stock Appreciation Right Agreement shall include (through incorporation of the provisions hereof by reference in the Agreement or otherwise) the substance of each of the following provisions:

(i) Term. No Stock Appreciation Right shall be exercisable after the expiration of ten (10) years from the date of its grant or such shorter period specified in the Stock Appreciation Right Agreement.

(ii) Strike Price. Each Stock Appreciation Right will be denominated in shares of Common Stock equivalents. The strike price of each Stock Appreciation Right shall not be less than one hundred percent (100%) of the Fair Market Value of the Common Stock equivalents subject to the Stock Appreciation Right on the date of grant.

(iii) Calculation of Appreciation. The appreciation distribution payable on the exercise of a Stock Appreciation Right will be not greater than an amount equal to the excess of (A) the aggregate Fair Market Value (on the date of the exercise of the Stock Appreciation Right) of a number of shares of Common Stock equal to the number of Common Stock equivalents in which the Participant is vested under such Stock Appreciation Right, and with respect to which the Participant is exercising the Stock Appreciation Right on such date, over (B) the strike price that will be determined by the Board at the time of grant of the Stock Appreciation Right.

(iv) Vesting. Subject to Section 2(g), at the time of the grant of a Stock Appreciation Right, the Board may impose such restrictions or conditions to the vesting of such Stock Appreciation Right as it, in its sole discretion, deems appropriate.

(v) Exercise. To exercise any outstanding Stock Appreciation Right, the Participant must provide written notice of exercise to the Company in compliance with the provisions of the Stock Appreciation Right Agreement evidencing such Stock Appreciation Right.

(vi) Payment. The appreciation distribution in respect to a Stock Appreciation Right may be paid in Common Stock, in cash, in any combination of the two or in any other form of consideration, as determined by the Board and contained in the Stock Appreciation Right Agreement evidencing such Stock Appreciation Right.

(vii) Termination of Continuous Service. In the event that a Participant's Continuous Service terminates, the Participant may exercise his or her Stock Appreciation Right (to the extent that the Participant was entitled to exercise such Stock Appreciation Right as of the date of termination) but only within such period of time ending on the earlier of (A) the date three (3) months following the termination of the Participant's Continuous Service (or such longer or shorter period specified in the Stock Appreciation Right Agreement), or (B) the expiration of the term of the Stock Appreciation Right as set forth in the Stock Appreciation Right Agreement. If, after termination, the Participant does not exercise his or her Stock Appreciation Right within the time specified herein or in the Stock Appreciation Right Agreement (as applicable), the Stock Appreciation Right shall terminate.

(viii) Compliance with Section 409A of the Code. Notwithstanding anything to the contrary set forth herein, any Stock Appreciation Rights granted under the Plan that are not exempt from the requirements of Section 409A of the Code shall contain such provisions so that such Stock Appreciation Rights will comply with the requirements of Section 409A of the Code. Such restrictions, if any, shall be determined by the Board and contained in the Stock Appreciation Right Agreement evidencing such Stock Appreciation Right

(d) Performance Awards.

(i) Performance Stock Awards. A Performance Stock Award is a Stock Award that may be granted, may vest, or may be exercised based upon the attainment during a Performance Period of certain Performance Goals. A Performance Stock Award may, but need not, require the completion of a specified period of Continuous Service. Subject to Section 2(g), the length of any Performance Period, the Performance Goals to be achieved during the Performance Period, and the measure of whether and to what degree such Performance Goals have been attained shall be conclusively determined by the Committee in its sole discretion. The maximum number of shares that may be granted to any Participant in a calendar year attributable to Stock Awards described in this Section 6(d)(i) shall not exceed five hundred thousand (500,000) shares of Common Stock. In addition, to the extent permitted by applicable law and the applicable Award Agreement, the Board may determine that cash may be used in payment of Performance Stock Awards.

(ii) Performance Cash Awards. A Performance Cash Award is a cash award that may be granted upon the attainment during a Performance Period of certain Performance Goals. A Performance Cash Award may also require the completion of a specified period of Continuous Service. Subject to Section 2(g), the length of any Performance Period, the Performance Goals to be achieved during the Performance Period, and the measure of whether and to what degree such Performance Goals have been attained shall be conclusively determined by the Committee in its sole discretion. The maximum value that may be granted to any Participant in a calendar year attributable to Performance Cash Awards described in this Section 6(d)(ii) shall not exceed one million dollars ($1,000,000). The Board may provide for or, subject to such terms and conditions as the Board may specify, may permit a Participant to elect for, the payment of any Performance Cash Award to be deferred to a specified date or event. The Committee may specify the form of payment of Performance Cash Awards, which may be cash or other property, or may provide for a Participant to have the option for his or her Performance Cash Award, or such portion thereof as the Board may specify, to be paid in whole or in part in cash or other property. In addition, to the extent permitted by applicable law and the applicable Award Agreement, the Board may determine that Common Stock authorized under this Plan may be used in payment of Performance Cash Awards, including additional shares in excess of the Performance Cash Award as an inducement to hold shares of Common Stock.

