CERUS CORP

FORM 8-K
(Current report filing)

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UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
Washington, D.C. 20549

FORM 8-K

CURRENT REPORT
Pursuant to Section 13 or 15(d)
of the Securities Exchange Act of 1934

Date of Report (Date of earliest event reported): January 5, 2015

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

Delaware	**0-21937**	**68-0262011**
(State or other jurisdiction of incorporation)	**(Commission File No.)**	**(IRS Employer Identification No.)**

2550 Stanwell Drive
Concord, California 94520
(Address of principal executive offices) (Zip Code)

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

Check the appropriate box below if the Form 8-K filing is intended to simultaneously satisfy the filing obligation of the registrant under any of the following provisions (see General Instruction A.2. below):

☐ Written communications pursuant to Rule 425 under the Securities Act (17 CFR 230.425)

☐ Soliciting material pursuant to Rule 14a-12 under the Exchange Act (17 CFR 240.14a-12)

☐ Pre-commencement communications pursuant to Rule 14d-2(b) under the Exchange Act (17 CFR 240.14d-2(b))

☐ Pre-commencement communications pursuant to Rule 13e-4(c) under the Exchange Act (17 CFR 240.13e-4(c))

Item 2.02 Results of Operations and Financial Condition

On January 5, 2015, Cerus Corporation (the "Company" or "Cerus") filed a preliminary prospectus supplement pursuant to Rule 424(b)(5) in which it disclosed that, although it has not finalized its full financial results for the fiscal year ended December 31, 2014, it expects to report that it had approximately $51 million of cash, cash equivalents and investments as of December 31, 2014. This amount is preliminary, has not been audited and is subject to change upon the completion of the audit of the Company's consolidated financial statements as of and for the year ended December 31, 2014. Additional information and disclosures would be required for a more complete understanding of the Company's financial position and results of operations as of December 31, 2014.

Forward-Looking Statements

This Item 2.02 of this report contains forward-looking statements, including, without limitation, statements relating to Cerus' cash position as of December 31, 2014. These forward-looking statements are based upon Cerus' current expectations. Actual results could differ materially from these forward-looking statements as a result of certain factors, including, without limitation, risks related to changes in estimated cash position based on the completion of financial closing procedures and the audit of Cerus' financial statements, and other risks detailed in Cerus' filings with the U.S. Securities and Exchange Commission (the "SEC"), including under the heading "Risk Factors" in Exhibit 99.1 hereto. You are cautioned not to place undue reliance on these forward-looking statements, which speak only as of the date of this report. Cerus does not undertake any obligation to update any forward-looking statements as a result of new information, future events, changed assumptions or otherwise.

The information in Item 2.02 of this report shall not be deemed to be "filed" for purposes of Section 18 of the Securities Exchange Act of 1934, as amended, or otherwise subject to the liabilities of that Section 11 and 12(a)(2) of the Securities Act of 1933, as amended. The information contained herein shall not be incorporated by reference into any filing with the SEC made by Cerus, whether made before or after the date hereof, regardless of any general incorporation language in such filing.

Item 8.01 Other Events.

The Company is filing information for the purpose of updating the risk factor disclosure contained in its prior public filings, including those discussed under the heading "Item 1A. Risk Factors" in its Quarterly Report on Form 10-Q for the quarter ended September 30, 2014, filed with the SEC on November 7, 2014. The Company is also supplementing and updating certain aspects of the description of its business from that described under the heading, "Item 1. Business" in the Company's Annual Report on Form 10-K for the year ended December 31, 2013, filed with the SEC on March 7, 2014. The updated Company disclosures are filed herewith as Exhibit 99.1 and are incorporated herein by reference.

Item 9.01. Financial Statements and Exhibits.

(d) Exhibits.

Exhibit	Description
99.1	Updated Company Disclosure.

SIGNATURE

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 hereunto duly authorized.

CERUS CORPORATION

Dated: January 5, 2015

By: /s/ Kevin D. Green
Kevin D. Green
Vice President, Finance and Chief Financial Officer

EXHIBIT INDEX

Exhibit	Description
99.1	Updated Company Disclosure.

As used in this Exhibit 99.1, "Cerus," "Cerus Corporation," the "Company," "we," "us" and "our" refer to Cerus Corporation, a Delaware corporation, and its wholly-owned subsidiary, Cerus Europe B.V. Cerus, INTERCEPT and INTERCEPT Blood System are U.S. registered trademarks of Cerus Corporation. All other trademarks, service marks and trade names included in this Exhibit 99.1 are the property of their respective owners.

FORWARD-LOOKING STATEMENTS

This Exhibit 99.1 contains "forward-looking statements" within the meaning of Section 27A of the Securities Act of 1933, as amended, or the Securities Act, and Section 21E of the Securities Exchange Act of 1934, as amended, or the Exchange Act. 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. Forward-looking statements may include, but are not limited to, statements about:

- future sales of and our ability to effectively commercialize and achieve market acceptance of the INTERCEPT Blood System, including our ability to comply with applicable U.S. and foreign laws, regulations and regulatory requirements;
- our ability to manage the growth of our business and attendant cost increases, including in connection with the commercialization of the INTERCEPT Blood System in the United States, as well as our ability to manage the risks attendant to our international operations;
- the timing or likelihood of regulatory submissions and approvals and other regulatory actions or interactions;
- our ability to obtain and maintain regulatory approvals of the INTERCEPT Blood System;
- our ability to obtain adequate clinical and commercial supplies of the INTERCEPT Blood System from our sole source suppliers;
- the initiation, scope, rate of progress, results and timing of our ongoing and proposed pre-clinical studies 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 pre-clinical and clinical development of the INTERCEPT Blood System;
- the ability of our products to inactivate the Ebola virus and other pathogens that may emerge in the future;
- our ability to protect our intellectual property and operate our business without infringing upon the intellectual property rights of others; and
- our estimates regarding the sufficiency of our cash resources and our need for additional funding.

In some cases, you can identify forward-looking statements by terms such as "may," "will," "should," "could," "would," "expects," "plans," "anticipates," "believes," "estimates," "projects," "predicts," "potential" and similar expressions intended to identify forward-looking statements. These statements reflect our current views with respect to future events, are based on assumptions and are subject to risks and uncertainties. Given these uncertainties, you should not place undue reliance on these forward-looking statements. We discuss many of these risks in greater detail under the heading "Risk Factors" below.

We can give no assurances that any of the events anticipated by the 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. We qualify all of the forward-looking statements in this Exhibit 99.1 by these cautionary statements. Also, these forward-looking statements represent our estimates and assumptions only as of the date such forward-looking statements are made. Except as required by law, we undertake no obligation to update or revise any forward-looking statements to reflect new information or future events or developments. 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.

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. The risks and uncertainties described below are not the only ones facing us. There may be additional risks faced by our business. Other events that we do not currently anticipate or that we currently deem immaterial also may adversely affect our financial condition or results of operations.

