CERUS CORP
Form 10-K
March 08, 2018

UNITED STATES

SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

FORM 10-K

ANNUAL REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934
For the fiscal year ended December 31, 2017

OR

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

Commission file number 000-21937

CERUS CORPORATION

(Exact name of registrant as specified in its charter)

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

(925) 288-6000

(Registrant’s telephone number, including area code)

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

Title of Each Class

	Name of Each Exchange on Which Registered
Common Stock, par value $0.001 per share	The Nasdaq Stock Market LLC

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

Preferred Share Purchase Rights

(Title of Class)

Indicate by check mark if the registrant is a well-known seasoned issuer, as defined in Rule 405 of the Securities Act. Yes No

Indicate by check mark if the registrant is not required to file reports pursuant to Section 13 or Section 15(d) of the Act. Yes No

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

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

Indicate by check mark if disclosure of delinquent filers pursuant to Item 405 of Regulation S-K, (§229.405 of this chapter) is not contained herein, and will not be contained, to the best of registrant’s knowledge, in definitive proxy or information statements incorporated by reference in Part III of this Form 10-K or any amendment to this Form 10-K.

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

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

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

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

The approximate aggregate market value of the common stock held by non-affiliates of the registrant as of the last business day of the registrant’s most recently completed second fiscal quarter, based upon the closing sale price of the registrant’s common stock listed on the Nasdaq Global Market, was $238 million. (1)

As of February 22, 2018, there were 129,597,267 shares of the registrant’s common stock outstanding.

DOCUMENTS INCORPORATED BY REFERENCE

Portions of the registrant's definitive proxy statement in connection with the registrant's 2018 Annual Meeting of Stockholders, to be filed with the Securities and Exchange Commission pursuant to Regulation 14A not later than 120 days after the end of the fiscal year ended December 31, 2017, are incorporated by reference into Part III of this Annual Report on Form 10-K.

(1) Based on a closing sale price of $2.51 per share on June 30, 2017. Excludes 13.9 million shares of the registrant's common stock held by executive officers, directors and stockholders that the registrant has concluded were affiliates at June 30, 2017.

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PART I

This Annual Report on Form 10-K contains forward-looking statements within the meaning of Section 27A of the Securities Act of 1933, as amended, and Section 21E of the Securities and Exchange Act of 1934, as amended, that involve risks and uncertainties. The forward-looking statements are contained principally in Item 1, "Business," Item 7, "Management's Discussion and Analysis of Financial Condition and Results of Operations," and in Item 1A, "Risk Factors." These statements relate to future events or to our future operating or financial performance and involve known and unknown risks, uncertainties and other factors that may cause our actual results, performance or achievements to be materially different from any future results, performances or achievements expressed or implied by the forward-looking statements. These forward-looking statements may include, but are not limited to, statements about:

- future sales of and our ability to effectively commercialize and achieve market acceptance of the INTERCEPT Blood System, including our ability to comply with applicable United States (U.S.), and foreign laws, regulations and regulatory requirements;
- our ability to successfully complete development, receive regulatory approvals and commercialize extended storage cryoprecipitate or other plasma derived biological products using the INTERCEPT Blood System;
- our ability to manage the growth of our business and attendant cost increases, including in connection with the commercialization of the INTERCEPT Blood System in the U.S., as well as our ability to manage the risks attendant to our international operations;
- the timing or likelihood of regulatory submissions and approvals and other regulatory actions or interactions, including our anticipated CE mark submission for the red blood cell system;
- our ability to obtain and maintain regulatory approvals of the INTERCEPT Blood System;
    - our ability to obtain adequate clinical and commercial supplies of the INTERCEPT Blood System from our sole source suppliers for a particular product or component they manufacture;
- the initiation, scope, rate of progress, results and timing of our ongoing and proposed preclinical and clinical trials of the INTERCEPT Blood System;
    - the successful completion of our research, development and clinical programs and our ability to manage cost increases associated with preclinical and clinical development of the INTERCEPT Blood System;
- the amount and availability of funding we may receive under our agreement with the Biomedical Advanced Research and Development Authority, or BARDA;
- our ability to transition distribution of the INTERCEPT Blood System from third parties to a direct sales model in certain international markets;
- the ability of our products to inactivate the emerging viruses and other pathogens that we may target in the future;
- our ability to protect our intellectual property and operate our business without infringing upon the intellectual property rights of others; and
- our estimates regarding the sufficiency of our cash resources and our need for additional funding.

In some cases, you can identify forward-looking statements by terms such as "anticipate," "will," "believe," "estimate," "expec "plan," "may," "should," "could," "would," "project," "predict," "potential," and similar expressions intended to identify such forward-looking statements. Forward-looking statements reflect our current views with respect to future events, are based on assumptions, and are subject to risks and uncertainties. There can be no assurance that any of the events anticipated by forward-looking statements will occur or, if any of them do occur, what impact they will have on our business, results of operations and financial condition. Certain important factors could cause actual results to differ materially from those discussed in such statements, including the rate of customer adoption in the U.S. and our ability to achieve market acceptance of our products in the U.S. and international markets, whether our preclinical and clinical data or data from commercial use will be considered sufficient by regulatory authorities to grant marketing approval for our products or for product extensions or additional claims for our products, our ability to obtain reimbursement approval for our products, our ability to complete the development and testing of additional configurations or redesigns of our products, our need for additional financing and our ability to access funding under

our agreement with BARDA, the impacts of regulation of our products by domestic and foreign regulatory authorities, our limited experience in sales, marketing and regulatory support for the INTERCEPT Blood System, our reliance on Fresenius Kabi AG and third parties to manufacture certain components of the INTERCEPT Blood System, incompatibility of our platelet system with some commercial platelet collection methods, our need to complete our red blood cell system's commercial design, more effective

product offerings by, or clinical setbacks of, our competitors, product liability, our use of hazardous materials in the development of our products, business interruption due to earthquake, our expectation of continuing losses, protection of our intellectual property rights, volatility in our stock price, on-going compliance with the requirements of the Sarbanes-Oxley Act of 2002, and other factors discussed below and under the caption “Risk Factors,” in Item 1A of this Annual Report on Form 10-K. We discuss many of these risks in this Annual Report on Form 10-K in greater detail in the section titled “Risk Factors” under Part I, Item 1A below. Given these uncertainties, you should not place undue reliance on these forward-looking statements. Also, forward-looking statements represent our estimates and assumptions only as of the date of this Annual Report on Form 10-K. You should read this Annual Report on Form 10-K and the documents that we incorporate by reference in and have filed as exhibits to this Annual Report on Form 10-K completely. Our actual future results may be materially different from what we expect. Except as required by law, we assume no obligation to update or revise any forward-looking statements to reflect new information or future events, even if new information becomes available in the future. You should not assume that our silence over time means that actual events are bearing out as expressed or implied in such forward-looking statements.

Item 1. Business

Overview

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.

Our INTERCEPT Blood System is for use with 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 but not limited to U.S. Food and Drug Administration, or FDA, approval in the U.S., 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 the U.S., certain countries in Europe, the Commonwealth of Independent States, or CIS, the Middle East, and Latin America and selected countries in other regions of the world. We sell both the platelet and plasma systems using our direct sales force and through distributors. If we are unable to gain widespread commercial adoption in markets where our blood safety products are approved for commercialization, including in the U.S., we will have difficulties achieving profitability.

The INTERCEPT Blood System for red blood cells, or the red blood cell system, is currently in development. In the U.S., we successfully completed a Phase 2 recovery and lifespan study in 2014. We successfully completed our European Phase 3 clinical trial of our red blood cell system for acute anemia patients, and in January 2018, we reported that the primary efficacy and safety endpoints were met in our European Phase 3 clinical trial for chronic anemia patients. Based on the results of these Phase 3 trials, we plan to file for CE mark approval of the red blood cell system in the European Union in the second half of 2018.

In order to successfully 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.

We were incorporated in California in 1991 and reincorporated in Delaware in 1996. Our wholly-owned subsidiary, Cerus Europe B.V., was formed in the Netherlands in 2006. Information regarding our revenue, net loss, and total assets for the last three fiscal years can be found in the consolidated financial statements and related notes found

elsewhere in this Annual Report on Form 10-K.

Product Development

Background

The INTERCEPT Blood System is designed to broadly target and inactivate blood-borne pathogens, such as viruses (for example, HIV, West Nile, SARS, hepatitis B and C), bacteria and parasites, as well as potentially harmful white blood cells, while preserving the therapeutic properties of platelet, plasma and red blood cell transfusion products. The INTERCEPT Blood System has been shown to inactivate a broad array of pathogens and has the potential to reduce the risk of transfusion related transmission of pathogens for which testing is not completely effective, is not available or is not performed. We believe that the INTERCEPT Blood System also has the potential to inactivate most new pathogens before they are identified and before tests are developed and adopted commercially to detect their presence in donated blood.