(e) Other Stock Awards. Other forms of Stock Awards valued in whole or in part by reference to, or otherwise based on, Common Stock may be granted either alone or in addition to Stock Awards provided for under Section 5 and the preceding provisions of this Section 6. Subject to the provisions of the Plan (including, but not limited to, Sections 2(g) and 2(h)), the Board shall have sole and complete authority to determine the persons to whom and the time or times at which such Other Stock Awards will be granted, the number of shares of Common Stock (or the cash equivalent thereof) to be granted pursuant to such Other Stock Awards and all other terms and conditions of such Other Stock Awards.

7. COVENANTS OF THE COMPANY.

(a) Availability of Shares. During the terms of the Stock Awards, the Company shall keep available at all times the number of shares of Common Stock reasonably required to satisfy such Stock Awards.

(b) Securities Law Compliance. The Company shall seek to obtain from each regulatory commission or agency having jurisdiction over the Plan such authority as may be required to grant Stock Awards and to issue and sell shares of Common Stock upon exercise of the Stock Awards; *provided, however*, that this undertaking shall not require the Company to register under the Securities Act the Plan, any Stock Award or any Common Stock issued or issuable pursuant to any such Stock Award. If, after reasonable efforts, the Company is unable to obtain from any such regulatory commission or agency the authority that counsel for the Company deems necessary for the lawful issuance and sale of Common Stock under the Plan, the Company shall be relieved from any liability for failure to issue and sell Common Stock upon exercise of such Stock Awards unless and until such authority is obtained.

(c) No Obligation to Notify. The Company shall have no duty or obligation to any holder of a Stock Award to advise such holder as to the time or manner of exercising such Stock Award. Furthermore, the Company shall have no duty or obligation to warn or otherwise advise such holder of a pending termination or expiration of a Stock Award or a possible period in which the Stock Award may not be exercised. The Company has no duty or obligation to minimize the tax consequences of a Stock Award to the holder of such Stock Award.

8. MISCELLANEOUS.

(a) Use of Proceeds from Sales of Common Stock. Proceeds from the sale of shares of Common Stock pursuant to Stock Awards shall constitute general funds of the Company.

(b) Corporate Action Constituting Grant of Stock Awards. Corporate action constituting a grant by the Company of a Stock Award to any Participant shall be deemed completed as of the date of such corporate action, unless otherwise determined by the Board, regardless of when the instrument, certificate, or letter evidencing the Stock Award is communicated to, or actually received or accepted by, the Participant.

(c) Stockholder Rights. No Participant shall be deemed to be the holder of, or to have any of the rights of a holder with respect to, any shares of Common Stock subject to such Stock Award unless and until such Participant has exercised the Stock Award pursuant to its terms and the Participant shall not be deemed to be a stockholder of record until the issuance of the Common Stock pursuant to such exercise has been entered into the books and records of the Company.

(d) No Employment or Other Service Rights. Nothing in the Plan, any Stock Award Agreement or other instrument executed thereunder or in connection with any Award granted pursuant to the Plan shall confer upon any Participant any right to continue to serve the Company or an Affiliate in the capacity in effect at the time the Stock Award was granted or shall affect the right of the Company or an Affiliate to terminate (i) the employment of an Employee with or without notice and with or without cause, (ii) the service of a Consultant pursuant to the terms of such Consultant's agreement with the Company or an Affiliate, or (iii) the service of a Director pursuant to the Bylaws of the Company or an Affiliate, and any applicable provisions of the corporate law of the state in which the Company or the Affiliate is incorporated, as the case may be.

(e) Incentive Stock Option $100,000 Limitation. To the extent that the aggregate Fair Market Value (determined at the time of grant) of Common Stock with respect to which Incentive Stock Options are exercisable for the first time by any Optionholder during any calendar year (under all plans of the Company and any Affiliates) exceeds one hundred thousand dollars ($100,000), the Options or portions thereof that exceed such limit (according to the order in which they were granted) shall be treated as Nonstatutory Stock Options, notwithstanding any contrary provision of the applicable Option Agreement(s).

(f) Investment Assurances. The Company may require a Participant, as a condition of exercising or acquiring Common Stock under any Stock Award, (i) to give written assurances satisfactory to the Company as to the Participant's knowledge and experience in financial and business matters and/or to employ a purchaser representative reasonably satisfactory to the Company who is knowledgeable and experienced in financial and business matters and that he or she is capable of evaluating, alone or together with the purchaser representative, the merits and risks of exercising the Stock Award; and (ii) to give written assurances satisfactory to the Company stating that the Participant is acquiring Common Stock subject to the Stock Award for the Participant's own account and not with any present intention of selling or otherwise distributing the Common Stock. The foregoing requirements, and any assurances given pursuant to such requirements, shall be inoperative if (A) the issuance of the shares upon the exercise or acquisition of Common Stock under the Stock Award has been registered under a then currently effective registration statement under the Securities Act, or (B) as to any particular requirement, a determination is made by counsel for the Company that such requirement need not be met in the circumstances under the then applicable securities laws. The Company may, upon advice of counsel to the Company, place legends on stock certificates issued under the Plan as such counsel deems necessary or appropriate in order to comply with applicable securities laws, including, but not limited to, legends restricting the transfer of the Common Stock.