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

We have invested a significant portion of our efforts and financial resources on the development of the INTERCEPT Blood System for platelets and plasma for the United States market. As a result, our business is substantially dependent on our ability to successfully commercialize the INTERCEPT Blood System in the United States in a timely manner. We only recently received U.S. regulatory approval of the INTERCEPT Blood System for platelets and plasma and while we plan to make the INTERCEPT Blood System commercially available in the United States, we have no experience commercializing any products in the United States and we may be unable to commercialize the INTERCEPT Blood System in the United States successfully or in a timely manner, or at all. In addition, due to the manufacturing lead time to produce products specific for use in the United States, we do not expect to commence commercializing the INTERCEPT Blood System for its approved labeled indications of use prior to the end of the first quarter of 2015 at the earliest. Prior to commercializing the INTERCEPT Blood System for its approved labeled indications of use in the United States, among other things, potential customers may first choose to validate our technology or conduct experience studies of the INTERCEPT Blood System prior to deciding whether to adopt the INTERCEPT Blood System for commercial use. In addition, potential customers will also be required to obtain site-specific licenses from the FDA Center for Biologics Evaluation and Research, or CBER, prior to engaging in interstate transport of blood components processed using the INTERCEPT Blood System, any of which could significantly delay or preclude our ability to successfully commercialize the INTERCEPT Blood System to those customers for the portion of their business involved in interstate commerce. If we are not successful in achieving market adoption of the INTERCEPT Blood System in the United States, we may never generate substantial revenue, and our business, financial condition, results of operations and growth prospects would be materially and adversely affected.

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

- achieve market acceptance and generate product sales through execution of sales agreements on commercially reasonable terms;
- enter into and maintain sufficient manufacturing arrangements for the U.S. market with our third party suppliers;
- create market demand for the INTERCEPT Blood System through our education, marketing and sales activities;
- hire, train, deploy and support a qualified U.S.-based commercial organization and field sales force;
- expand the labeled indications of use for the INTERCEPT Blood System and/or design, develop and test new product configurations;
- comply with requirements established by the FDA, including post-marketing requirements and label restrictions; and
- comply with other U.S. healthcare regulatory requirements.

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

- the highly concentrated U.S. blood collection market that is dominated by a small number of blood collection organizations;
- regulatory and licensing requirements, including those relating to U.S.-based blood centers being required to obtain site-specific licenses from CBER prior to engaging in interstate transport of blood components processed using the INTERCEPT Blood System;
- changed or increased regulatory restrictions or requirements;
- any supply or manufacturing problems or delays arising with any of our suppliers, many of whom are our sole suppliers for the particular product or component they manufacture, including those related to 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;
- 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 and effective from the broad constituencies involved in the healthcare system.

In addition to the above, our ability to commercialize the INTERCEPT Blood System in the United States is dependent on our ability to operate without infringing on the intellectual property rights of others. For example, we are aware of a United States patent issued to a third-party that covers methods to remove psoralen compounds from blood products. We have reviewed the patent and believe there exists substantial questions concerning its validity. We cannot be certain, however, that a court would hold the patent to be invalid or not infringed by our platelet or plasma systems upon commercialization of those products in the United States. In this regard, whether we would, upon commercialization of our platelet or plasma systems in the United States, infringe this patent will not be known with certainty unless and until a court interprets the patent in the context of litigation. In

the event that we are found to infringe any valid claim of this patent, we may, among other things, be required to pay damages, cease the use and sale of our platelet and plasma systems and/or obtain a license from the owner of the patent, which we may not be able to do at a reasonable cost or at all.

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

The INTERCEPT Blood System may not achieve broad market adoption.

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

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

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

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

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

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

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

products. In the United States, our products are not directly subject to reimbursement by governmental or commercial third party payors for health care services. The costs and expenses related to donor blood are typically included in the price to a hospital of a unit of blood. As such, the costs and expenses related to use of the INTERCEPT Blood System will not be directly reimbursed by a third party payor, but instead may be incorporated within the existing reimbursement structure for medical procedure and/or products at the site of patient care. If the costs to the hospital for INTERCEPT-processed blood products are not easily, readily, or fully incorporated into the existing United States reimbursement structure, hospital billing and/or reimbursement for these products could be impacted, thus negatively impacting hospitals' acceptance and uptake of these products.

The market for the INTERCEPT Blood System is highly concentrated with few customers, including often-dominant regional or national blood collection entities. Even where our products receive regulatory approval and reimbursement is available, failure to effectively market, promote, distribute, price or sell our products to any of these large customers could significantly delay or even diminish potential product revenue in those geographies. In addition, the lack of widespread adoption of the INTERCEPT Blood System has adversely affected and may in the future adversely affect further market adoption of the INTERCEPT Blood System. Moreover, the market for pathogen reduction systems in the United States is highly concentrated and dominated by a small number of blood collection organizations. Accordingly, there may be an extended period during which some potential U.S.-based customers may first choose to validate our technology or run experience studies themselves before deciding to adopt the system for commercial use, which may never occur. In the United States, the American Red Cross represents the largest single portion of the blood collection market. Although we currently have an agreement with the American Red Cross to support our planned IDE study in Puerto Rico to treat platelet donations with the INTERECEPT Blood System, there is no guarantee that the American Red Cross will continue to use our products commercially following our IDE study, even if we successfully complete this study. In many countries in Western Europe and in Japan, various national blood transfusion services or Red Cross organizations collect, store and distribute virtually all of their respective nations' blood and blood components supply. In Europe, the largest markets for our products are in Germany, France, and England. In Germany, decisions on product adoption and subsequent reimbursement are made on a regional or even blood center-by-blood center basis, but depend on both local approvals and centralized regulatory approvals from the Paul Ehrlich Institute, or PEI. Product specifications that receive marketing authorization from the PEI may differ from market requirements. While INTERCEPT-treated platelets and plasma have received in-country regulatory approval and reimbursement rates have been established in France, adoption throughout France has been limited to certain blood centers. Decisions on product adoption in England are centralized with the National Blood Service and we understand that the National Blood Service has implemented bacterial detection testing for platelets without first considering pathogen reduction. In Japan, the Japanese Red Cross controls a significant majority of blood transfusions and exerts a high degree of influence on the adoption and use of blood safety measures in Japan. The Japanese Red Cross has been reviewing preclinical and clinical data on pathogen reduction of blood over a number of years and has yet to make a formal determination to adopt any pathogen reduction approach. We also understand that the Japanese Red Cross has begun formal evaluation of a competing technology. Before the Japanese Red Cross considers our products, we understand that we may need to commit to making certain product configuration changes, which may not be economically or technologically feasible for us to accomplish.

We expect to continue to generate losses.

We may never achieve a profitable level of operations. Our research and development and selling, general and administrative expenses have resulted in substantial losses since our inception. The platelet and plasma systems have only recently been approved in the United States and are not approved in many countries around the world. Although platelet and plasma systems have been approved in the United States, we do not expect to commence commercializing the INTERCEPT Blood System for its approved labeled indications of use in the United States prior to the end of the first quarter of 2015 at the earliest. The red blood cell system is in the development stage and may never emerge from the development stage as a marketed product. We may be required to reduce the sales price for our products in order to make our products economically attractive to our customers and to governmental and private payors, which may reduce or altogether eliminate our gross profit on sales. At our present and expected near-term sales levels of the platelet and plasma systems, our costs to manufacture, distribute, market, sell, and support the systems are and are expected to continue to be in excess of our revenue. We expect our losses to continue at least until we are able to gain widespread commercial adoption, which may never occur. In addition to increased selling, general and administrative expenses in connection with the commercial launch of the platelet and plasma systems in the United States, we expect to incur additional research and development costs associated with planning, enrolling and completing our required post-approval study and the studies under our IDEs, with pursuing potential regulatory approvals in other geographies where we do not currently sell our platelet and plasma systems, with planning and conducting *in vitro* studies and clinical development of our red blood cell system in Europe and the United States, and with completing chemistry, manufacturing and control, or CMC, activities to support a potential CE Mark submission for our red blood cell system in Europe, which is planned for the second half of 2016, which costs could be substantial and could extend the period during which we expect to operate at a loss.

In certain countries, governments have issued regulations relating to the pricing and profitability of medical products and medical product companies. Health care reform in the United States has also placed downward pressure on the pricing of medical products and has introduced new taxation on medical devices that could further impact our profit margins once we begin selling our products in the United States.