Products, Product Candidates and Development Activities

The following table identifies our products, product candidates and product development activities and their current status:

Product or Product Candidate Under Development	Product or Development Status
INTERCEPT Blood System—Platelets	•Commercialized in the U.S. and a number of countries in Europe, the CIS, the Middle East, and selected countries in other regions around the world
	•U.S. post-approval haemovigilance study enrolling patients
	•U.S. post-approval recovery study of platelets treated with the INTERCEPT Blood System, currently in discussion with FDA
INTERCEPT Blood System—Plasma	•Commercialized in the U.S. and a number of countries in Europe, the CIS, the Middle East, and selected countries in other regions around the world
INTERCEPT Blood System—Red Blood Cells	•Phase 1 clinical trial completed in 2010
	•U.S. Phase 2 recovery and lifespan study completed in 2014
	•U.S. Phase 3 clinical trial, known as the ReDeS study, enrolling patients
	•U.S. Phase 3 acute anemia clinical trial, known as the ReCePI study, planned to be initiated
	•Additional U.S. studies also planned
	•European Phase 3 acute anemia clinical trial completed in 2014; European Phase 3 chronic anemia clinical trial completed in 2017
	•European CE mark submission planned in second half of 2018

INTERCEPT Blood System for Platelets and Plasma

The platelet system and plasma system are designed to inactivate blood-borne pathogens in platelets and plasma donated for transfusion. Both systems received CE mark approval in Europe and are currently marketed and sold in a number of countries around the world including the U.S., Europe, the CIS, the Middle East and selected countries in other regions of the world. Separate approvals for use of INTERCEPT-treated platelet and plasma products have been obtained in France and Switzerland. In Germany and Austria, where approvals must be obtained by individual blood centers for use of INTERCEPT-treated platelets and plasma, several centers have obtained such approvals for use of INTERCEPT-treated platelets and one center has obtained such approval for use of INTERCEPT-treated plasma. Many countries outside of Europe accept the CE mark and have varying additional administrative or regulatory processes that must be completed before the platelet system or plasma system can be made commercially available. In general, these processes do not require additional clinical trials. Regardless, some potential customers may desire to conduct their own clinical studies before adopting the platelet system or plasma system.

The FDA has approved the platelet system for ex vivo preparation of pathogen-reduced apheresis platelet components collected and stored in 100% plasma or InterSol in order to reduce the risk of transfusion-transmitted infection, or TTI, including sepsis, and 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 two post-approval studies - a haemovigilance study to evaluate the incidence of acute lung injury following transfusion of INTERCEPT treated platelets; and a recovery study of platelets treated with the platelet system that is currently in discussion with FDA. The first patient enrolled in that study in December 2015. The FDA has also 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.

Although we received FDA approval of our platelet and plasma systems in December 2014, our commercial efforts in 2018 will continue to be largely focused on implementing INTERCEPT to customers with whom we have previously signed agreements and continuing to develop awareness of INTERCEPT's product profile relative to other platelet and plasma products, including conventional, un-treated components. Prior to broader customer adoption in the U.S., 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. Several blood centers have submitted for their interstate licenses. Until those licenses are obtained, U.S. blood centers will be limited to sales to hospital customers within the state in which the INTERCEPT-treated platelets or plasma are processed. Further, the hospital customers of these blood centers will need to go through the administrative process of generating internal tracking codes to integrate INTERCEPT-treated products into their inventories, which may further delay customer adoption in the U.S. In addition, in order to address the entire market in the U.S., we will need to develop, test and obtain FDA approval of additional configurations of the platelet system. For example, in the U.S., we understand a significant number of platelet concentrates are derived from larger volumes collected from apheresis donors split into three therapeutic transfusable doses, or triple doses. Future configurations of the platelet system will be

needed to treat platelet donations with such processing parameters. In addition, we estimate that the majority of platelets used in the U.S. 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 triple dose collections and random donor platelets, we will need to perform additional product development and testing, including additional clinical trials, and will need to obtain FDA approval of a premarket application, or PMA, supplement. In addition, we plan to perform in vitro studies and seek a PMA supplement to use our plasma system to produce extended-storage cryoprecipitate and possibility other plasma derived biological products. These development activities will be costly 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 our products.

INTERCEPT Blood System for Red Blood Cells

The red blood cell system is designed to inactivate blood-borne pathogens in red blood cells donated for transfusion. We completed a series of in vitro and in vivo tests with the red blood cell system, including successfully completing recovery and survival studies measuring red cell recovery twenty-four hours after transfusion. Previously, we terminated Phase 3 clinical trials for acute and chronic anemia using a prior generation of the red blood cell system due to the detection of antibody reactivity to INTERCEPT-treated red blood cells in two patients in the trial for chronic anemia. The antibody eventually cleared and the patients had no adverse health consequences. After unblinding the data from the original Phase 3 clinical trials, we found that we had met the primary endpoint in the clinical trial for acute anemia. We evaluated the antibodies detected and developed process changes to diminish the likelihood of antibody reactivity in red blood cells treated with our modified process. There has been no antibody reactivity associated with INTERCEPT-treated red blood cells in any of the subsequent configurations, studies or trials we have completed since modifying the process used in the red blood cell system. Accordingly, we received authorization from European regulators to proceed with Phase 3 clinical trials for acute anemia and, separately, chronic anemia. We announced the successful completion of our Phase 3 clinical trial of the red blood cell system for acute anemia patients in January 2015 and for chronic anemia patients in January 2018, based on the results of those trials plan to submit for CE mark approval in the European Union in the second half of 2018. Although we plan to complete additional development activities to support an anticipated CE mark submission for the red blood cell system, such development activities could prolong development of our red blood cell system, and we do not expect to receive any regulatory approvals of our red blood cell system in the next twelve months, if ever.

In January 2015, we announced that the completed European Phase 3 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 3 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. 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. Additionally, in January 2018, we announced that the European Phase 3 clinical trial of chronic anemia evaluating INTERCEPT-treated red blood cells in thalassemia patients met its primary efficacy and safety endpoints. Based on the results of these trials, we plan to submit for CE mark approval in the European Union in the second half of 2018. We understand that while the data generated from our European Phase 3 clinical trials may be sufficient to receive CE mark approval, we may need to generate additional safety data from commercial use in

order to achieve broad market acceptance. As part of our development and chemistry, manufacturing and control, or CMC, activities, we will need to successfully complete validation studies on sufficient quantities of the final red blood cell system prior to receiving any regulatory approvals in Europe.

In the U.S., we successfully completed a Phase 2 recovery and lifespan study in 2014. In 2017, we initiated a Phase 3 clinical double-blind study, known as the ReDeS study, to assess the safety and efficacy of INTERCEPT-treated RBCs when compared to conventional RBCs in regions impacted by the Zika virus epidemic. The ReDeS study is expected to be expanded to other areas at risk for transfusion-transmitted infections due to the Zika virus, such as Florida. The first stage of the trial is a double-blind, controlled, parallel group trial where 600 adult patients will be randomized to receive up to 28 days of transfusion support with INTERCEPT-treated RBCs or conventional RBCs, with a primary endpoint of hemoglobin increment following transfusion. In a second optional stage, up to 20,000 patients would receive RBC transfusion support with up to 50,000 RBC units in an open-label, single-arm treatment use study. Also in 2017, we received investigational device exemption, or IDE, approval from the FDA to initiate a Phase 3 clinical trial, known as the ReCePI study, that is designed to evaluate the efficacy and safety of INTERCEPT-treated RBCs in patients requiring transfusion for acute blood loss during surgery. A total of 600 patients are expected to be enrolled in the ReCePI study in up to 20 participating sites in the U.S. Patients will be randomized on a 1:1 basis with patients in the treatment arm transfused with red

blood cells treated with INTERCEPT and patients in the control arm transfused with conventional RBCs. The primary efficacy endpoint is the proportion of patients experiencing acute kidney injury as an assessment of RBC efficacy in providing tissue oxygenation, measured as an increase in serum creatinine compared to pre-surgery, baseline levels within 48 hours after the surgery. The ReDeS and ReCePI studies are being funded as part of our agreement with BARDA. In addition to successfully conducting and completing the ReDeS and ReCePI studies, we will need to successfully conduct and complete an additional Phase 3 clinical trial for chronic anemia in the U.S. before the FDA will consider our red blood cell product for approval. We also understand that one or more additional in vitro studies will be required to be successfully completed and submitted to the FDA prior to any initiation of an additional Phase 3 clinical trial for chronic anemia. There can be no assurance that we will be able to successfully satisfy any such in vitro studies, nor can there be any assurance that we and the FDA will agree to any trial protocol we propose or that we will otherwise obtain FDA clearance to initiate an additional Phase 3 clinical trial for chronic anemia. We also understand that the FDA will require us to place a clinical hold on any clinical trial if we see a hemolytic reaction associated with treatment with emergent antibodies with amustaline specificity in patients receiving INTERCEPT-treated red blood cells in that trial. Should we experience such an incident, we will need to investigate the underlying cause of the hemolytic reaction, which in many patient populations may be difficult for us to assess imputability which may lead to a complete halt of the clinical trial, may irreparably harm our red blood cell product's reputation and we may be forced to suspend or terminate development activities related to the red blood cell system in the U.S., which would have a material adverse effect on our business and business prospects. We also must complete other prerequisites, including developing and validating an analytical method to test GMP manufactured compounds used in the red blood cell system to show that they consistently meet specifications and additional CMC activities in order to proceed with our planned CE mark submission.