(g) Withholding Obligations. Unless prohibited by the terms of a Stock Award Agreement, the Company may, in its sole discretion, satisfy any federal, state or local tax withholding obligation relating to an Award by any of the following means (in addition to the Company's right to withhold from any compensation paid to the Participant by the Company) or by a combination of such means: (i) causing the Participant to tender a cash payment; (ii) withholding shares of Common Stock from the shares of Common Stock issued or otherwise issuable to the Participant in connection with the Award; (iii) withholding cash from an Award settled in cash; or (iv) by such other method as may be set forth in the Award Agreement.

(h) Electronic Delivery. Any reference herein to a "written" agreement or document shall include any agreement or document delivered electronically or posted on the Company's intranet.

(i) Deferrals. To the extent permitted by applicable law, the Board, in its sole discretion, may determine that the delivery of Common Stock or the payment of cash, upon the exercise, vesting or settlement of all or a portion of any Award may be deferred and may establish programs and procedures for deferral elections to be made by Participants. Deferrals by Participants will be made in accordance with Section 409A of the Code. Consistent with Section 409A of the Code, the Board may provide for distributions while a Participant is still an employee. The Board is authorized to make deferrals of Stock Awards and determine when, and in what annual percentages, Participants may receive payments, including lump sum payments, following the Participant's termination of employment or retirement, and implement such other terms and conditions consistent with the provisions of the Plan and in accordance with applicable law.

(j) Compliance with Section 409A of the Code. To the extent that the Board determines that any Award granted under the Plan is subject to Section 409A of the Code, the Award Agreement evidencing such Award shall incorporate the terms and conditions necessary to avoid the consequences specified in Section 409A(a)(1) of the Code. To the extent applicable, the Plan and Award Agreements shall be interpreted in accordance with Section 409A of the Code and Department of Treasury regulations and other interpretive guidance issued thereunder, including without limitation any such regulations or other guidance that may be issued or amended after the Effective Date. Notwithstanding any provision of the Plan to the contrary, in the event that following the Effective Date the Board determines that any Award may be subject to Section 409A of the Code and related Department of Treasury guidance (including such Department of Treasury guidance as may be issued after the Effective Date), the Board may adopt such amendments to the Plan and the applicable Award Agreement or adopt other policies and procedures (including amendments, policies and procedures with retroactive effect), or take any other actions, that the Board determines are necessary or appropriate to (i) exempt the Award from Section 409A of the Code and/or preserve the intended tax treatment of the benefits provided with respect to the Award, or (ii) comply with the requirements of Section 409A of the Code and Department of Treasury

regulations and other interpretive guidance issued thereunder, including without limitation any such regulations or other guidance that may be issued or amended after the Effective Date.

9. Adjustments upon Changes in Common Stock; Other Corporate Events.

(a) Capitalization Adjustments. In the event of a Capitalization Adjustment, the Board shall appropriately adjust: (i) the class(es) and maximum number of securities subject to the Plan pursuant to Section 3(a), (ii) the class(es) and maximum number of securities that may be issued pursuant to the exercise of Incentive Stock Options pursuant to Section 3(d), (iii) the class(es) and maximum number of securities that may be awarded to any person pursuant to Section 3(e) and 6(d)(i), and (iv) the class(es) and number of securities and price per share of stock subject to outstanding Stock Awards. The Board shall make such adjustments, and its determination shall be final, binding and conclusive.

(b) Dissolution or Liquidation. Except as otherwise provided in the Stock Award Agreement, in the event of a dissolution or liquidation of the Company, all outstanding Stock Awards (other than Stock Awards consisting of vested and outstanding shares of Common Stock not subject to the Company's right of repurchase) shall terminate immediately prior to the completion of such dissolution or liquidation, and the shares of Common Stock subject to the Company's repurchase option may be repurchased by the Company notwithstanding the fact that the holder of such Stock Award is providing Continuous Service.

(c) Transactions. The provisions of this Section 9(c) shall apply to each outstanding Stock Award in the event of a Transaction unless otherwise provided in the instrument evidencing the Stock Award, in any other written agreement between the Company or any Affiliate and the Participant, or in any director compensation policy of the Company.

(i) Stock Awards May Be Assumed. In the event of a Transaction, any surviving corporation or acquiring corporation (or the surviving or acquiring corporation's parent company) may assume or continue any or all outstanding Stock Awards or may substitute similar stock awards for any or all outstanding Stock Awards (including, but not limited to, awards to acquire the same consideration paid to the stockholders of the Company pursuant to the Transaction), and any reacquisition or repurchase rights held by the Company in respect of Common Stock issued pursuant to any outstanding Stock Awards may be assigned by the Company to the surviving corporation or acquiring corporation (or the surviving or acquiring corporation's parent company). For clarity, in the event of a Transaction, any surviving corporation or acquiring corporation (or the surviving or acquiring corporation's parent company) may choose to assume or continue only a portion of an outstanding Stock Award, to substitute a similar stock award for only a portion of an outstanding Stock Award, or to assume or continue, or substitute similar stock awards for, the outstanding Stock Awards held by some, but not all, Participants. The terms of any such assumption, continuation or substitution shall be set by the Board.