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

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

Additionally, a meaningful amount of our revenue currently comes from sales to our distributor in Russia. Low worldwide oil prices and the current political conflict stemming from

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

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

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

- development;
- testing;
- manufacturing;
- labeling;
- storage;
- clinical trials;
- product safety;
- pre-market clearance or approval;
- sales and distribution;
- use standards and documentation;
- conformity assessment procedures;
- product traceability and record keeping procedures;
- post-launch surveillance;
- quality;
- advertising and promotion;
- product import and export; and
- reimbursement.

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

Clinical and Preclinical

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

Enrollment criteria for certain of our clinical trials may be quite narrow, further delaying the clinical trial process. For instance, clinical trials previously conducted using INTERCEPT-treated plasma for patients with thrombotic thrombocytopenic purpura lasted approximately four years due in part to the difficulties associated with enrolling qualified patients. In addition, enrollment criteria have impacted the speed with which we have been able to enroll patients for our ongoing Phase III red blood cell system trial in chronic anemia in Europe. Consequently, we

may be unable to recruit suitable patients into clinical trials on a timely basis, if at all, which may lead to higher costs or the inability to complete the clinical trials. We cannot rely on interim results of trials to predict their final results, and acceptable results in early trials might not be repeated in later trials. Any trial may fail to produce results satisfactory to the FDA or foreign regulatory authorities. In addition, preclinical and clinical data can be interpreted in different ways, which could delay, limit or prevent regulatory approval. Negative or inconclusive results from a preclinical study or clinical trial, or adverse medical events during a clinical trial could cause a preclinical study or clinical trial to be repeated, require other studies to be performed or cause a program to be terminated, even if other studies or trials relating to a program are successful.

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

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

Outside the United States, regulations vary by country, including the requirements for regulatory and marketing approvals or clearance, the time required for regulatory review and the sanctions imposed for violations. In addition to CE mark documentation, countries outside the European Union may require clinical data submissions, registration packages, import licenses or other documentation. Regulatory authorities in Japan, China, Taiwan, South Korea, Vietnam, Thailand, and Singapore and elsewhere, may require, among other requirements, that our products be widely adopted commercially in Europe or approved by the FDA before they are considered for approval or may delay approval decisions until our products are more widely adopted commercially and approved by the FDA. In addition to the regulatory requirements applicable to us and to our products, there are regulatory requirements in several countries around the world, including the United States, Germany, Canada, Austria, Australia and other countries, applicable to prospective customers of INTERCEPT Blood System products, the blood centers that process and distribute blood and blood products. In those countries, blood

centers and other customers are required to obtain approved license supplements from the appropriate regulatory authorities before making available blood products processed with our pathogen reduction systems to hospitals and transfusing physicians. Our customers may lack the resources or capability to obtain such regulatory approvals. For example, in the United States, blood centers will be required to obtain site-specific licenses from CBER prior to engaging in interstate transport of blood components processed using the INTERCEPT Blood System. These requirements or regulators' delays in approving license applications or supplements may deter some blood centers from using our products. Blood centers that do submit applications or supplements for manufacturing and sale may face disapproval or delays in approval that could provide further delay or deter them from using our products. The regulatory impact on potential customers could slow or limit the potential sales of our products.

Red Blood Cell System

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

In 2003, we terminated Phase III clinical trials evaluating a prior generation of the red blood cell system in acute and chronic anemia patients. The trials were terminated due to the detection of antibody reactivity to INTERCEPT-treated red blood cells in two patients in the 2003 Phase III clinical trial for chronic anemia. Although the antibody reactivity was not

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

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

We completed our European Phase III clinical trial of our red blood cell system for acute anemia patients and have another European Phase III clinical trial of our red blood cell system for chronic anemia patients ongoing. Although we plan to undertake additional development and CMC activities to support an anticipated CE Mark submission planned for the second half of 2016, such studies, including the studies required by the FDA prior to its review of any proposed U.S. Phase III clinical trial protocol, could prolong development of the red blood cell system, and we do not expect to receive any regulatory approvals of our red blood cell system for a few years, if ever. We understand that while the acute anemia Phase III clinical trial in Europe may be sufficient to receive CE mark approval in Europe, a successful outcome with potentially more safety data in the ongoing Phase III chronic anemia clinical trial may also be required for our red blood cell system to achieve broad market acceptance. In addition, the trials may need to be supplemented by additional, successful Phase III clinical trials for approval in certain countries. If such additional Phase III clinical trials are required, they would likely need to demonstrate equivalency of INTERCEPT-treated red blood cells compared to conventional red blood cells. A number of trial design issues that could impact efficacy, regulatory approval and market acceptance will need to be resolved prior to the initiation of further clinical trials. As part of our development and CMC activities, we will need to complete a number of *in vitro* studies, finalize

development of the final commercial configuration of the red blood cell system and manufacture and validate sufficient quantities of the final red blood cell system prior to receiving any regulatory approvals in Europe and may have to complete additional activities prior to receiving regulatory approvals in the United States. Many of these activities will require capital beyond that which we currently have, and we will be required to obtain additional capital in order to complete the development of and obtain any regulatory approvals for the red blood cell system. If we are unsuccessful in advancing the red blood cell system through clinical trials, resolving process and product design issues or in obtaining subsequent regulatory approvals and acceptable reimbursement rates, we may never realize a return on our research and development expenses incurred to date for the red blood cell system program. Regulatory delays can also materially impact our product development costs. If we continue to experience delays in testing, conducting trials or approvals, our product development costs will increase. Even if we were to successfully complete and receive approval for our red blood cell system, potential customers may object to working with a potent chemical, like S-303, the active compound in the red blood cell system, or may require modifications to automate the process, which would result in additional development costs, any of which could limit any market acceptance of the red blood cell system.

Platelet and Plasma Systems

In 2007, we obtained a CE mark approval (extended in 2012) from European Union regulators for our platelet system and will need to obtain an extension every five years. We or our customers have received approval for INTERCEPT-treated platelets in France, Switzerland, Germany and Austria. We or our customers may also be required to conduct additional testing in order to obtain regulatory approval in countries that do not recognize the CE mark as being adequate for commercializing the INTERCEPT Blood System in those countries. The level of additional product testing varies by country, but could be expensive or take a long time to complete. In addition, regulatory agencies are able to withdraw or suspend previously issued approvals.

In 2006, we obtained a CE mark approval (extended in 2011) from European Union regulators for our plasma system. We or our customers have received approval for INTERCEPT-treated plasma in France, Switzerland, and Germany. In some countries, including several in Europe, we or our customers may be required to perform additional clinical studies or submit manufacturing and marketing applications in order to obtain regulatory approval.

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

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

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

Post-Marketing Approval

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

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

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

- repair, replacement, recall or seizure of our products;
- operating restrictions or partial suspension or total shutdown of production;
- delaying or refusing our requests for approval of new products, new intended uses or modifications to our existing products;
- refusal to grant export or import approval for our products;
- withdrawing marketing approvals that have already been granted, resulting in prohibitions on sales of our products; and
- criminal prosecution.

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

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

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

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

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

- untitled letters, warning letters, fines, injunctions, consent decrees and civil penalties;
- unanticipated expenditures to address or defend such actions;
- customer notifications or repair, replacement, refunds, recall, detention or seizure of our products;

- operating restrictions or partial suspension or total shutdown of production;
- refusing or delaying our requests for premarket approval of new products or modified products;
- withdrawing marketing approvals that have already been granted;
- refusal to grant export or import approval for our products; or
- criminal prosecution.