Additional information regarding our interactions with the FDA, and potential future clinical development of the INTERCEPT Blood System in Europe and in the U.S. can be found under "Item 1A—Risk Factors" of this Annual Report on Form 10-K, under the risk factor titled "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."

Information regarding our revenues for the years ended December 31, 2017, 2016 and 2015 can be found in "Item 7—Management's Discussion and Analysis of Financial Condition and Results of Operations", and "Financial Statement Schedules—Financial Statements" of this Annual Report on Form 10-K.

INTERCEPT Blood System Technology

Both our platelet system and plasma system employ the same technology. Platelet or plasma components collected from blood donors are transferred into plastic INTERCEPT disposable kits and are mixed with our proprietary compound, amotosalen, a small molecule compound that has an affinity for nucleic acid.

The disposable kits are then placed in an illumination device, or illuminator, where the mixture is exposed to ultra-violet A, or UVA, light. If pathogens such as viruses, bacteria or parasites, as well as leukocytes, or white cells, are present in the platelet or plasma components, the energy from the UVA light causes the amotosalen to bond with the nucleic acid. Since platelets and plasma do not rely on nucleic acid for therapeutic efficacy, the INTERCEPT Blood System is designed to preserve the therapeutic function of the platelet and plasma components when used in human transfusions.

The ability of amotosalen to form both cross-links between strands of nucleic acid and links to single nucleic acid strands results in a strong chemical bond between the amotosalen and the nucleic acid of the pathogens. The presence

of these bonds is designed to prevent replication of the nucleic acid within pathogens, effectively inactivating the pathogens. A high level of inactivation has been demonstrated in a broad range of pathogens studied by us and others in laboratory testing. For instance, INTERCEPT has demonstrated inactivation of a number of single stranded nucleic acid-based viruses such as HIV, hepatitis B, hepatitis C (using a model virus), West Nile, chikungunya and certain influenza viruses.

Following the inactivation process, residual amotosalen and by-products are reduced by more than 99% through use of a compound adsorption device, which is an integrated component of the disposable kit. We have performed extensive toxicology testing on the residual amotosalen and its by-products and good safety margins have been demonstrated. Any remaining amotosalen which may be transfused, should any exist, is rapidly excreted by humans.

Leukocytes, also known as white blood cells, are typically present in platelet and plasma components collected for transfusion and can cause adverse transfusion reactions as well as an often fatal disease called graft-versus host disease. Leukocytes, like pathogens, rely on nucleic acid for replication and cellular function. The INTERCEPT Blood System, with its combination of the amotosalen and UVA light, is designed to inactivate leukocytes in the same manner it inactivates pathogens.

Like the platelet and plasma systems, the red blood cell system is designed to prevent pathogen replication by using a small molecule additive compound to form bonds with nucleic acid in pathogens that may be present in donated red blood cell collections. The red blood cell system is designed to preserve the therapeutic qualities of the red blood cells, which, like platelets and plasma, do not rely on nucleic acid for their therapeutic efficacy. The red blood cell system uses another of our proprietary compounds, amustaline. Unlike the platelet and plasma systems, the chemical bonds from amustaline are not triggered by UVA light, but instead, by the pH level of the red blood cell components. After mixture with the red blood cell components in plastic disposable kits and resulting nucleic-acid bonding, amustaline is designed to rapidly break down into a form that is no longer chemically reactive with nucleic acid. As with the platelet and plasma systems, a high level of inactivation in a broad range of pathogens has been demonstrated with the red blood cell system in the clinical setting. We plan on conducting additional pathogen-inactivation studies of the red blood cell system, broadening our understanding of the pathogens the system may be able to inactivate.

By treating blood components with INTERCEPT within a day of collection, the inactivation of bacteria prevents bacterial growth that could create increased risk of inflammatory response or dangerous levels of endotoxins. Extensive clinical testing has been done on platelet and plasma products treated with the INTERCEPT Blood System, as well as post-marketing haemovigilance studies of the treated blood products in routine use.

We believe that, due to their mechanisms of action, the platelet system, plasma system, and red blood cell system will potentially inactivate blood-borne pathogens that have not yet been tested with our systems, including emerging and future threats to the blood supply. We do not claim, however, that our INTERCEPT Blood System will inactivate all pathogens, including prions, and our inactivation claims are limited to those contained in our product specifications. There can also be no assurance that INTERCEPT will inactivate even those pathogens where claims exist, in every instance or under every processing condition.

Manufacturing and Supply

We have used, and intend to continue to use, third parties to manufacture and supply the devices, disposable kits and inactivation compounds that make up the INTERCEPT Blood System for use in clinical trials and for commercialization. We rely solely on Fresenius Kabi AG, or Fresenius, for the manufacture of disposable kits for the platelet and plasma systems and rely on other contract manufacturers for the production of our inactivation compounds, compound adsorption components of the disposable kits and illuminators used in the INTERCEPT Blood System. We currently do not have alternate manufacturers for the components in our products or product candidates beyond those that we currently rely on, but we are currently in the process of identifying potential alternate manufacturers. Under our amended and restated manufacturing and supply agreement we entered into with Fresenius in October 2015, Fresenius is obligated to sell, and we are obligated to purchase, finished disposable kits for the platelet, plasma and red blood cell systems from Fresenius for both clinical and commercial use. The agreement permits us to purchase platelet, plasma and red blood cell systems from third parties to the extent necessary to maintain supply qualifications with such third parties or where local or regional manufacturing is needed to obtain product registrations or sales. Pricing terms are initially fixed and decline at specified annual production levels. The agreement also contemplates that we and Fresenius will jointly fund and collaborate on certain specified initiatives focused on new product development or enhancements, potential implementation of automation, installation of new equipment, capacity expansion and cost reduction. We are required to make contributions toward those joint collaboration projects in certain specified installment amounts. In addition, we will make a one-time, lump sum payment of €5.5 million, or the Milestone Payment, to Fresenius on December 31 of the year in which certain production volumes are achieved, or December 31, 2022, whichever comes first. The term of the agreement with Fresenius extends through July 1, 2025, and will automatically renew for successive additional two year periods unless terminated by either party upon two years' prior written notice, in the case of the initial term, or one year prior written notice, in the case of any renewal term. We and Fresenius each have normal and customary termination rights, including termination for material breach.

Components of compound adsorption devices used in platelet and plasma disposable kits are manufactured by Porex Corporation, or Porex. In April 2017, we entered into an amended and restated manufacturing and supply agreement with Porex for the continued supply of the compound adsorption devices. Porex is our sole supplier for certain components of and manufacturing of the compound adsorption devices. Under the amended and restated Porex agreement, we are no longer subject to a minimum annual purchase requirement; however, Porex has the right to terminate the agreement, upon twelve months' prior written notice, if annual production falls below a mutually agreed threshold. If not sooner terminated, the amended and restated Porex agreement expires on December 31, 2019. Although we are actively seeking to develop alternative manufacturers and components, commercially viable alternatives are likely several years away.

We also have an amended and restated supply agreement with Brotech Corporation d/b/a Purolite Company, or Purolite, for the supply of raw materials used to make the compound adsorption devices. 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.

Pursuant to a contract that we and Nova Biomedical Corporation, or Nova, entered into in September 2008, Nova is manufacturing illuminators for us. The term of our agreement with Nova automatically renews for successive one year terms each September in the event neither party delivers written notice of its intent to terminate twelve months prior to each September renewal date. We do not currently have plans to terminate our agreement with Nova and believe that Nova currently plans to continue operating under the agreement for the foreseeable future.

We operate with an amended manufacturing and supply agreement with Ash Stevens, Inc., or Ash Stevens, for the synthesis of amotosalen, the inactivation compound used in our platelet and plasma systems. Under this amended agreement, we are not subject to minimum annual purchase requirements. We have incurred these maintenance fees in the past. The term of the amended manufacturing and supply agreement with Ash Stevens automatically extended at the end of 2017 and now continues until December 31, 2019, and will continue to automatically renew for successive two year periods, unless terminated by either party upon providing at least one year prior written notice, in our case, or at least two years prior written notice, in the case of Ash Stevens. Neither party has delivered notice of its intent to terminate the agreement.

We and our contract manufacturers, including Fresenius and Nova, purchase certain raw materials for our disposable kits, inactivation compounds, materials and parts associated with compound adsorption devices and UVA illuminators from a limited number of suppliers. Some of those raw material suppliers require minimum annual purchase amounts. While we believe that there are alternative sources of supply for such materials, parts and devices, we have not validated or qualified any alternate manufacturers. As such, establishing additional or replacement suppliers for any of the raw materials, parts and devices, if required, will likely not be accomplished quickly and could involve significant additional costs and potential regulatory reviews. For example, we understand that certain plastics used to make INTERCEPT disposable kits are no longer available. As a result, we and our manufacturers have identified alternate plastics for the manufacture of our disposable kits, and in January 2018, we received CE Mark approval for the use of the alternate plastics for the manufacture of the disposable kits for the platelet system. However, we will need to qualify and validate those alternate plastics in the U.S. and for our plasma product in Europe before we can utilize them in commercial manufacturing. Any acceleration of demand in the U.S. or increased demand for our plasma products prior to receiving approval may result in a run-out of the obsolete plastic and in-turn, an inability for us to meet that potential increased demand.