(ii) Stock Awards Held by Current Participants. In the event of a Transaction in which the surviving corporation or acquiring corporation (or the surviving or acquiring corporation's parent company) does not assume or continue outstanding Stock Awards, or substitute similar stock awards for outstanding Stock Awards, then with respect to any such Stock Awards that have not been assumed, continued or substituted and that are held by Participants whose Continuous Service has not terminated prior to the effective time of the Transaction (referred to as the "***Current Participants***"), the vesting (and exercisability, if applicable) of such Stock Awards shall be accelerated in full (and with respect to Performance Stock Awards, vesting shall be deemed to be satisfied at the greater of (x) the target level of performance or (y) the actual level of performance measured in accordance with the applicable Performance Goals as of the date of the Transaction) to a date prior to the effective time of the Transaction (contingent upon the closing or completion of the Transaction) as the Board shall determine (or, if the Board does not determine such a date, to the date that is five (5) days prior to the effective time of the Transaction), and such Stock Awards shall terminate if not exercised (if applicable) prior to the effective time of the Transaction in accordance with the exercise procedures determined by the Board, and any reacquisition or repurchase rights held by the Company with respect to such Stock Awards shall lapse (contingent upon the closing or completion of the Transaction).

(iii) Stock Awards Held by Participants other than Current Participants. In the event of a Transaction in which the surviving corporation or acquiring corporation (or the surviving or acquiring corporation's parent company) does not assume or continue outstanding Stock Awards, or substitute similar stock awards for outstanding Stock Awards, then with respect to any such Stock Awards that have not been assumed, continued or substituted and that are held by Participants other than Current Participants, such Stock Awards shall terminate if not exercised (if applicable) prior to the effective time of the Transaction in accordance with the exercise procedures determined by the Board; *provided, however*, that any reacquisition or repurchase rights held by the Company with respect to such Stock Awards shall not terminate and may continue to be exercised notwithstanding the Transaction.

(iv) Payment for Stock Awards in Lieu of Exercise. Notwithstanding the foregoing, in the event any outstanding Stock Award held by a Participant will terminate if not exercised prior to the effective time of a Transaction, the Board may provide that the Participant may not exercise such Stock Award but instead will receive a payment, in such form as may be determined by the Board, equal in value to the excess, if any, of (A) the value of the property the Participant would have received upon the exercise of such Stock Award immediately prior to the effective time of the Transaction, over (B) any exercise price payable by the Participant in connection with such exercise. For clarity, such payment may be zero if the value of such property is equal to or less than the exercise price. Payments under this provision may be delayed to the same extent that payment of consideration to the holders of the Common Stock in connection with the Transaction is delayed as a result of escrows, earn outs, holdbacks or any other contingencies.

(d) Change in Control. Unless provided otherwise in the Stock Award Agreement for a Stock Award, in any other written agreement or plan between the Company or any Affiliate and the Participant, or in any director compensation policy of the Company, a Stock Award will not be subject to additional acceleration of vesting and exercisability upon or after a Change in Control.

10. Termination or Suspension of the Plan.

(a) Plan Term. Unless sooner terminated by the Board pursuant to Section 2, the Plan shall automatically terminate on April 21, 2026. No Awards may be granted under the Plan while the Plan is suspended or after it is terminated.

(b) No Impairment of Rights. Termination of the Plan shall not impair rights and obligations under any Award granted while the Plan is in effect except with the written consent of the affected Participant.

11. Effective Date of Plan.

This Plan originally became effective on the Effective Date. This amendment and restatement of the Plan is effective June 1, 2022.

12. Choice of Law.

The law of the State of California shall govern all questions concerning the construction, validity and interpretation of this Plan, without regard to such state's conflict of laws rules.

13. Definitions. As used in the Plan, the definitions contained in this Section 13 shall apply to the capitalized terms indicated below:

(a) "***Affiliate***" means, at the time of determination, any "parent" or "subsidiary" of the Company as such terms are defined in Rule 405 of the Securities Act. The Board shall have the authority to determine the time or times at which "parent" or "subsidiary" status is determined within the foregoing definition.

(b) "***Appreciation Award***" means (i) a stock option or stock appreciation right granted under either of the Prior Plans or the Inducement Plan or (ii) an Option or Stock Appreciation Right, in each case with respect to which the exercise or strike price is at least one hundred percent (100%) of the Fair Market Value of the Common Stock subject to the stock option or stock appreciation right, or Option or Stock Appreciation Right, as applicable, on the date of grant.

(c) "***Award***" means a Stock Award or a Performance Cash Award.

(d) "***Award Agreement***" means a written agreement between the Company and a Participant evidencing the terms and conditions of an Award.

(e) "***Board***" means the Board of Directors of the Company.

(f) "***Capitalization Adjustment***" means any change that is made in, or other events that occur with respect to, the Common Stock subject to the Plan or subject to any Stock Award after the Effective Date without the receipt of consideration by the Company (through merger, consolidation, reorganization, recapitalization, reincorporation, stock dividend, dividend in property other than cash, stock split, liquidating dividend, combination of shares, exchange of shares, change in corporate structure or other transaction not involving the receipt of consideration by the Company. Notwithstanding the foregoing, the conversion of any convertible securities of the Company shall not be treated as a transaction "without receipt of consideration" by the Company.