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

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

Any modifications to the platelet and plasma systems that could significantly affect their safety or effectiveness, including significant design and manufacturing changes, or that would constitute a major change in their intended use, manufacture, design, components, or technology requires approval of a new premarket approval application, or PMA, or PMA supplement. However, certain changes to a PMA-approved device do not require submission and approval of a new PMA or PMA supplement and may only require notice to FDA in a PMA Annual Report. The FDA requires every supplier to make this determination in the first instance, but the FDA may review any supplier's decision. The FDA may not agree with our decisions regarding whether new clearances or approvals are necessary. Our products could be subject to recall if the FDA determines, for any reason, that our products are not safe or effective or that appropriate regulatory submissions were not made. If new regulatory approvals are required, this could delay or preclude our ability to market the modified system. For example, due to the obsolescence of certain parts, we will likely need to redesign the illuminators used in the platelet and plasma systems. In addition, in order to address the entire market in the United States, we will need to develop and test additional configurations of the platelet system, including to make the platelet system compatible with platelets suspended in 100% plasma, triple dose collections and random donor platelets. Our failure to obtain FDA and foreign regulatory approvals of new platelet and plasma product configurations could significantly limit revenues from sales of the platelet and plasma systems. In any event, delays in receipt or failure to receive approvals, the loss of previously received approvals, or the failure to comply with any other existing or future regulatory requirements, could reduce our sales and negatively impact our profitability potential and future growth prospects.

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

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

We have a wholly-owned subsidiary, headquartered in The Netherlands, dedicated primarily to selling and marketing the platelet and plasma systems in Europe, the CIS and the Middle East. Our commercial activities for the United States, Latin and South America and Asia are based out of our headquarters in Concord, California. We have recently begun building out our commercial organization in the United States and as a result our team based in the United States has limited to no experience selling and marketing our platelet and plasma systems. We will need to maintain and continue to increase our competence in a number of functions, including sales, marketing, regulatory, inventory and logistics, customer service, credit and collections, risk management, and quality assurance systems in order to successfully support our commercialization activities in all of the jurisdictions we currently sell and market, or anticipate selling and marketing, our products. Many of these competencies require compliance with United States, European Union, South American, Asian and local standards and practices, including regulatory, legal and tax requirements, with some of which we have limited experience. In this regard, should we obtain regulatory approval in an increased number of geographies, we will need to ensure that we maintain a sufficient number of personnel or develop new business processes to ensure ongoing compliance with the multitude of regulatory requirements in those territories. Hiring, training and retaining new personnel is costly, time consuming and distracting to existing employees and management. We have limited experience operating on a global scale and we may be unsuccessful complying with the variety and complexity of laws and regulations in a timely manner, if at all. In addition, in some cases, the cost of obtaining approval and maintaining compliance with certain regulations and laws may exceed the revenue that we recognize from such a territory, which would adversely affect our results of operations and could adversely affect our financial condition.

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 any necessary in-country regulatory approvals, as well as market and sell the INTERCEPT Blood System, provide customer and technical product support, maintain inventories, and adhere to our quality system in all material respects, among other activities. Generally, our distribution agreements require distributors to purchase minimum quantities in a given year over the term of the agreement. Failure by our distributors to meet these minimum purchase obligations may impact our financial results. In addition, failure by our distributors to provide an accurate forecast impacts our ability to predict the timing of revenue and our ability to accurately forecast our product supply needs. While our contracts generally require distributors to exercise diligence, these distributors may fail to commercialize the INTERCEPT Blood System in their respective territories. For example, our distributors may fail to sell product inventory they have purchased from us to end customers or may sell competing products ahead of or in conjunction with INTERCEPT. In addition, initial purchases of illuminators or INTERCEPT disposable kits by

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

Currently, a fairly concentrated number of distributors make up a significant portion of our revenue and we may have little recourse, short of termination, in the event that a distributor fails to execute according to our expectations and contractual provisions. In 2013 and 2014, we experienced weaker than expected growth due to declining performance by certain of our distributors. We have recently transitioned certain territories to new distribution partners who we felt were capable of improved performance relative to their predecessors. Because these are new distribution partners who have limited experience marketing and selling our products, we cannot be certain that these new distribution partners will perform better than their predecessors. In other territories, we transitioned to a Cerus direct sales model. We believe this transition will provide us with better visibility into and control of sales execution. Implementing such changes has negatively impacted the volume of INTERCEPT disposable kit sales as distribution partners sell through their disposable kit inventory and may continue to negatively impact the volume of INTERCEPT disposable kit sales in future periods. In certain cases, our distributors hold the regulatory approval to sell INTERCEPT for their particular geography. The loss of these distributors would require us to negotiate a transfer of the applicable regulatory approvals to us which may be difficult to do in a timely manner, or at all. We expect that our product revenues will be adversely impacted with the loss or transition of one or more of these distributors. If we chose to terminate additional distributor agreements, we would either need to reach agreement with, qualify, train and supply a replacement distributor or supply and service end-user customer accounts in those territories ourselves. Although our distribution agreements generally provide that the distributor will promptly and efficiently transfer its existing customer agreements to us, there can be no assurance that this will happen in a timely manner or at all. Doing so may be disruptive for our customers and our reputation may be damaged as a result. Our distribution partners may have more established relationships with potential end user customers than a new distributor or we may have in particular territory, which could adversely impact our ability to successfully commercialize our products in these territories. In addition, it may take longer for us to be paid if payment timing and terms in these new arrangements are less favorable to us than those in our existing distributor arrangements. As we service end-user accounts directly rather than through distributors, we incur additional expense and our working capital is negatively impacted due to longer periods from cash collection from direct sales customers when compared to the timing of cash collection from our former distribution partners. Current or transitioning distributors may irreparably harm relationships with local existing and prospective customers and our standing with the blood banking community in general. In the event that we are unable to

find alternative distributors or mobilize our own sales efforts in the territories in which a particular distributor operates, customer supply, our reputation and our operating results may be adversely affected. In addition, in territories where new distributors are responsible for servicing end-user accounts, there will be a period of transition in order to properly qualify and train these new distributors, which may disrupt the operations of our customers and adversely impact our reputation and operating results.

We have no experience in commercializing products in the United States. To the extent that we are unable to develop and maintain an effective and qualified U.S.-based commercial organization, we may not be able to successfully commercialize our platelet and plasma systems in the United States.

Our ability to generate significant revenue from our platelet and plasma systems depends in part on our ability to achieve market acceptance of, and to otherwise effectively market, our platelet and plasma systems in the United States. As a company, we have no experience in commercializing any products in the United States. We are also still in the process of establishing a U.S-based sales and marketing organization. For example, we intend to hire additional medical science liaisons, or MSLs, to help educate hospitals and physicians on our products, clinical trial history and publications. MSLs are highly educated and trained professionals and the hiring market for MSLs is highly competitive. As such, we will need to commit significant additional management and other resources to building out our MSL team as well as the growth of our sales and marketing organization. We may be unable to develop and maintain adequate MSL, sales and marketing capabilities for the U.S. market and we also may not be able to devote sufficient resources to the advertising, promotion and sales efforts for the platelet and plasma systems in the United States. We will also have to compete with other life sciences and medical device companies to recruit, hire, train and retain the MSL, sales and marketing personnel that we anticipate we will need in the future. For these and other reasons, we may be unable to develop and maintain an effective and qualified U.S.-based commercial organization in a cost-effective manner or realize a positive return on our investment. If we are unable to develop and maintain an effective and qualified U.S.-based commercial organization in a timely manner or at all, we may fail to realize the full sales potential of our platelet and plasma systems in the United States.

Our manufacturing supply chain exposes us to significant risks.