Marketing, Sales and Distribution

The market for the INTERCEPT Blood System, including the U.S. market, is dominated by a relatively 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. The American Red Cross represents the largest single portion of the blood collection market in the U.S. While we believe adoption of the INTERCEPT Blood System will afford the American Red Cross with many benefits, we cannot guarantee the volume or timing of commercial purchases that the American Red Cross may make, if any, under our multi-year commercial agreement that we and the American Red Cross entered into in February 2016. Furthermore, the U.S. blood banking market is undergoing consolidation which may continue and further concentrate the potential customer base. 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. The largest European markets for our products are in Germany, France, and England.

In Germany, decisions on product adoption are made on a regional or blood center-by-blood center basis. While obtaining CE marks allow us to sell the platelet and plasma systems to blood centers in Germany, blood centers in Germany must still obtain both local manufacturing approval and national marketing authorization from the Paul Ehrlich Institute, or PEI, a German governmental regulatory body overseeing the marketing authorization of certain

medical products, before being allowed to sell platelet and plasma components treated with the INTERCEPT Blood System to transfusing hospitals and physicians. To date, several blood centers in Germany have received such requisite approvals and authorizations for the platelet system and one blood center has received such approval for the plasma system. Given the competitive nature of the German blood banking market, pricing for blood components is relatively low compared to other markets. This dynamic, in turn, requires us to focus our marketing efforts on the potential economic and logistical benefits of using INTERCEPT compared to conventional blood components as well as the potential safety benefits of INTERCEPT-treated blood components. Following the inclusion of pathogen-inactivated platelets for national reimbursement by the German Institute for the Hospital Remuneration System as of January 1, 2018, German customers who do not currently have an approved marketing authorization application, or MAA, will first need to obtain one before using the INTERCEPT Blood System. The review period for a new MAA can be up to twelve months following submission and we cannot assure you that any of the potential German customers submitting a new MAA will obtain it. Without broad approvals of MAA applications obtained by potential German customers, our ability to successfully commercialize INTERCEPT in Germany will be negatively impacted, which may adversely affect our results of operations and financial results.

In France, broad product adoption is dependent on a central decision by the Établissement Français du Sang, or EFS, a public organization responsible for all collection, testing preparation and distribution of blood products in France. In July 2017, we entered into new agreements with the EFS to supply illuminators, platelet and plasma disposable kits and while no commitment has been made by EFS to adopt the platelet system across France, EFS has begun to standardize production of its platelets using the INTERCEPT Blood System. National deployment of the INTERCEPT Blood System for platelets throughout France will require a coordinated and highly managed roll-out and any setback or failure could negatively impact the timing and success of adoption. We cannot provide any assurance that national deployment of INTERCEPT in France would be sustainable, should it occur, or that we will be able to secure any subsequent contracts with EFS or that the terms, including the pricing or committed volumes, if any, of any future contract will be equivalent or superior to the terms under our current contract. If we are unable to successfully support EFS' national adoption of the INTERCEPT Blood System for platelets or the final commercial terms of any subsequent contract are less favorable than the terms under our existing contract, our financial results may be adversely impacted.

In England, decisions on product adoption are centralized in the National Blood Service, or NHSBT, which collects, tests, processes and supplies blood products to hospitals in England and North Wales. The National Blood Service has implemented and used bacterial detection for platelets for the past several years instead of pathogen inactivation. More recently, the National Blood Service has implemented the INTERCEPT Blood System for platelets in one of its centers for validation of the technology. In July 2015, the National Blood Service issued a public tender to solicit bids for both pathogen inactivation and bacterial detection, to which we responded. In December 2015, the National Blood Service announced that it had terminated the potential tender for pathogen inactivation. We do not know when, if ever, the NHBST will consider adoption of a product for pathogen reduction, including INTERCEPT.

In Japan, the Japanese Red Cross controls a significant majority of blood centers and exerts a high degree of influence on the adoption and use of blood safety measures. 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 complete certain product configuration changes, which are currently under development but may not be economically or technologically feasible for us to complete.

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 party payors. In many jurisdictions, due to the structure of the blood products industry, we have little control over budget and reimbursement discussions, which generally occur between blood centers, healthcare facilities such as hospitals, and national or regional ministries of health and private payors. Even if a particular blood center is prepared to adopt the INTERCEPT Blood System, its hospital customers may not accept or may not have the budget to purchase INTERCEPT-treated blood products. Since blood centers would likely not eliminate the practice of screening donors or testing blood for some pathogens prior to transfusion, even after implementing our products, some blood centers may not be able to identify enough cost offsets or hospital pricing increases to afford to purchase our products. Budgetary concerns may be further exacerbated by economic legislation in certain countries and by proposals by legislators at both the U.S. federal and state levels, regulators, healthcare facilities and third party payors to keep healthcare costs down, which may limit the adoption of new technologies, including our products. In some jurisdictions, commercial use of our products may not be covered by governmental or commercial third party payors for health care services and may never be covered. In the U.S., the costs and expenses incurred by the blood center related to donor blood are typically included in the price that the blood center charges a hospital for a unit of blood. The Centers for Medicare & Medicaid Services published a separate reimbursement code and premium pricing for pathogen-reduced platelet and plasma components under the Healthcare Common Procedure Coding System, or HCPCS. The reimbursement pricing for our products under HCPCS will be driven by actual costs charged to hospitals

for INTERCEPT-treated components. Even after blood components treated with our products are approved for reimbursement by governmental or commercial third party payors, including under HCPCS codes, the costs and expenses related to use of the INTERCEPT Blood System will not be directly reimbursed, but instead may be incorporated within the reimbursement structure for medical procedures and/or products at the site of patient care. If the costs to the hospital for INTERCEPT-processed blood products cannot be easily, readily, or fully incorporated into the existing reimbursement structure, hospital billing and/or reimbursement for these products could be impacted, thus negatively impacting hospitals' acceptance and uptake of our products.

We maintain a wholly-owned subsidiary, Cerus Europe B.V., headquartered in the Netherlands, which focuses its efforts on marketing and selling the INTERCEPT Blood System in a number of countries in Europe, the CIS, the Middle East and selected countries in other regions around the world. We have a small scientific affairs group in the U.S. and the Netherlands that supports our commercialization efforts as well as medical science liaisons, or MSLs, to help educate hospitals and physicians on our products, clinical trial history and publications. We have a small number of employees focused on servicing the markets in Asia-Pacific and Latin American regions and rely primarily on distributors to market and sell our products in those regions.

We have entered into distribution agreements, generally on a geographically exclusive basis, with distributors in countries where we have limited abilities to commercialize our products directly. In certain of these jurisdictions, we rely on these distributors to obtain any necessary in-country regulatory approvals, in addition to marketing and selling the INTERCEPT Blood System, providing customer and technical product support, maintaining inventories, and adhering to our quality system in all material respects, among other activities. Selected areas where we have entered into geographically exclusive distribution agreements include but are not limited to certain countries in the CIS, Italy, the Middle East, Latin America, South Africa and Southeast Asia, as well as the People's Republic of China. Our success in these regions is dependent on our ability to support our distributors and our distributor's ability to market and sell our products and to maintain and service customer accounts, including technical service. Our distribution agreements account for a significant amount of our revenues. As such, declining performance or the outright termination or loss of certain distributor relationships could harm our existing business, may impact our growth potential, and could result in higher operating costs for us. As our distributors play a critical role in our commercialization efforts, we evaluate their performance on an ongoing basis. As we continue to evaluate our distributors, we may take further actions in the future which may have an impact on our operating results. For instance, over the course of 2013 and 2014, we implemented several changes designed to improve market penetration in our distributor territories, including by adding additional sales, technical and marketing support, as well as by providing supplementary training to improve the effectiveness of distributor field personnel. In the past, we have transitioned certain territories to new distribution partners who we felt were capable of improved performance relative to their predecessors as well as transitioned some of these territories to a Cerus direct sales effort, which we believed would provide us with better visibility into and control of sales execution. As a result of these changes, we experienced a decrease in the volume of INTERCEPT disposable kit sales for the impacted territories as those distribution partners sold through their disposable kit inventory. In addition, the new distributors and our own direct sales force continue to require some time to develop the market with the same proficiency as previous distributors. We cannot provide assurance that they will be successful in achieving the same level of operations or proficiency as our previous distributors. We expect that it may take longer for us to be paid with some distributors or customers taking longer to pay invoices than the payment terms we have historically experienced.

Government Contract

Revenue from the cost reimbursement provisions under our government contract varies by year. A portion of our government contract revenue is subject to renegotiation of reimbursement rates or termination of the contract at the election of the U.S. government. In addition, U.S. government contracts typically contain unfavorable provisions and are subject to audit and modification by the government at its sole discretion. Generally, government contracts, including our agreement with BARDA, contain provisions permitting unilateral termination or modification, in whole or in part, at the U.S. government's convenience. See Note 2 in the Notes to Consolidated Financial Statements under "Item 15—Financial Statement Schedules—Financial Statements" of this Annual Report on Form 10-K for information on our government contract revenue and other financial information for the years ended December 31, 2017, 2016 and 2015. Further discussion of the factors impacting our government contracts revenue and the related impact on our ability to operate our business can be found under "Item 1A—Risk Factors" of this Annual Report on Form 10-K, under the risk factors titled "A significant portion of the funding for the development of the red blood cell system is expected to come from our BARDA agreement, and if BARDA were to eliminate, reduce or delay funding from our contract, this could have a significant, negative impact on our revenues and cash flows, and we may be forced to suspend or terminate our U.S. red blood cell development program or obtain alternative sources of funding" and "Unfavorable provisions in government contracts, including in our contract with BARDA, may harm our business, financial condition and operating results."