(g) "***Cause***" means with respect to a Participant, the occurrence of any of the following events: (i) such Participant's commission of any felony or any crime involving fraud, dishonesty or moral turpitude under the laws of the United States or any state thereof; (ii) such Participant's attempted commission of, or participation in, a fraud or act of dishonesty against the Company; (iii) such Participant's intentional, material violation of any contract or agreement between the Participant and the Company or of any statutory duty owed to the Company; (iv) such Participant's unauthorized use or disclosure of the Company's confidential information or trade secrets; or (v) such Participant's gross misconduct. The determination that a termination of the Participant's Continuous Service is either for Cause or without Cause shall be made by the Company in its sole discretion. Any determination by the Company that the Continuous Service of a Participant was terminated by reason of dismissal without Cause for the purposes of outstanding Awards held by such Participant shall have no effect upon any determination of the rights or obligations of the Company or such Participant for any other purpose.

(h) "***Change in Control***" means the occurrence, in a single transaction or in a series of related transactions, of any one or more of the following events:

(i) any Exchange Act Person becomes the Owner, directly or indirectly, of securities of the Company representing more than fifty percent (50%) of the combined voting power of the Company's then outstanding securities other than by virtue of a merger, consolidation or similar transaction . Notwithstanding the foregoing, a Change in Control shall not be deemed to occur (A) on account of the acquisition of securities of the Company by an investor, any affiliate thereof or any other Exchange Act Person from the Company in a transaction or series of related transactions the primary purpose of which is to obtain financing for the Company through the issuance of equity securities or (B) solely because the level of Ownership held by any Exchange Act Person (the "***Subject Person***") exceeds the designated percentage threshold of the outstanding voting securities as a result of a repurchase or other acquisition of voting securities by the Company reducing the number of shares outstanding, provided that if a Change in Control would occur (but for the operation of this sentence) as a result of the acquisition of voting securities by the Company, and after such share acquisition, the Subject Person becomes the Owner of any additional voting securities that, assuming the repurchase or other acquisition had not occurred, increases the percentage of the then outstanding voting securities Owned by the Subject Person over the designated percentage threshold, then a Change in Control shall be deemed to occur;

(ii) there is consummated a merger, consolidation or similar transaction involving (directly or indirectly) the Company and, immediately after the consummation of such merger, consolidation or similar transaction, the stockholders of the Company immediately prior thereto do not Own, directly or indirectly, either (A) outstanding voting securities representing more than fifty percent (50%) of the combined outstanding voting power of the surviving Entity in such merger, consolidation or similar transaction or (B) more than fifty percent (50%) of the combined outstanding voting power of the parent of the surviving Entity in such merger, consolidation or similar transaction, in each case in substantially the same proportions as their Ownership of the outstanding voting securities of the Company immediately prior to such transaction;

(iii) there is consummated a sale, lease, exclusive license or other disposition of all or substantially all of the consolidated assets of the Company and its Subsidiaries, other than a sale, lease, license or other disposition of all or substantially all of the consolidated assets of the Company and its Subsidiaries to an Entity, more than fifty percent (50%) of the combined voting power of the voting securities of which are Owned by stockholders of the Company in substantially the same proportions as their Ownership of the outstanding voting securities of the Company immediately prior to such sale, lease, license or other disposition; or

(iv) individuals who, on the date this Plan is adopted by the Board, are members of the Board (the "Incumbent Board") cease for any reason to constitute at least a majority of the members of the Board; *provided, however*, that if the appointment or election (or nomination for election) of any new Board member was approved or recommended by a majority vote of the members of the Incumbent Board then still in office, such new member shall, for purposes of this Plan, be considered as a member of the Incumbent Board.

For clarity, the term Change in Control shall not include a sale of assets, merger or other transaction effected exclusively for the purpose of changing the domicile of the Company.

Notwithstanding the foregoing or any other provision of this Plan, the definition of Change in Control (or any analogous term) in an individual written agreement between the Company or any Affiliate and the Participant shall supersede the foregoing definition with respect to Awards subject to such agreement; *provided, however*, that (x) if no definition of Change in Control or any analogous term is set forth in such an individual written agreement, the foregoing definition shall apply, and (y) no Change in Control (or any analogous term) will be deemed to occur with respect to Awards subject to such an individual written agreement without a requirement that the Change in Control (or any analogous term) actually occur.

(i) "***Code***" means the Internal Revenue Code of 1986, as amended.

(j) "***Committee***" means a committee of one (1) or more Directors to whom authority has been delegated by the Board in accordance with Section 2(c).

(k) "***Common Stock***" means the common stock of the Company.

(l) "***Company***" means Cerus Corporation, a Delaware corporation.

(m) "***Consultant***" means any person, including an advisor, who is (i) engaged by the Company or an Affiliate to render consulting or advisory services and is compensated for such services, or (ii) serving as a member of the board of directors of an Affiliate and is compensated for such services. However, service solely as a Director, or payment of a fee for such service, shall not cause a Director to be considered a "Consultant" for purposes of the Plan.

(n) "***Continuous Service***" means that the Participant's service with the Company or an Affiliate, whether as an Employee, Director or Consultant, is not interrupted or terminated. A change in the capacity in which the Participant renders service to the Company or an Affiliate as an Employee, Consultant or Director or a change in the entity for which the Participant renders such service, provided that there is no interruption or termination of

the Participant's service with the Company or an Affiliate, shall not terminate a Participant's Continuous Service. For example, a change in status from an employee of the Company to a consultant to an Affiliate or to a Director shall not constitute an interruption of Continuous Service. To the extent permitted by law, the Board or the chief executive officer of the Company, in that party's sole discretion, may determine whether Continuous Service shall be considered interrupted in the case of any leave of absence approved by that party, including sick leave, military leave or any other personal leave. Notwithstanding the foregoing, a leave of absence shall be treated as Continuous Service for purposes of vesting in a Stock Award only to such extent as may be provided in the Company's leave of absence policy, in the written terms of any leave of absence agreement or policy applicable to the Participant, or as otherwise required by law.