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

In November 2013, we amended our manufacturing and supply agreement with Fresenius with the new terms effective January 1, 2014. Under the amended agreement, Fresenius is obligated to sell, and we are obligated to purchase up to a certain specified annual volume of finished disposable kits for the platelet and plasma systems from Fresenius for both clinical and commercial use. Once the specified annual volume of disposable kits is purchased from Fresenius, we are able to purchase additional quantities of disposable kits from other third-party manufactures. The amended terms also provide for fixed pricing for finished kits with successive

decreases in pricing at certain annual production volumes. In addition, the amendment requires us to purchase additional specified annual volumes of sets per annum if and when an additional Fresenius manufacturing site is identified and qualified to make INTERCEPT disposable kits, subject to mutual agreement on pricing for disposable kits manufactured at the additional site. Fresenius is also obligated to purchase and maintain specified inventory levels of our proprietary inactivation compounds and compound adsorption devices from us at fixed prices. The term of the amended manufacturing and supply agreement with Fresenius extends through December 31, 2018, subject to termination by either party upon thirty months prior written notice, in the case of Fresenius, or twenty-four months prior written notice, in our case. We and Fresenius each have normal and customary termination rights, including termination for material breach. Fresenius is our sole supplier for the manufacture of these products. Fresenius may fail to manufacture an adequate supply of INTERCEPT disposable kits which would harm our business. In October 2014, Fresenius announced plans to cease manufacturing certain of its non-Cerus product lines and to significantly reduce its workforce at the manufacturing facility at which our products are made. Disruptions to our supply chain as a result of any potential ensuing protests, strikes or other work-stoppages would be detrimental to our business and operating results. We do not currently have plans to terminate our amended agreement with Fresenius and understand that Fresenius currently plans to continue operating under the amended agreement. However, in the event Fresenius refuses or is unable to continue operating under the amended agreement, we may be unable to maintain inventory levels or otherwise meet customer demand, and our business and operating results would be materially and adversely affected.

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

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

Our supply agreement with Porex was amended in December 2014 and now expires on December 31, 2016. Porex is our sole supplier for such components of the compound adsorption devices. We are subject to certain minimum annual purchase requirements under our agreement with Porex and are required to compensate Porex if we do not meet such minimum annual purchase requirements. We entered into an amended and restated supply agreement with Purolite in April 2014. The amended supply agreement expires in April 2021 and will automatically renew for an additional year unless either party has provided notice not to renew at least two years prior to the expiration. Under the terms of the amended agreement, pricing is volume based and is subject to annual, prospective adjustments based on a Producer Price Index subject to an

annual cap. Our agreement with NOVA, which manufacturers our illuminators, extends through September 2015 and is automatically renewable for one year terms, but may be terminated by NOVA on at least twelve months' prior written notice.

Facilities at which the INTERCEPT Blood System or its components are manufactured may cease operations for planned or unplanned reasons or may unilaterally change the formulations of certain commercially available reagents that we use, causing at least temporary interruptions in supply. Even a temporary failure to supply adequate numbers of INTERCEPT Blood System components may cause an irreparable loss of customer goodwill. Although we are actively evaluating alternate suppliers for certain of our products and components, we do not have qualified suppliers beyond those on which we currently rely, and we understand that Fresenius relies substantially on sole suppliers of certain materials for our products. Identification and qualification of alternate suppliers will be time consuming and costly. If we conclude that supply of the INTERCEPT Blood System or components from Fresenius and others is uncertain, we may choose to build and maintain inventories of raw materials, work-in-process components, or finished goods, which would consume capital resources faster than we anticipate and may cause our supply chain to be less efficient.

Currently NOVA is manufacturing illuminators to meet customer demand and maintain our own inventory levels. Subject to obsolescence, we may be required to identify and qualify replacement components for illuminators and in doing so, we may be required to conduct additional studies, which could include clinical trials to demonstrate equivalency or validate any required design or component changes. Future supply of illuminators is limited to availability of components, some of which are in short supply or are no longer manufactured. Certain of our components are in limited supply and are used as spare parts for the maintenance of illuminators used by our customers. We and our customers rely on the availability of spare parts to ensure that customer platelet and plasma production is not interrupted. If we are not able to supply spare parts for the maintenance of customer illuminators, our ability to keep existing customers or sign up new customers may be negatively impacted. Certain parts used in our illuminator are obsolete. Although we have sufficient inventory of parts to manufacture the current generation of illuminators for anticipated demand in the United States and other geographies, we will likely need to redesign the illuminators used in the platelet and plasma systems, which may be expensive and will require approval of a new PMA or PMA supplement. Our failure to obtain FDA and foreign regulatory approvals of a new illuminator could significantly limit revenues from sales of the platelet and plasma systems. In any event, delays in receipt or failure to receive these approvals could reduce our sales and negatively impact our profitability potential and future growth prospects. In addition, our illuminators contain embedded proprietary software that runs on software code we have developed and that we own. Changes to certain components due to obsolescence, illuminator redesign or market demand, may require us to modify the existing software code or to develop new illuminator software. Our ability to develop new illuminator software, correct coding flaws and generally maintain the software code is reliant on third-party contractors who, in some cases, have sole knowledge of the software code. Our ability to develop and maintain the illuminator software may be impaired if we are not able to continue contracting with those key third-party contracted developers or if we are unable to source alternate employees or consultants to do so.

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

Raw materials, components or finished product may not meet specifications or may be subject to other nonconformities. In several instances over the past two years, nonconformities in certain component lots have caused delays in manufacturing of INTERCEPT disposable kits. Non-conformities can increase our expenses and reduce gross margins. Should non-conformities occur in the future, we may be unable to manufacture products to meet customer demand, which would result in lost sales and could cause irreparable damage to our customer relationships. Later discovery of problems with a product, manufacturer or facility may result in additional restrictions on the product, manufacturer or facility, including withdrawal of the product from the market. We are subject to risks and costs of product recall, which include not only potential out-of-pocket costs, but also potential interruption to our supply chain. In such an event, our customer relations could be harmed and we would incur unforeseen losses.

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

We may encounter unforeseen manufacturing difficulties which, at a minimum, may lead to higher than anticipated costs, scrap rates, manufacturing overhead variances or delays in manufacturing products. In addition, we may not receive timely or accurate demand information from distributors or may not accurately forecast demand ourselves for the INTERCEPT Blood System. As a result, we may carry excess work-in-process or finished goods inventory, which would consume capital resources and may become obsolete, or our inventory may be inadequate to meet customer demand. We have entered into certain public tenders, some which call for us to maintain certain minimum levels of inventory. If our suppliers fail to produce components or our finished products satisfactorily, timely, at acceptable costs, and in sufficient quantities, we may incur delays, shortfalls and additional expenses, or non-compliance with certain public tenders which may in turn result in permanent harm to our customer relations or loss of customers. Conversely, we may choose to overstock inventory in order to mitigate any unforeseen potential disruption to manufacturing which could consume our cash resources faster than we anticipate and may cause our supply chain to be less efficient. Our platelet and plasma systems' disposable kits have a two-year shelf life from the date of manufacture. We and our distributors may be unable to ship product to customers prior to the expiration of the product shelf life, a risk that is heightened if we elect to increase our inventory levels in order to migrate supply disruptions. We will need to destroy or consume the outdated inventory in product demonstration activities, which may in turn lead to elevated product demonstration costs or reduced gross margins.