Competition

Our products face a wide variety of competition from entities competing directly with alternative pathogen reducing technologies for platelets and/or plasma, as well as from entities developing and selling diagnostic screening products to detect and prevent contaminated products from being transfused, and from process and procedural decisions involving blood banking operations including but not limited to shortened shelf-life of blood components. Many of our competitors have mature, well-established products or have other products which are sold to U.S. based blood centers and many have more commercial resources than we do. In addition, competitors may choose to seek a lower class of approval than our products, which may be easier and less costly for them to maintain and may be perceived as sufficient by the marketplace. We believe that the INTERCEPT Blood System has certain competitive advantages over competing blood-borne pathogen reduction methods that are either on the market or known to us to be in development. The INTERCEPT Blood System is designed for use in blood centers, which allows for integration with current blood collection, processing and storage procedures. Certain competing products currently on the market, such as solvent detergent-treated plasma, use centralized processing that takes blood products away from the blood center in order to be treated at a central facility before being shipped back out to the blood centers or hospitals for ultimate transfusion, which may result in higher costs.

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 Class II CE marks for such

system for both platelets and plasma. MacoPharma has received a CE mark for a UVC-based pathogen reduction product for platelets. MacoPharma currently has a Phase 3 clinical trial underway in Germany to generate additional data for expanded approvals. We understand that Terumo BCT also developed a pathogen reduction system for whole blood and has recently completed a clinical trial of its whole blood system in Ghana, receiving a Class II CE mark. Terumo BCT's products may offer certain competitive advantages over our INTERCEPT Blood System.

In the U.S., INTERCEPT-treated plasma faces competition from Octapharma AG, which received FDA approval in January 2013 to sell treated fresh frozen plasma for certain indications which treated fresh frozen plasma is currently commercially available, as well as from diagnostic and testing companies currently approved for the detection of pathogens in donated blood products, including bacterial and viral pathogens. Our platelet product faces competition from a number of diagnostic and testing companies currently approved for the detection of pathogens including bacterial and viral pathogens in donated blood products and may face competition from other technologies if approved.

In Japan, we understand that Terumo BCT's platelet and plasma pathogen reduction product is currently being evaluated by the Japanese Red Cross. Terumo Corporation is a large Japan-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 need to either establish operations in Japan or partner with a local Japanese company.

We believe that the primary competitive factors in the market for pathogen reduction of blood products include the breadth and effectiveness of pathogen reduction processes, the amount of demonstrated reduction in transfusion related adverse events subsequent to adopting pathogen reduction technology, robustness of treated blood components upon transfusion, the scope and enforceability of patent or other proprietary rights, perceived product value relative to perceived risk, product supply, perceived ease of use, perception of safety, efficacy and economics of pathogen reduction systems, and marketing and sales capability. In addition, we believe the length of time required for products to be developed and to receive regulatory and, in some cases, reimbursement approval are also important competitive factors. We believe that the INTERCEPT Blood System will compete favorably with respect to these factors, although there can be no assurance that it will be able to do so. Our success will depend in part on our ability to convince prospective customers of the benefits of and need to adopt pathogen reduction technology and specifically our system relative to other technologies, our ability to obtain and retain regulatory approvals for our products, and our ability to continue supplying quality and effective products to our customers and prospective customers.

Further discussion of the major competitors to our blood product business can be found under "Item 1A—Risk Factors" of this Annual Report on Form 10-K, under the risk factor titled "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."

Patents, Licenses and Proprietary Rights

Our commercial success will depend in part on our ability to obtain patents, to protect trade secrets, to operate without infringing upon the proprietary rights of others and to prevent others from infringing on our proprietary rights. Our policy is to seek to protect our proprietary position by, among other methods, filing U.S. and foreign patent applications related to our proprietary technology, inventions and improvements that are important to the development of our business. As of December 31, 2017, we owned approximately 10 issued or allowed U.S. patents and approximately 96 issued or allowed foreign patents related to the INTERCEPT Blood System. Our patents expire at various dates between 2018 and 2031. Recent patent applications will, if granted, result in patents with later expiration

dates. In addition, we have a license from Fresenius to U.S. and foreign patents relating to the INTERCEPT Blood System, which expire at various dates between 2018 and 2024. Due to the complexity of our products, we believe it is the protection afforded to our products by the portfolio of intellectual property rights that best protect our proprietary system rather than any one particular patent or trade secret. Proprietary rights relating to our planned and potential products will be protected from unauthorized use by third parties only to the extent that they are covered by valid and enforceable patents or are effectively maintained as trade secrets. The laws of certain foreign countries do not protect our intellectual property rights to the same extent as do the laws of the U.S.

We are aware of a recently expired U.S. patent issued to a third-party that covers methods to remove psoralen compounds from blood products. We have reviewed the patent and believe there exist substantial questions concerning its validity. We cannot be certain, however, that a court would hold the patent to be invalid or not infringed by our platelet or plasma systems. In this regard, whether or not we have infringed this patent will not be known with certainty unless and until a court interprets the patent in the context of litigation. In the event that we are found to infringe any valid claim of this patent, we may, among other things, be required to pay damages. Further discussion of the factors impacting our intellectual property and the related impact on our ability to operate our

business can be found under “Item 1A—Risk Factors” of this Annual Report on Form 10-K, under the risk factor titled “We may not be able to protect our intellectual property or operate our business without infringing intellectual property rights of others.”

Seasonality

Our business is dependent on the marketing and commercialization of the INTERCEPT Blood System to customers such as blood banks, hospitals, distributors and other health care providers that have a need for a pathogen reduction system to treat blood products for transfusion. Since we have not experienced purchasing patterns from our customers based on seasonal trends, we do not expect seasonality to have a material effect on our business, although purchasing patterns and inventory levels can fluctuate.

Inventory Requirements and Product Return Rights

Our platelet and plasma disposable kits have received regulatory approval for shelf lives from 18 to 24 months. Illuminators and replacement parts do not have regulated expiration dates. We own work-in-process inventory for certain components of INTERCEPT disposable kits, finished INTERCEPT disposable kits, illuminators, and certain replacement parts for our illuminators. Our supply chain for certain of these components, held as work-in-process on our consolidated balance sheets, may potentially take over one year to complete production before being utilized in finished disposable kits. We maintain inventory based on our current sales projections, and at each reporting period, we evaluate whether our work-in-process inventory would be consumed for production of finished units in order to sell to existing and prospective customers within the next twelve-month period. It is not customary for our production cycle for inventory to exceed twelve months. Instead, we use our best judgment to factor in lead times for the production of our finished units to meet our current demands. If actual results differ from those estimates, work-in-process inventory could potentially accumulate for periods exceeding one year. Inventory is recorded at the lower of cost, determined on a first in, first out basis, or market value. We use significant judgment to analyze and determine if the composition of our inventory is obsolete, slow-moving, or unsalable and frequently review such determinations. We rely on our direct sales team and distributors to provide accurate forecasts of sales in their territory. If our forecasts or those of our distributors are inaccurate, we could face backlog situations or conversely, may produce and carry an abundance of inventory that would consume cash faster than we have currently planned. Generally, we write-down specifically identified unusable, obsolete, slow-moving, or known unsalable inventory that has no alternative use to net realizable value in the period that it is first recognized, by using a number of factors, including product expiration dates, open and unfulfilled orders, and sales forecasts. Any write-down of our inventory to net realizable value establishes a new cost basis and will be maintained even if certain circumstances suggest that the inventory is recoverable in subsequent periods.

We sell the INTERCEPT Blood System directly to blood banks, hospitals, universities, and government agencies, as well as to distributors in certain regions. Generally, our contracts with our customers do not provide for open return rights, except within a reasonable time after receipt of goods in the case of defective or non-conforming product.

Customers and Financial Information about Geographic Areas

Our customers are concentrated and consist of blood collection organizations, some of which are nationalized, public and private hospitals, and distributors. Distributors that purchase our products and sell to end-user customers comprise a significant amount of our existing sales. The loss of any one of our customers would have an adverse impact on our business. The following table illustrates concentration of sales over the past three years:

	Year Ended December 31,		
	2017	2016	2015
Etablissement Francais du Sang	22%	*	23%
Advanced Technology Company K.S.C.	*	12%	*

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

To date, we have not experienced collection difficulties from these customers. For additional details about these customers for the years ended December 31, 2017, 2016 and 2015, as well as information regarding our net revenues by geographical location and location of our long-lived assets, see Note 16 in the Notes to Consolidated Financial Statements under “Item 15—Financial Statement Schedules—Financial Statements” of this Annual Report on Form 10-K.