(o) "***Corporate Transaction***" means the occurrence, in a single transaction or in a series of related transactions, of any one or more of the following events:

(i) a sale or other disposition of all or substantially all, as determined by the Board in its sole discretion, of the consolidated assets of the Company and its Subsidiaries;

(ii) a sale or other disposition of at least ninety percent (90%) of the outstanding securities of the Company;

(iii) the consummation of a merger, consolidation or similar transaction following which the Company is not the surviving corporation; or

(iv) the consummation of a merger, consolidation or similar transaction following which the Company is the surviving corporation but the shares of Common Stock outstanding immediately preceding the merger, consolidation or similar transaction are converted or exchanged by virtue of the merger, consolidation or similar transaction into other property, whether in the form of securities, cash or otherwise.

(p) "***Covered Employee***" shall have the meaning provided in Section 162(m)(3) of the Code and the regulations promulgated thereunder.

(q) "***Director***" means a member of the Board.

(r) "***Disability***" means, with respect to a Participant, the inability of such Participant to engage in any substantial gainful activity by reason of any medically determinable physical or mental impairment which can be expected to result in death or can be expected to last for a continuous period of not less than twelve (12) months, as provided in Section 22(e)(3) and 409A(a)(2)(c)(i) of the Code.

(s) "***Effective Date***" means the original effective date of this Plan document, which is the date of the annual meeting of stockholders of the Company held in 2008. This restatement of the Plan document is effective on June 1, 2022, the date of the annual meeting of the stockholders of the Company held in 2022.

(t) "***Employee***" means any person employed by the Company or an Affiliate. However, service solely as a Director, or payment of a fee for such services, shall not cause a Director to be considered an "Employee" for purposes of the Plan.

(u) "***Entity***" means a corporation, partnership, limited liability company or other entity.

(v) "***Exchange Act***" means the Securities Exchange Act of 1934, as amended.

(w) "***Exchange Act Person***" means any natural person, Entity or "group" (within the meaning of Section 13(d) or 14(d) of the Exchange Act), except that "Exchange Act Person" shall not include (i) the Company or any Subsidiary of the Company, (ii) any employee benefit plan of the Company or any Subsidiary of

the Company or any trustee or other fiduciary holding securities under an employee benefit plan of the Company or any Subsidiary of the Company, (iii) an underwriter temporarily holding securities pursuant to an offering of such securities, (iv) an Entity Owned, directly or indirectly, by the stockholders of the Company in substantially the same proportions as their Ownership of stock of the Company; or (v) any natural person, Entity or "group" (within the meaning of Section 13(d) or 14(d) of the Exchange Act) that, as of the Effective Date of the Plan as set forth in Section 11, is the Owner, directly or indirectly, of securities of the Company representing more than fifty percent (50%) of the combined voting power of the Company's then outstanding securities.

(x) "***Fair Market Value***" means, as of any date, the value of the Common Stock determined as follows:

(i) If the Common Stock is listed on any established stock exchange or traded on any established market, the Fair Market Value of a share of Common Stock shall be the closing sales price for such stock (or the closing bid, if no sales were reported) as quoted on such exchange or market (or the exchange or market with the greatest volume of trading in the Common Stock) on the date of determination, as reported in *The Wall Street Journal* or such other source as the Board deems reliable. Unless otherwise provided by the Board, if there is no closing sales price (or closing bid if no sales were reported) for the Common Stock on the date of determination, then the Fair Market Value shall be the closing selling price (or closing bid if no sales were reported) on the last preceding date for which such quotation exists.

(ii) In the absence of such markets for the Common Stock, the Fair Market Value shall be determined by the Board in good faith.

(y) "***Full Value Award***" means (i) a stock award granted under either of the Prior Plans or the Inducement Plan or (ii) a Stock Award, in each case that is not an Appreciation Award.

(z) "***Incentive Stock Option***" means an option granted pursuant to Section 5 of the Plan that is intended to be, and qualifies as, an "incentive stock option" within the meaning of Section 422 of the Code and the regulations promulgated thereunder.

(aa) "***Non-Employee Director***" means a Director who either (i) is not a current employee or officer of the Company or an Affiliate, does not receive compensation, either directly or indirectly, from the Company or an Affiliate for services rendered as a consultant or in any capacity other than as a Director (except for an amount as to which disclosure would not be required under Item 404(a) of Regulation S-K promulgated pursuant to the Securities Act ("***Regulation S-K***")), does not possess an interest in any other transaction for which disclosure would be required under Item 404(a) of Regulation S-K, and is not engaged in a business relationship for which disclosure would be required pursuant to Item 404(b) of Regulation S-K; or (ii) is otherwise considered a "non-employee director" for purposes of Rule 16b-3.

(bb) "***Nonstatutory Stock Option***" means any option granted pursuant to Section 5 of the Plan that does not qualify as an Incentive Stock Option.