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

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

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

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

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

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

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

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

In addition, there has been a recent trend of increased U.S. federal and state regulation of payments and transfers of value provided to healthcare professionals or entities. On February 8, 2013, the Centers for Medicare & Medicaid Services, or CMS, released its final rule implementing section 6002 of the Affordable Care Act known as the Physician Payment Sunshine Act that imposes new annual reporting requirements on device manufacturers for payments and other transfers of value provided by them, directly or indirectly, to physicians and teaching hospitals, as well as ownership and investment interests held by physicians and their family members. A manufacturer's failure to submit timely, accurately and completely the required information for all payments, transfers of value or ownership or investment interests may result in civil monetary penalties of up to an aggregate of $150,000 per year, and up to an aggregate of $1.0 million per year for "knowing failures." The period between August 1, 2013, and December 31, 2013 was the first reporting period, for which manufacturers were required to report aggregate payment data to CMS by March 31, 2014. Manufacturers also will be required to report to CMS detailed payment and transfers of value data and submit legal attestation to the accuracy of such data during Phase 2 of the program, which began May 2014 and extends for at least 30 days. Thereafter, manufacturers must submit reports by the 90th day of each subsequent calendar year. Due to the difficulty in complying with the Physician Payment Sunshine Act, we cannot assure you that we will successfully report all payments and transfers of value provided by us, and any failure to comply could result in significant fines and penalties. Some states, such as California and Connecticut, also mandate implementation of commercial compliance programs, and other states, such as Massachusetts and Vermont, impose restrictions on device manufacturer marketing practices and tracking and reporting of gifts, compensation and other remuneration to healthcare professionals and entities. The shifting commercial compliance environment and the need to build and maintain robust and expandable systems to comply with different compliance and reporting requirements in multiple jurisdictions increase the possibility that we may fail to comply fully with one or more of these requirements.

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

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

In addition, the scope and enforcement of these laws is uncertain and subject to rapid change in the current environment of healthcare reform, especially in light of the lack of applicable precedent and regulations. U.S. federal or state regulatory authorities might challenge our current or future activities under these laws. Any such challenge could have a material adverse effect on our reputation, business, results of operations and financial condition. Any U.S.

federal or state or foreign regulatory review of us, regardless of the outcome, would be costly and time-consuming. Additionally, we cannot predict the impact of any changes in these laws, whether or not retroactive.

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

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

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

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

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

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

The equipment and materials used to collect platelets vary by manufacturer and by geographic region. Platelets may be collected from a single donor by apheresis using an automated collection machine. Apheresis devices currently used in the United States and European markets differ, among other characteristics, in their ability to collect platelets in reduced volumes of plasma. Platelet concentrates may also be prepared from whole blood by pooling together platelets from multiple donors. There are two commonly used methods for preparing whole blood platelets: the buffy coat method, which is used extensively in Europe, and the pooled random donor method, which is used in the United States. Our platelet system is designed to work with platelets collected and stored in storage solutions, called InterSol and SSP+, and for platelets suspended in 100% plasma, although our label indications in the United States do not currently provide for platelets suspended in 100% plasma. Fresenius is the exclusive manufacturer of InterSol and MacoPharma of SSP+, both widely-used platelet additive solutions. Many of our customers and prospective customers use InterSol or SSP+ in connection with INTERCEPT treatment. Similarly, many of our customers combine multiple plasma components from whole blood donations before treating the combined product with INTERCEPT. Grifols makes such a product (Plasmix). Customers' ability to use our INTERCEPT products may be impaired should manufacturers of those products, including those sold by Grifols, not provide access to the products allowing for the combination of multiple components. Should Fresenius, MacoPharma, or Grifols fail to obtain or maintain regulatory approval for InterSol, SSP+, or Plasmix, respectively, or if any should decide to cease distribution of those respective products to customers and prospective customers, our ability to sell the INTERCEPT Blood System may be impaired. In addition, we may be required to produce and demonstrate additional acceptable data for usage of the INTERCEPT Blood System with various combinations of collection platforms and storage solutions before we could receive additional regulatory approvals from the FDA and elsewhere.

In order to address the entire market in the United States, Japan, and potentially elsewhere, we will need to develop and test additional configurations of the platelet system. For example, in the United States, we understand a significant number of platelet concentrates are derived from larger volumes collected from apheresis donors split into three therapeutic transfusable doses. Future configurations of the platelet system will be needed to treat platelet donations with such processing parameters. We estimate that the majority of platelets used in the United States are collected by apheresis, though a significant minority are prepared from pooled random donor platelets derived from whole blood collections. In the United States, our platelet system is currently only approved for apheresis collections and for use with platelets suspended in a storage solution. In order to gain regulatory approvals for a pathogen reduction system compatible with triple dose collections, platelets suspended in 100% plasma, and random donor platelets, we will need to perform additional product development and testing, including additional clinical trials, and will require approval of a PMA supplement. Our failure to obtain FDA and foreign regulatory approvals of these new configurations could significantly limit revenues from sales of the platelet system. In any event, delays in receipt or failure to receive approval could reduce our sales and negatively impact our profitability potential and future growth prospects. Similarly, to achieve market acceptance in certain geographies, we may be required to design, develop and test new product configurations for the platelet and plasma

systems. These development activities will increase our costs significantly and may not be successful. We may need to demonstrate the safety and efficacy of our platelet system using a variety of configurations before our platelet system would be approved for such configurations. Delays in obtaining any future approvals would adversely affect our ability to introduce new or enhanced products in a timely manner, which in turn would harm our revenue and potential future profitability.

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

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

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

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

We expect our products will continue to encounter significant competition. The INTERCEPT Blood System products compete with other approaches to blood safety currently in

use and may compete with future products that may be developed by others. Our success will depend in part on our ability to respond quickly to customer and prospective customer needs, successfully receive and maintain regulatory approvals, and adapt to medical and technological changes brought about by the development and introduction of new products. Competitors' products or technologies may make our products obsolete or non-competitive before we are able to generate any significant revenue. In addition, competitors or potential competitors may have substantially greater financial and other resources than we have. They may also have greater experience in preclinical testing, human clinical trials and other regulatory approval procedures. If competitors' products experience significant problems, customers and potential customers may question the safety and efficacy of all pathogen reduction technologies, including the INTERCEPT Blood System. Such questions and concerns may impair our ability to market and sell the INTERCEPT Blood System.

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

These alternative strategies may be more effective in inactivating certain types of pathogens from blood products, including certain non-lipid-enveloped viruses, such as hepatitis A and E viruses, which our products have not demonstrated an ability to inactivate, or human parvovirus B-19, which is also a non-lipid-enveloped virus, for which our products have not demonstrated a high level of inactivation. While studies have demonstrated that our products can effectively inactivate a broad spectrum of pathogens in blood components, market adoption of our products may be reduced if customers determine that competitors' products inactivate a broader range of pathogens that are of particular interest to the transfusion medicine community. In addition, customers and prospective customers may believe that our competitors' products are safer or more cost effective than INTERCEPT Blood System products. In Europe, several companies, including Grifols S.A., Octapharma AG, MacoPharma International and Kedrion Biopharma, are developing or selling commercial pathogen reduction systems or services to treat fresh frozen plasma. Terumo BCT, a subsidiary of Terumo Corporation, has developed a pathogen reduction system for blood products and has been issued CE marks for a pathogen reduction system for both platelets and plasma. We understand that Terumo BCT is also developing a pathogen reduction system for whole blood. Terumo BCT's product candidate, if successful, may offer competitive advantages over our INTERCEPT Blood System. Terumo Corporation is a large Japanese-based, multinational corporation with more mature products and relationships than we have. Our ability to commercialize our products in certain markets, particularly in Japan, may be negatively affected by Terumo's resources and their pre-existing relationships with regulators and customers. Should Terumo BCT's product be approved for use and commercialized in Japan, we would likely directly compete with them and we believe we would likely either need to establish operations in Japan or partner with a local Japanese company.