Research and Development Expenses

A significant portion of our operating expenses is related to research and development and we intend to maintain a strong commitment to our research and development efforts. We have incurred total research and development expenses of $33.7 million, $31.3 million and $25.6 million for the years ended December 31, 2017, 2016 and 2015, respectively. As we look ahead, we anticipate that the

regulatory submission processes related to planned PMA supplements for the platelet and plasma systems in the U.S. will require continued investment in research and development activities, as will our ongoing clinical, development and CMC work for our red blood cell system in Europe. In the U.S., we expect to incur increasing research and development expenses associated with pursuing licensure of the Red Blood System including the ReDeS study, the ReCePI study and an additional Phase 3 clinical trial for chronic anemia in the U.S., in vitro studies, and other activities to pursue FDA approval of our red blood cell system. To the extent available, many of the U.S. red blood cell activities may be reimbursed by BARDA, though no guarantee can be made that our progress will be satisfactory to BARDA or that funds will be available to either BARDA or us. In addition, we plan to continue spending on new product development and enhancements to our illumination device which may increase research and development expenses. See Note 2 in the Notes to Consolidated Financial Statements under “Financial Statement Schedules—Financial Statements” of this Annual Report on Form 10-K for costs and expenses related to research and development, and other financial information for the years ended December 31, 2017, 2016 and 2015.

Government Regulation

We and our products are comprehensively regulated in the U.S. by the FDA and by comparable governmental authorities in other jurisdictions.

Our European investigational plan has been based on the INTERCEPT Blood System being categorized as Class III drug/device combination under the Medical Device Directives, or the MDD, of the European Union.

The European Union requires that medical devices affix the CE mark, an international symbol of adherence to quality assurance standards and compliance with the MDD. We initially received the CE mark for our platelet system and separately for our plasma system in 2002 and 2006, respectively. We will need to obtain a CE mark extension in our name from European Union regulators for both our platelet and plasma systems every five years. The renewal of the approval for CE mark for the platelet system was received in May 2017 while the renewal of the approval for CE mark for the plasma system was received in September 2016. A separate CE mark certification must be received for the red blood cell system to be sold in the European Union and in other countries recognizing the CE mark. In addition, France, Switzerland, Germany, and Austria require separate approvals for INTERCEPT-treated blood products.

The FDA regulates drugs, medical devices and biologics under the Federal Food, Drug, and Cosmetic Act and other laws, including, in the case of biologics, the Public Health Service Act. These laws and implementing regulations govern, among other things, the development, testing, manufacturing, record keeping, storage, labeling, advertising, promotion and pre-market clearance or approval of products subject to regulation. The steps required before a medical device may be approved for marketing in the U.S. pursuant to a PMA include:

- preclinical laboratory and animal tests;
- submission to the FDA of an investigational device exemption for human clinical testing, which must become effective before human clinical trials may begin;
- appropriate tests to show the product’s safety;
- adequate and well-controlled human clinical trials to establish the product’s safety and efficacy for its intended indications;
- submission to the FDA of a PMA; and
- FDA review of the PMA in order to determine, among other things, whether the product is safe and effective for its intended uses.

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 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 plan to conduct development activities, clinical studies and in vitro studies for our platelet system to expand our label claims to include, among others, storage of INTERCEPT-treated platelets for up to seven days rather than five days, random donor platelets and a new processing set for triple dose collections. In addition, we plan to perform in vitro studies and seek a PMA supplement to use our plasma system to produce extended-storage cryoprecipitate and possibility other plasma derived biological products.

As a condition to the FDA approval of the platelet system, we are required to conduct two post-approval studies of the platelet system studies - a haemovigilance study to evaluate the incidence of acute lung injury following transfusion of INTERCEPT treated platelets; and a recovery study of platelets treated with the platelet system that is currently in discussion with FDA. 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. In addition, there is a risk that post-approval studies will show results inconsistent with our previous studies.

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 FDA approval of a new PMA or PMA supplement. However, certain changes to a PMA-approved device do not require submission and approval of a new PMA or PMA supplement and may only require notice to FDA in a PMA Annual Report. The FDA requires every supplier to make this determination in the first instance, but the FDA may review any supplier's decision. The FDA may not agree with our decisions regarding whether new clearances or approvals are necessary. Our products could be subject to recall if the FDA determines, for any reason, that our products are not safe or effective or that appropriate regulatory submissions were not made. If new regulatory approvals are required, this could delay or preclude our ability to market the modified system. For example, due to the obsolescence of certain parts, we redesigned the illuminator used in the platelet and plasma systems. We understand that certain plastics used to make INTERCEPT disposable kits are no longer available. As a result, we and our manufacturers have identified alternate plastics and we have received CE Mark approval for our platelet product using the alternate plastics but will need to qualify and validate those plastics in the U.S. and for our plasma product in Europe before we can utilize them in commercial manufacturing. We are seeking FDA approval of the redesigned illuminator and the same new plastics for the platelet and plasma disposable kits that have received CE mark approval for Europe. We will need obtain FDA approval of the redesigned illuminator and plastics before they can be commercially sold in the U.S. Should we be unable to obtain approval, our operations and financial results will be adversely affected. In addition, in order to address the entire market in the U.S., we will need to develop and test additional configurations of the platelet system, including making the platelet system compatible with platelets triple dose collections and random donor platelets. Our failure to obtain FDA and foreign regulatory approvals of new platelet and plasma product configurations, the new plastics, or the redesigned illuminator could significantly limit revenues from sales of the platelet and plasma systems.

With FDA approval of our platelet and plasma systems, we are required to continue to comply with applicable FDA and other regulatory requirements related to, among other things, labeling, packaging, storage, advertising, promotion, record-keeping and reporting of safety and other information. In addition, our manufacturers and their facilities are required to comply with extensive FDA and foreign regulatory agency requirements, including, in the U.S., ensuring that quality control and manufacturing procedures conform to FDA-mandated current Good Manufacturing Practice, or cGMP, and Quality System Regulation, or 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 FDA or other foreign regulatory authorities may require us to recall products as a result of adverse events or production problems. Additionally, we are required 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, uses. If the FDA determines that our promotional materials or training constitute 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 authorities might take action if they consider our promotional or training materials to constitute promotion of an off-label use, or

a violation or any other federal or state law that applies to us, such as laws prohibiting false claims for reimbursement. Any enforcement action brought by a federal, state or foreign authority could result in significant civil, criminal and/or administrative penalties, damages, fines, disgorgement, exclusion from participation in government programs, such as Medicare and Medicaid, injunctions, private "qui tam" actions brought by individual whistleblowers in the name of the government, or refusal to allow us to enter into government contracts, contractual damages, administrative burdens, diminished profits and future earnings, additional reporting requirements and/or oversight if we become subject to a corporate integrity agreement or similar agreement. In addition, 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.

CBER is the center within the FDA principally responsible for regulating the INTERCEPT Blood System. In addition to regulating our blood safety products, CBER also regulates the blood collection centers and would regulate any blood products that they prepare using the INTERCEPT Blood System. Prior to broader customer adoption in the U.S., U.S.-based blood centers will need to complete their process validations and obtain site-specific licenses from CBER before making INTERCEPT-treated blood products available to their interstate hospital customers. Any significant product change that we make may require amendments or supplements to those

site-specific licenses that a U.S.-based blood center customer has obtained. Additionally, the hospital customers of any of our new blood center customers will need to go through the administrative process of generating internal tracking codes to integrate INTERCEPT-treated products into their inventories, which may result in further delay of customer adoption in the U.S. We plan to continue working with U.S.-based blood centers to support these activities as any delay in obtaining these licenses would adversely impact our ability to sell products in the U.S.

We believe that in deciding whether the INTERCEPT Blood System is safe and effective regulatory authorities have taken, and are expected to take, into account whether it adversely affects the therapeutic efficacy of blood components as compared to the therapeutic efficacy of blood components not treated with INTERCEPT. Data from human clinical studies must demonstrate the safety of treated blood components and their therapeutic comparability to untreated blood components. In addition, regulatory authorities will weigh INTERCEPT's safety, including potential toxicities of the inactivation compounds, and other risks against the benefits of using the system in a blood supply that has become safer. We have conducted many toxicology studies designed to demonstrate the INTERCEPT Blood System's safety. There can be no assurance that regulatory authorities will not require further toxicology or other studies of our products. Based on discussions with the FDA and European regulatory authorities, we believe that data only from laboratory and animal studies, not data from human clinical studies, will be required to demonstrate the system's efficacy in reducing pathogens. In light of these criteria, our clinical trial programs for the INTERCEPT Blood System consist of studies that differ from typical Phase 1, Phase 2 and Phase 3 clinical studies.

The preclinical and clinical studies of the INTERCEPT Blood System for red blood cells have been conducted using prototype system disposables and devices. In addition to the clinical trials, a number of manufacturing and validation activities must be completed before we could sell the red blood cell product.

Further discussion of our regulatory and clinical trial status can be found in "Item 1A—Risk Factors" of this Annual Report on Form 10-K, under the risk factor titled: "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."