(cc) "***Officer***" means a person who is an officer of the Company within the meaning of Section 16 of the Exchange Act and the rules and regulations promulgated thereunder.

(dd) "***Option***" means an Incentive Stock Option or a Nonstatutory Stock Option to purchase shares of Common Stock granted pursuant to the Plan.

(ee) "***Option Agreement***" means a written agreement between the Company and an Optionholder evidencing the terms and conditions of an Option grant. Each Option Agreement shall be subject to the terms and conditions of the Plan.

(ff) "***Optionholder***" means a person to whom an Option is granted pursuant to the Plan or, if permitted under the terms of this Plan, such other person who holds an outstanding Option.

(gg) "***Other Stock Award***" means an award based in whole or in part by reference to the Common Stock which is granted pursuant to the terms and conditions of Section 6(e).

(hh) "***Other Stock Award Agreement***" means a written agreement between the Company and a holder of an Other Stock Award evidencing the terms and conditions of an Other Stock Award grant. Each Other Stock Award Agreement shall be subject to the terms and conditions of the Plan.

(ii) "***Outside Director***" means a Director who either (i) is not a current employee of the Company or an "affiliated corporation" (within the meaning of Treasury Regulations promulgated under Section 162(m) of the Code), is not a former employee of the Company or an "affiliated corporation" who receives compensation for prior services (other than benefits under a tax-qualified retirement plan) during the taxable year, has not been an officer of the Company or an "affiliated corporation," and does not receive remuneration from the Company or an "affiliated corporation," either directly or indirectly, in any capacity other than as a Director, or (ii) is otherwise considered an "outside director" for purposes of Section 162(m) of the Code.

(jj) "***Own,***" "***Owned,***" "***Owner,***" "***Ownership***" A person or Entity shall be deemed to "Own," to have "Owned," to be the "Owner" of, or to have acquired "Ownership" of securities if such person or Entity, directly or indirectly, through any contract, arrangement, understanding, relationship or otherwise, has or shares voting power, which includes the power to vote or to direct the voting, with respect to such securities.

(kk) "***Participant***" means a person to whom an Award is granted pursuant to the Plan or, if applicable, such other person who holds an outstanding Stock Award.

(ll) "***Performance Cash Award***" means an award of cash granted pursuant to the terms and conditions of Section 6(d)(ii).

(mm) "***Performance Criteria***" means the one or more criteria that the Board shall select for purposes of establishing the Performance Goals for a Performance Period. The Performance Criteria that shall be used to establish such Performance Goals may be based on any one of, or combination of, the following: (i) earnings per share; (ii) earnings before interest, taxes and depreciation; (iii) earnings before interest, taxes, depreciation and amortization; (iv) total stockholder return; (v) return on equity; (vi) return on assets, investment, or capital employed; (vii) operating margin; (viii) gross margin; (ix) operating income; (x) net income (before or after taxes); (xi) net operating income; (xii) net operating income after tax; (xiii) pre-tax profit; (xiv) operating cash flow; (xv) sales or revenue targets; (xvi) increases in revenue or product revenue; (xvii) expenses and cost reduction goals; (xviii) improvement in or attainment of working capital levels; (xix) economic value added (or an equivalent metric); (xx) market share; (xxi) cash flow; (xxii) cash flow per share; (xxiii) share price performance; (xxiv) debt reduction; (xxv) implementation or completion of projects or processes; (xxvi) customer satisfaction; (xxvii) stockholders' equity; and (xxviii) to the extent that an Award is not intended to comply with Section 162(m) of the Code, other measures of performance selected by the Board. Partial achievement of the specified criteria may result in the payment or vesting corresponding to the degree of achievement as specified in the Stock Award Agreement or the written terms of a Performance Cash Award. The Board shall, in its sole discretion, define the manner of calculating the Performance Criteria it selects to use for such Performance Period.

(nn) "***Performance Goals***" means, for a Performance Period, the one or more goals established by the Board for the Performance Period based upon the Performance Criteria. Performance Goals may be based on a Company-wide basis, with respect to one or more business units, divisions, Affiliates, or business segments, and in either absolute terms or relative to the performance of one or more comparable companies or the performance of one or more relevant indices. At the time of the grant of any Award, the Board is authorized to determine whether, when calculating the attainment of Performance Goals for a Performance Period: (i) to exclude restructuring and/or other nonrecurring charges; (ii) to exclude exchange rate effects, as applicable, for non-U.S. dollar denominated net sales and operating earnings; (iii) to exclude the effects of changes to

generally accepted accounting standards required by the Financial Accounting Standards Board; (iv) to exclude the effects of any statutory adjustments to corporate tax rates; and (v) to exclude the effects of any "extraordinary items" as determined under generally accepted accounting principles. In addition, the Board retains the discretion to reduce or eliminate the compensation or economic benefit due upon attainment of Performance Goals.

(oo) "***Performance Period***" means the period of time selected by the Board over which the attainment of one or more Performance Goals will be measured for the purpose of determining a Participant's right to and the payment of a Stock Award or a Performance Cash Award. Performance Periods may be of varying and overlapping duration, at the sole discretion of the Board.

(pp) "***Performance Stock Award***" means a Stock Award granted under the terms and conditions of Section 6(d)(i).

(qq) "***Plan***" means this Cerus Corporation 2008 Equity Incentive Plan.