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

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

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

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

We are exposed to potential liability risks inherent in the testing and marketing of medical devices. We may be liable if any of our products cause injury, illness or death. Although we will have completed preclinical and clinical safety testing prior to marketing our products, there may be harmful effects caused by our products that we are unable to identify in preclinical or clinical testing. In particular, unforeseen, rare reactions or adverse side effects related to long-term use of our products may not be observed until the products are in widespread commercial use. Because of the limited duration and number of patients receiving blood components treated with the INTERCEPT Blood System products in clinical trials, it is possible that harmful effects of our products not observed in preclinical and clinical testing could be discovered after a marketing approval has been received. For example, in cases where we have obtained regulatory approval for our products, we have demonstrated pathogen reduction to specified levels based on well-established tests. However, there is no way to determine, after treatment by our products, whether our products have completely inactivated all of the pathogens that may be present in blood components. There is also no way to determine whether any residual amount of a pathogen remains in the blood component treated by our products and there is no way to exclude that such residual amount would be enough to cause disease in the transfused patient. For ethical reasons, we cannot conduct human testing to determine whether an individual who receives a transfusion of a blood component containing a pathogen that was inactivated using the INTERCEPT Blood System might show positive results if tested for an antibody against that pathogen. While we believe, based on the clinical experience of our scientists, that the level of inactivated pathogens would likely be too small to induce a detectable antibody response in diagnostic tests, we cannot exclude that a transfused patient might show positive results if tested for an antibody against that pathogen. We could be subject to a claim from a patient that tests positive, even though that patient did not contract a disease. In addition, should personnel at clinical study sites or ultimately, potential customers, be harmed by S-303, or believe they have been or could be harmed by S-303, our insurance coverage may be insufficient to provide coverage for any related potential liabilities. S-303 is considered a potent chemical and is the active compound of our red blood cell system.

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

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

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

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

In addition, under the FDA's medical device reporting regulations, we are required to report to the FDA any incident in which our products may have caused or contributed to a death or serious injury or in which our product malfunctioned and, if the malfunction were to recur, would likely cause or contribute to death or serious injury. Repeated product malfunctions may result in a voluntary or involuntary product recall. We are also required to follow detailed recordkeeping requirements for all firm-initiated medical device corrections and removals, and to

report such corrective and removal actions to FDA if they are carried out in response to a risk to health and have not otherwise been reported under the medical device reporting regulations. If we do not adequately address problems associated with our devices, we may face additional regulatory enforcement action, including FDA warning letters, product seizure, injunctions, administrative penalties, or civil or criminal fines. We may also be required to bear other costs or take other actions that may have a negative impact on our sales as well as face significant adverse publicity or regulatory consequences, which could harm our business, including our ability to market our products in the future.

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

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

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

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

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

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

Our loan and security agreement with Oxford Finance provides for up to $30.0 million in term loans due on June 1, 2019, of which $10.0 million in term loans has been borrowed to date. All of our current and future assets, except for intellectual property and 35% of our investment in our subsidiary, Cerus Europe B.V., are secured for our borrowings under the loan and security agreement. The loan and security agreement requires that we comply with certain covenants applicable to us and our subsidiary, including among other things, covenants restricting dispositions, changes in business, management, ownership or business locations, mergers or acquisitions, indebtedness, encumbrances, distributions, investments, transactions with affiliates and subordinated debt, any of which could restrict our business and operations, particularly our ability to respond to changes in our business or to take specified actions to take advantage of certain business opportunities that may be presented to us. Our failure to comply with any of the covenants could result in a default under the loan and security agreement, which could permit the

lenders to declare all or part of any outstanding borrowings to be immediately due and payable, or to refuse to permit additional borrowings under the loan and security agreement. If we are unable to repay those amounts, the lenders under the loan and security agreement could proceed against the collateral granted to them to secure that debt, which would seriously harm our business. In addition, should we be unable to comply with these covenants or if we default on any portion of our outstanding borrowings, the lenders can also impose a 5% penalty and restrict access to additional borrowings under the loan and security agreement. Moreover, while we currently have the ability to borrow an additional $10.0 million under the loan and security agreement, our ability to access the final $10.0 million under the loan and security agreement is subject to our ability to achieve a certain revenue threshold, which condition we may not be able to meet and which and could adversely affect our liquidity. In addition, although we expect to borrow additional funds under the loan and security agreement, before we do so, we must first satisfy ourselves that we will have access to future alternate sources of capital, including cash flow from our own operations, equity capital markets or debt capital markets in order to repay any principal borrowed, which we may be unable to do, in which case, our liquidity and ability to fund our operations may be substantially impaired.

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

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

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

We are highly dependent upon our executive management team and other critical personnel, including our specialized research and development, regulatory and operations personnel, many of whom have been employed with us for many years and have a significant

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

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

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

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

Our business is increasingly dependent on complex and interdependent information technology systems, including internet-based systems, databases and programs, to support our business processes as well as internal and external communications. These computer systems are potentially vulnerable to breakdown, malicious intrusion and computer viruses which may result in the impairment of production and key business processes or loss of data or information. Additionally, our systems are potentially vulnerable to data security breaches—whether by employees or others—which may expose sensitive data to unauthorized persons. Such data security breaches could lead to the loss of trade secrets or other intellectual property, or could lead to the public exposure of personal information (including sensitive personal information) of our employees, clinical trial patients, distributors, customers and others. Such disruptions and breaches of security could have a material adverse effect on our business, financial condition and results of operations.

In addition, our existing enterprise resource planning system, a critical system used to run our business, will no longer be supported by the developer of that system. Accordingly, we have recently implemented a new enterprise resource planning system (the ERP System). The new ERP System is extremely complex and impacts a significant number of our business processes. Should we experience unforeseen difficulties with our new ERP System, we may experience disruptions to our operations, increased costs in troubleshooting and resolving the issues, and erosion in confidence from customers and employees, any of which could have a material adverse effect on our business and operations.

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

Under Section 382 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 net operating loss carryforwards and other pre-change tax attributes (such as research tax credits) 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. If a limitation were to apply, utilization of a portion of our domestic net operating loss and tax credit carryforwards could be limited in future periods and a portion of the carryforwards could expire before being available to reduce future income tax liabilities.

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

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

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

We cannot be certain that our patents or patents that we license from others will be enforceable and afford protection against competitors. Our patents or patent applications, if issued, may be challenged, invalidated or circumvented. Our patent rights may not provide us with proprietary protection or competitive advantages against competitors with similar technologies. Others may independently develop technologies similar to ours or independently duplicate our technologies. For example, we are aware of a United States patent issued to a third-party that covers methods to remove psoralen compounds from blood products. We have reviewed the patent and believe there exists substantial questions concerning its validity. We cannot be certain, however, that a court would hold the patent to be invalid or not infringed by our platelet or plasma systems upon commercialization of those products in the United States. In this regard, whether we would, upon commercialization of our platelet or plasma systems in the United States, infringe this patent will not be known with certainty unless and until a court interprets the patent in the context of litigation. In the event that we are found to infringe any valid claim of this patent, we may, among other things, be required to pay damages, cease the use and sale of our platelet and plasma systems and/or obtain a license from the owner of the patent, which we may not be able to do at a reasonable cost or at all. Our patents expire at various dates between now and 2031. Recent patent applications will, if granted, result in patents with later expiration dates. In addition, we

have a license from Fresenius to United States and foreign patents relating to the INTERCEPT Blood System, which expire at various dates from 2015 to 2024. Due to the extensive time required for development, testing and regulatory review of our potential products, our patents may expire or remain in existence for only a short period following commercialization. This would reduce or eliminate any advantage of the patents.