U.S. Health Care Reimbursement and Reform

Our ability to commercialize our products successfully in the U.S. will depend in part on the extent to which appropriate reimbursement levels for the cost of the products and related treatment are obtained. The INTERCEPT Blood System is currently sold to U.S. based blood collection entities. Because our products are not directly reimbursable by governmental or commercial third party payors, adoption of the INTERCEPT Blood System will, in part, require coverage and adequate reimbursement to be provided for the procedures and treatments which utilize INTERCEPT-processed blood products. There is no uniform policy of coverage and reimbursement among third-party payors, as such, coverage and reimbursement can differ significantly from payor to payor. Even if favorable coverage and reimbursement status is attained for a particular procedure or treatment, less favorable coverage policies and reimbursement rates may be implemented in the future. If the costs to hospitals for INTERCEPT-processed blood products acquired from blood collection entities cannot be easily, readily, or fully incorporated into the hospital's existing coverage and reimbursement structure, adoption of our products may be negatively affected.

In the U.S., there have been a number of legislative and regulatory changes to the healthcare system that could affect our future results of operations. For example, the Patient Protection and Affordable Care Act, or the ACA, and ongoing cost saving efforts may have an impact on our ability to profitably commercialize the INTERCEPT Blood System in the U.S. and elsewhere. The ACA and other health care reform in the U.S. include provisions that place downward pressure on the pricing of medical products and also introduce new taxation on medical devices (the

effective date of which has been delayed), which could further impact our profit margins.

Since its enactment, there have been judicial and Congressional challenges to numerous provisions of the ACA. Since January 2017, President Trump has signed two Executive Orders designed to delay the implementation of certain provisions of the ACA or otherwise circumvent some of the requirements for health insurance mandated by the ACA. Concurrently, Congress has considered legislation that would repeal or repeal and replace all or part of the ACA. While Congress has not passed comprehensive repeal legislation, two bills affecting the implementation of certain taxes under the ACA have been signed into law. The Tax Cuts and Jobs Act of 2017 includes a provision repealing, effective January 1, 2019, the tax-based shared responsibility payment imposed by the ACA on certain individuals who fail to maintain qualifying health coverage for all or part of a year that is commonly referred to as the “individual mandate. Additionally, on January 22, 2018, President Trump signed a continuing resolution on appropriations for fiscal year 2018 that delayed the implementation of certain ACA-mandated fees. Congress also could consider additional legislation to replace or replace elements of the ACA. Policy changes, including potential modification or repeal of all or parts of the ACA or the implementation of new health care legislation could result in significant changes to the health care system.

Further discussion of the impact of health care reform and laws governing our business practices on our business can be found in “Item 1A—Risk Factors” of this Annual Report on Form 10-K, under the risk factors titled “Legislative, regulatory, or other 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” and “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.”

Employees

As of December 31, 2017, we had 215 employees, 83 of whom were engaged in research and development and 132 in selling, general and administrative activities. Of the 132 employees engaged in selling, general, and administrative activities, 38 were employed by our European subsidiary, Cerus Europe B.V. None of our employees are covered by collective bargaining agreements, and we believe that our relationship with our employees is good.

Available Information

We maintain a website at www.cerus.com; however, information found on our website is not incorporated by reference into this report. We make available free of charge on or through our website our annual report on Form 10-K, quarterly reports on Form 10-Q, current reports on Form 8-K and amendments to those reports filed or furnished pursuant to Section 13(a) or 15(d) of the Securities Exchange Act of 1934, as amended, or Exchange Act, as soon as reasonably practicable after we electronically file such material with, or furnish it to, the Securities Exchange Commission.

Financial Information

Our financial information including our consolidated balance sheets, consolidated statements of operations, consolidated statements of comprehensive loss, consolidated statements of stockholders’ equity, consolidated statements of cash flows, and the related footnotes thereto, can be found under “Financial Statement Schedules” in Part IV of this Annual Report on Form 10-K.

Item 1A. Risk Factors

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

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

We have invested a significant portion of our efforts and financial resources on the development of the INTERCEPT Blood System for platelets and plasma for the U.S. market. As a result, our business is substantially dependent on our ability to successfully commercialize the INTERCEPT Blood System in the U.S. in a timely manner. In December 2014, we received U.S. regulatory approval of the INTERCEPT Blood System for platelets and plasma, with certain restrictions regarding usage and although the INTERCEPT Blood System is now commercially available in the U.S., we have no prior experience commercializing any products in the U.S. and we may be unable to commercialize the INTERCEPT Blood System in the U.S. successfully or in a timely manner, or at all. The broad successful commercial adoption of any product, particularly involving novel technologies, is often dependent upon the seller earning a level of trust from and familiarity with customers, which can take time to develop. In addition, although we received FDA approval of our platelet and plasma systems in December 2014, our commercial efforts in 2018 will continue to be largely focused on implementing INTERCEPT to customers with whom we have previously signed agreements and continuing to develop awareness of INTERCEPT's product profile relative to other platelet and plasma products, including conventional, un-treated components. Significant product revenue from customers in the U.S. may not occur, if at all, until we have been able to successfully implement the platelet and plasma systems and demonstrate that they are economical, safe and efficacious for potential customers. Similar to our experience in foreign jurisdictions, some potential customers in the U.S. have chosen to first validate our technology or conduct other pre-adoption activities prior to purchasing or deciding whether to adopt the INTERCEPT Blood System for commercial use, which may never occur. In addition, potential customers and certain existing customers must obtain site-specific licenses from the Center for Biologics Evaluation and Research, or CBER, prior to engaging in interstate transport of blood components processed using the INTERCEPT Blood System, which could significantly delay or preclude our ability to successfully commercialize the INTERCEPT Blood System to those customers for the portion of their business involved in interstate commerce. In addition, significant changes to our product or the way in which our product is used may require that those customers file supplements or amendments to their site-specific licenses from CBER to continue to sell blood components processed using the INTERCEPT Blood System. Until those licenses and any required supplements are obtained, U.S. blood centers will be limited to sales to hospital customers within the state in which the INTERCEPT-treated platelets or plasma are processed. Further, the hospital customers of any of our new blood center customers will need to go through the administrative process of generating internal tracking codes to integrate INTERCEPT-treated products into their inventories, which may further delay customer adoption in the U.S. The availability of platelets in the U.S. is currently constrained. Should U.S. blood centers prioritize obtaining and selling conventional, untreated platelet components over INTERCEPT-treated components, we may not achieve widespread market adoption. If we are not successful in achieving market adoption of the INTERCEPT Blood System in the U.S., we may never generate substantial product revenue, and our business, financial condition, results of operations and growth prospects would be materially and adversely affected.

Our ability to successfully commercialize the INTERCEPT Blood System for platelets and plasma in the U.S. will depend on our ability to:

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

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

- the highly concentrated U.S. blood collection market that is dominated by a small number of blood collection organizations;
- availability of donors;
- regulatory and licensing requirements, including the CBER licensing process that U.S.-based blood centers are required to follow in order to obtain and maintain the required site-specific licenses to engage in interstate transport of blood components processed using the INTERCEPT Blood System;
- changed or increased regulatory restrictions or requirements;
- the amount available for reimbursement pursuant to codes we have obtained under the Healthcare Common Procedure Coding System, or HCPCS, and pricing for outpatient use of INTERCEPT-treated blood components;
- any supply or manufacturing problems or delays arising with any of our suppliers, many of whom are our sole suppliers for the particular product or component they manufacture, 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;
- successful customer transition to the disposable kits manufactured with the alternate plastics, once approved by FDA;
- dependency upon any third party manufacturer that supplies products required by blood centers to process and store blood components consistent with our approved specifications and claims, including but not limited to, apheresis collection devices, disposable blood bags and reagents, and PAS;
- changes in healthcare laws and policy, including changes in requirements for blood product coverage by U.S. federal healthcare programs; and
- acceptance of the INTERCEPT Blood System as safe, effective and economical from the broad constituencies involved in the healthcare system.

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

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

The INTERCEPT Blood System may not achieve broad market adoption.

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

The use of the platelet system results in some processing loss of platelets. If the loss of platelets leads to increased costs, or the perception of increased costs for our customers, or 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. Additionally existing customers may not believe they can justify any perceived operational change or inefficiency by itself or in conjunction with a blood component availability shortage. Certain customers that attempt to optimize collection practices in order to produce the highest volume of transfusable units with those collections may experience a less optimized yield as result of adopting INTERCEPT over conventional platelet products. Certain studies have indicated that transfusion of conventionally prepared platelets may yield higher post-transfusion platelet counts (according to a measurement called "corrected count increment") and may be more effective than transfusion of INTERCEPT-treated platelets. Although certain other studies demonstrate that INTERCEPT-treated platelets retain therapeutic function comparable to conventional platelets, prospective

customers may choose not to adopt our platelet system due to considerations relating to corrected count increment, efficacy or other factors.

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

In 2015, we conducted a Phase 1 clinical study protocol under an IDE to treat plasma derived from convalesced patients that were previously infected with the Ebola virus and had 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 the IDE was limited to pathogen reduction claims that relied on existing clinical data that we had regarding reduction of certain pathogens in donated plasma. Accordingly, the study was not designed to generate any data on the efficacy of INTERCEPT to inactivate the Ebola virus, and we still do not have any clinical or commercial data on the efficacy of INTERCEPT to inactivate the Ebola virus, and therefore, we 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 an Ebola virus outbreak is a primary concern.