(rr) "***Restricted Stock Award***" means an award of shares of Common Stock which is granted pursuant to the terms and conditions of Section 6(a).

(ss) "***Restricted Stock Award Agreement***" means a written agreement between the Company and a holder of a Restricted Stock Award evidencing the terms and conditions of a Restricted Stock Award grant. Each Restricted Stock Award Agreement shall be subject to the terms and conditions of the Plan.

(tt) "***Restricted Stock Unit Award***" means a right to receive shares of Common Stock which is granted pursuant to the terms and conditions of Section 6(b).

(uu) "***Restricted Stock Unit Award Agreement***" means a written agreement between the Company and a holder of a Restricted Stock Unit Award evidencing the terms and conditions of a Restricted Stock Unit Award grant. Each Restricted Stock Unit Award Agreement shall be subject to the terms and conditions of the Plan.

(vv) "***Rule 16b-3***" means Rule 16b-3 promulgated under the Exchange Act or any successor to Rule 16b-3, as in effect from time to time.

(ww) "***Securities Act***" means the Securities Act of 1933, as amended.

(xx) "***Stock Appreciation Right***" means a right to receive the appreciation on Common Stock that is granted pursuant to the terms and conditions of Section 6(c).

(yy) "***Stock Appreciation Right Agreement***" means a written agreement between the Company and a holder of a Stock Appreciation Right evidencing the terms and conditions of a Stock Appreciation Right grant. Each Stock Appreciation Right Agreement shall be subject to the terms and conditions of the Plan.

(zz) "***Stock Award***" means any right to receive Common Stock granted under the Plan, including an Incentive Stock Option, a Nonstatutory Stock Option, a Restricted Stock Award, a Restricted Stock Unit Award, a Stock Appreciation Right, a Performance Stock Award or any Other Stock Award.

(aaa) "***Stock Award Agreement***" means a written agreement between the Company and a Participant evidencing the terms and conditions of a Stock Award grant. Each Stock Award Agreement shall be subject to the terms and conditions of the Plan.

(bbb) "***Subsidiary***" means, with respect to the Company, (i) any corporation of which more than fifty percent (50%) of the outstanding capital stock having ordinary voting power to elect a majority of the board of directors of such corporation (irrespective of whether, at the time, stock of any other class or classes of such

corporation shall have or might have voting power by reason of the happening of any contingency) is at the time, directly or indirectly, Owned by the Company, and (ii) any partnership, limited liability company or other entity in which the Company has a direct or indirect interest (whether in the form of voting or participation in profits or capital) of more than fifty percent (50%).

(ccc) "***Ten Percent Stockholder***" means a person who Owns (or is deemed to Own pursuant to Section 424(d) of the Code) stock possessing more than ten percent (10%) of the total combined voting power of all classes of stock of the Company or any Affiliate.

(ddd) "***Transaction***" means a Corporate Transaction or a Change in Control.

Exhibit 31.1

CERTIFICATION

I, William M. Greenman, certify that:

1. I have reviewed this quarterly report on Form 10-Q of Cerus Corporation;

2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;

3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;

4. The registrant's other certifying officer(s) and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:

   a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;

   b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;

   c) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and

   d) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and

5. The registrant's other certifying officer(s) and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):

   a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and

   b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: August 4, 2022

/s/ William M. Greenman

William M. Greenman
President and Chief Executive Officer
(Principal Executive Officer)

Exhibit 31.2

CERTIFICATION

I, Kevin D. Green, certify that:

1. I have reviewed this quarterly report on Form 10-Q of Cerus Corporation;

2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;

3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;

4. The registrant's other certifying officer(s) and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:

   a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;

   b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;

   c) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and

   d) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and

5. The registrant's other certifying officer(s) and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):

   a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and

   b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: August 4, 2022

/s/ Kevin D. Green

Kevin D. Green
Vice President, Finance and Chief Financial Officer
(Principal Financial Officer)

Exhibit 32.1

CERTIFICATION

Pursuant to the requirement set forth in Rule 13a-14(b) of the Securities Exchange Act of 1934, as amended, (the "Exchange Act") and Section 1350 of Chapter 63 of Title 18 of the United States Code (18 U.S.C. §1350), William M. Greenman, the Chief Executive Officer of Cerus Corporation (the "Company"), and Kevin D. Green, the Chief Financial Officer of the Company, each hereby certifies that, to the best of their knowledge:

1. The Company's Quarterly Report on Form 10-Q for the period ended June 30, 2022, to which this Certification is attached as Exhibit 32.1 (the "Periodic Report"), fully complies with the requirements of Section 13(a) or Section 15(d) of the Exchange Act, and

2. The information contained in the Periodic Report fairly presents, in all material respects, the financial condition and results of operations of the Company.

IN WITNESS WHEREOF, the undersigned have set their hands hereto as of the 4th day of August, 2022.

/s/ William M. Greenman
William M. Greenman
President and Chief Executive Officer (Principal Executive Officer)

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

This certification accompanies the Form 10-Q to which it relates, is not deemed filed with the Securities and Exchange Commission and is not to be incorporated by reference into any filing of Cerus Corporation under the Securities Act of 1933, as amended, or the Securities Exchange Act of 1934, as amended (whether made before or after the date of the Form 10-Q), irrespective of any general incorporation language contained in such filing.