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

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

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

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

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

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

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

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

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

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

COMPANY OVERVIEW

Our Business

We are a biomedical products company focused on developing and commercializing the INTERCEPT Blood System to enhance blood safety. The INTERCEPT Blood System, which is based on our proprietary technology for controlling biological replication, is designed to reduce blood-borne pathogens in donated blood components intended for transfusion.

We have worldwide rights for our INTERCEPT Blood System for three blood components: plasma, platelets, and red blood cells. The INTERCEPT Blood System for platelets, or platelet system, and the INTERCEPT Blood System for plasma, or plasma system, have received a broad range of regulatory approvals, including U.S. Food and Drug Administration, or FDA, approval in the United States and Class III CE marks in the European Union and other jurisdictions that recognize CE mark approval, and are being marketed and sold in a number of countries around the world, including certain countries in Europe, The Commonwealth of Independent States, or CIS, and the Middle East. We sell both the platelet and plasma systems using our direct sales force and through distributors. The INTERCEPT Blood System for red blood cells, or the red blood cell system, is currently in development. We recently announced that both our U.S. Phase II recovery and lifespan study of the red blood cell system and our European Phase III clinical trial of the red blood cell system for acute anemia patients met their respective primary endpoints. Based on the results of the recently-completed European Phase III acute anemia clinical trial, we plan to file for CE mark approval in the European Union in the second half of 2016.

We currently 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. Although our revenues have grown over time, if we are unable to gain widespread commercial adoption in markets where our blood safety products are approved for commercialization, including in the United States, 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 increased 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.

Recent Developments

Platelet and Plasma Systems

In December 2014, the FDA approved the platelet system for *ex vivo* preparation of pathogen-reduced apheresis platelet components in order to reduce the risk of transfusion-transmitted infection, or TTI, including sepsis, and to potentially reduce the risk of transfusion-associated graft versus host disease. As part of the FDA's approval of the platelet system, we are required to successfully conduct and complete a post-approval hemovigilance study to evaluate the incidence of acute lung injury following transfusion of INTERCEPT processed platelets. Also in December 2014, the FDA approved the plasma system for *ex vivo* preparation of plasma in order to reduce the risk of TTI when treating patients requiring therapeutic plasma transfusion.

We are preparing for the combined commercial launch of the plasma and platelet systems in the United States. Prior to customer adoption in the United States, U.S.-based blood centers will need to complete their process validations and obtain site-specific licenses from the FDA Center for Biologics Evaluation and Research, or CBER, before making INTERCEPT-treated blood products available to their interstate hospital customers. We plan to work with U.S.-based blood centers to support these activities and anticipate initial customer adoption in the first half of 2015. However, we do not anticipate meaningful revenue in 2015 from sales of the plasma and platelet systems in the United States as our commercial activities in 2015 will largely be focused on supporting initial customer adoption. In addition, in order to address the entire market in the United States, we will need to develop, test and obtain FDA approval of additional configurations of the platelet system. For example, in the United States, we understand a

significant number of platelet concentrates are derived from larger volumes collected from apheresis donors split into three therapeutic transfusable doses. Future configurations of the platelet system will be needed to treat platelet donations with such processing parameters. In addition, we understand that a significant portion of the U.S. blood centers store their platelet components suspended in 100% plasma. Further, we estimate that the majority of platelets used in the United States are collected by apheresis, which is part of our FDA-approved label for the platelet system, though a significant minority are prepared from pooled random donor platelets derived from whole blood collections. In order to gain FDA approval for a pathogen reduction system compatible with platelets suspended in 100% plasma, random donor platelets and triple dose collections, we will need to perform additional product development and testing, including additional clinical trials, and will require FDA approval of a premarket approval application supplement. These development activities will increase our costs significantly and may not be successful. Our failure to obtain FDA and foreign regulatory approvals of these new configurations could significantly limit revenues from sales of the platelet system.

Red Blood Cell System

Europe . We are conducting an ongoing Phase III clinical trial of the red blood cell system in Europe for chronic anemia patients. In addition, we recently completed an additional Phase III clinical trial of the red blood cell system for acute anemia patients. In January 2015, we announced that the completed Phase III clinical trial of red blood cells treated with the INTERCEPT Blood System for acute anemia in cardiovascular surgery patients met its primary endpoint, with preliminary analysis demonstrating that the mean hemoglobin content (53.1g) of INTERCEPT-treated red blood cell components, or RBCs, on day 35 of storage met the protocol-defined criteria for equivalence based on the inferiority margin of 5g compared to conventional RBCs (55.8g). The randomized, double-blind, controlled, multi-center Phase III clinical trial of the red blood cell system evaluated the efficacy of the red blood cell system to process RBCs with quality and mean hemoglobin content (>40 g) suitable to support transfusion according to the European Directorate for the Quality of Medicines. The blood components were transfused to 51 cardiovascular surgery patients at two German clinical trial sites to evaluate transfusion efficacy and overall safety. Patients undergoing procedures for either coronary artery bypass grafting, valve repair or combined procedures received study transfusions during a seven-day treatment period that included the day of surgery and six days post-operatively. The patients received either INTERCEPT-treated RBCs or control RBCs not treated for pathogen inactivation. The primary endpoint of equivalence of mean hemoglobin content between INTERCEPT RBCs and conventional RBCs was met within the protocol specified 5g equivalence margin based on over 750 study RBC components manufactured. The secondary efficacy endpoints also demonstrated suitability for transfusion based on mean hematocrit of 60.4% (acceptance range: 55-70%) and mean end of storage hemolysis of 0.28% (acceptance range < 0.8%). There were no statistical differences in the adverse event rates between recipients of INTERCEPT-treated and control RBCs. There were no clinically relevant trends in severe or serious treatment related adverse events by system organ class. The observed adverse events were within the expected spectrum of co-morbidity and mortality for patients of similar age and with advanced cardiovascular diseases undergoing cardiovascular surgery requiring red cell transfusion. No patients exhibited an immune response to INTERCEPT-treated RBCs. Based on the results of this trial, we plan to file for CE mark approval in the European Union in the second half of 2016. We understand that while the acute anemia Phase III clinical trial in Europe may be sufficient to receive CE mark approval in Europe, a successful outcome with potentially more safety data in the ongoing chronic anemia Phase III clinical trial may also be required for our red blood cell system to achieve broad market acceptance. As part of our development and chemistry, manufacturing and control, or CMC, activities, we will need to complete a number of *in vitro* studies, finalize development of the final

commercial configuration of the red blood cell system and manufacture and validate sufficient quantities of the final red blood cell system prior to receiving any regulatory approvals in Europe.

United States . In December 2014, we announced that our U.S. Phase II recovery and lifespan study of red blood cells treated with the INTERCEPT Blood System met its primary endpoint, with the preliminary analysis demonstrating that greater than 75% of treated red blood cells continued to circulate 24 hours following transfusion. This randomized, single-blind, controlled, multi-center Phase II clinical trial of the red blood cell system evaluated 26 healthy subjects at two clinical trial sites in the United States. Each subject received two transfusions of the subject's own red blood cells, one INTERCEPT-treated, and the other a control not treated for pathogen reduction. Red blood cell units were stored for 35 days prior to transfusion. The primary endpoint of the study, a mean INTERCEPT red blood cell recovery of greater than 75% at 24 hours post-transfusion, was met. The INTERCEPT red blood cells had a recovery of 83% compared to 85% for control red blood cells, and both INTERCEPT-treated and control red blood cells met the criteria for red blood cell recovery recommended by the FDA. We plan to complete certain other prerequisites, as well as to complete our development and CMC activities and planned CE Mark submission, before proposing a Phase III clinical trial protocol for the red blood cell system in support of potential regulatory approval in the United States.