We have conducted studies of our products in both in vitro and in vivo environments using well-established tests that are accepted by regulatory bodies. When an in vitro test was not generally available or not well-established, we conducted in vivo studies in mammalian models to predict human responses. Although we have no reason to believe that the in vitro and in vivo studies are not predictive of actual results in humans, we cannot be certain that the results of these in vitro and in vivo studies accurately predict the actual results in humans in all cases. In addition, strains of infectious agents in living donors may be different from those strains commercially available or for which we have tested and for which we have received approval of the inactivation claims for our products. To the extent that actual results in human patients differ, commercially available or tested strains prove to be different, or customers or potential customers perceive that actual results differ from the results of our in vitro or in vivo testing, market acceptance of our products may be negatively impacted.

If customers experience operational or technical problems with the use of INTERCEPT Blood System products, market acceptance may be reduced or delayed. For example, if adverse events arise from incomplete reduction of pathogens, improper processing or user error, or if testing of INTERCEPT-treated blood samples fails to reliably confirm pathogen reduction, whether or not directly attributable to the INTERCEPT Blood System, customers may refrain from purchasing our products. Furthermore, should customers communicate operational problems or suspected product failure, we will need to investigate and report imputability to the relevant regulatory authorities in a timely

manner. We or others may be required to file reports on such complaints or product failure before we have the ability to obtain conclusive data as to imputability which may cause concern with existing and prospective customers or regulators. For example, in connection with the nation-wide deployment of INTERCEPT in France, our customer, EFS, has encountered instances of leakage in the disposable kits. Although the relative number of reports is not disproportionate to the number we have seen in other markets, because of the high number of new sites, and the high utilization rates throughout France, the absolute number of incidents has triggered a report to the French National Agency for Medicines and Health Products Safety, or ANSM. We are working with EFS to gain access to the sites and personnel reporting the leaks in order to investigate and determine root cause and imputability in an effort to resolve the issue and if we are unable to successfully resolve the issue, then we may be required to recall our products, either voluntarily or at the direction of ANSM. In addition, the United States is currently experiencing a shortage of platelet components in many markets. Should customers feel that INTERCEPT treatment has a negative impact on the number of transfusable platelet units able to be manufactured from available donors, our ability to convince a blood center to treat increasing proportions of its platelet units may be negatively impacted. Moreover, there is a risk that further studies that we or others may conduct, including the post-approval studies we are required to conduct as a condition to the FDA approval of the platelet system, will show results inconsistent with previous studies. Should this happen, potential customers may delay or choose not to adopt our products and existing customers may cease use of our products. In addition, some hospitals may decide to purchase and transfuse both

INTERCEPT-treated blood components and conventional blood components. Managing such a dual inventory of blood products may be challenging, and hospitals may need to amend their product labels and inventory management systems before being able to move forward with INTERCEPT. This may require coordination between hospital suppliers and blood centers, which in turn may cause delay in market adoption. Further, in certain markets, potential customers may require us to develop, sell, and support data management application software for their operations before they would consider adopting INTERCEPT. Such software development efforts may be costly or we may be unsuccessful in developing a data management application that would be broadly accepted. Developing, maintaining and supporting software can be time consuming, costly and may require resources and skill sets that we do not possess. Failure to do so may limit market adoption in geographies where we commercialize the INTERCEPT Blood System, including the U.S.

Market adoption of our products is affected by blood center and healthcare facility budgets and the availability of reimbursement from governments, managed care payors, such as insurance companies, and/or other third parties. In many jurisdictions, due to the structure of the blood products industry, we have little control over budget and reimbursement discussions, which generally occur between blood centers, healthcare facilities such as hospitals, and national or regional ministries of health and private payors. Even if a particular blood center is prepared to adopt the INTERCEPT Blood System, its hospital customers may not accept or may not have the budget to purchase INTERCEPT-treated blood products. Since blood centers would likely not eliminate the practice of screening donors or testing blood for some pathogens prior to transfusion, even after implementing our products, some blood centers may not be able to identify enough cost offsets or hospital pricing increases to afford to purchase our products. Budgetary concerns may be further exacerbated by economic legislation in certain countries and by proposals by legislators at both the U.S. federal and state levels, regulators, healthcare facilities and third party payors to keep healthcare costs down, which may limit the adoption of new technologies, including our products. In some jurisdictions, commercial use of our products may not be covered by governmental or commercial third party payors for health care services and may never be covered. In the U.S., we obtained HCPCS reimbursement codes for INTERCEPT treated platelets and plasma in the outpatient setting in 2015. The costs and expenses incurred by the blood center related to donor blood are typically included in the price that the blood center charges a hospital for a unit of blood. Even after blood components treated with our products are approved for reimbursement by governmental or commercial third party payors, including under HCPCS codes, the costs and expenses related to use of the INTERCEPT Blood System will not be directly reimbursed, but instead may be incorporated within the reimbursement structure for medical procedures and/or products at the site of patient care. If the costs to the hospital for INTERCEPT-processed blood products cannot be easily, readily, or fully incorporated into the existing reimbursement structure, hospital billing and/or reimbursement for these products could be impacted, thus negatively impacting hospitals' acceptance and uptake of our products.

The market for the INTERCEPT Blood System is highly concentrated with few customers, including often-dominant regional or national blood collection entities. Even where our products receive regulatory approval and reimbursement is available, failure to effectively market, promote, distribute, price or sell our products to any of these customers could significantly delay or even diminish potential product revenue in those geographies. Moreover, the market for pathogen reduction systems in the U.S. is highly concentrated and dominated by a small number of blood collection organizations. In the U.S., the American Red Cross represents the largest single portion of the blood collection market. While we entered into a multi-year commercial agreement with the American Red Cross in February 2016, we cannot guarantee the volume or timing of commercial purchases that the American Red Cross may make, if any, under our agreement. Our ability to gain significant market penetration in the U.S. is largely dependent on utilization of INTERCEPT and distribution of INTERCEPT treated blood components by the American Red Cross. The American Red Cross is a large organization and broad-based utilization of INTERCEPT and distribution of INTERCEPT treated products may be concentrated in a limited number of centers or may occur slowly, if at all. Conversely, given the large relative size of the American Red Cross, should they deploy the technology rapidly, our resources may be inadequate to fulfill the American Red Cross's and other customers' demands, which could result in a loss of product revenues or

customer contracts, or both. In many countries in Western Europe and in Japan, various national blood transfusion services or Red Cross organizations collect, store and distribute virtually all of their respective nations' blood and blood components supply. In Europe, the largest markets for our products are in Germany, France, and England. In Germany, decisions on product adoption are made on a regional or even blood center-by-blood center basis, but depend on both local approvals and centralized regulatory approvals from the Paul Ehrlich Institute, or PEI. Obtaining these approval requires blood center support and effort to obtain the approvals, which even if they put forth the effort to obtain those approval, may take a significant period of time to obtain, if ever. Product specifications that receive marketing authorization from the PEI may differ from product specifications that have been adopted in other territories where we rely on CE mark approval, thereby necessitating market specific modifications to the commercial product, which may not be economical or technically feasible for us. Following the inclusion of pathogen-inactivated platelets for national reimbursement by the German Institute for the Hospital Remuneration System as of January 1, 2018, German customers who do not currently have an approved marketing authorization application, or MAA, will first need to obtain one before using our product. The review period for a new MAA can be up to twelve months following submission and we cannot assure that any of the potential German customers submitting a new MAA will obtain it. Without broad approvals of MAA applications obtained by potential German customers, our ability to successfully commercialize INTERCEPT in Germany will be negatively impacted, which may adversely affect our results of operations and financial results.

In July 2017, we entered into new agreements with the EFS to supply illuminators, platelet and plasma disposable kits and while no commitment has been made by EFS to adopt the platelet system across France, EFS has begun to standardize production of its platelets using the INTERCEPT Blood System. National deployment of the INTERCEPT Blood System for platelets throughout France will require a coordinated and highly managed roll-out and any set back or failure could negatively impact the timing and success of adoption. We cannot provide any assurance that national deployment of INTERCEPT in France would be sustainable, should it occur or that we will be able to secure any subsequent contracts with EFS or that the terms, including the pricing or committed volumes, if any, of any future contract will be equivalent or superior to the terms under our current contract. If we are unable to successfully support EFS' national adoption of the INTERCEPT Blood System for platelets or the final commercial terms of any subsequent contract are less favorable than the terms under our existing contract, our financial results may be adversely impacted.

In Japan, the Japanese Red Cross controls a significant majority of blood transfusions and exerts a high degree of influence on the adoption and use of blood safety measures in Japan. The Japanese Red Cross has been reviewing preclinical and clinical data on pathogen reduction of blood over a number of years and has yet to make a formal determination to adopt any pathogen reduction approach. We also understand that the Japanese Red Cross has begun formal evaluation of a competing technology. Before the Japanese Red Cross considers our products, we understand that we may need to commit to making certain product configuration changes, which are currently under development but may not be economically or technologically feasible for us to accomplish.

Given the concentrated nature of many of the largest potential customers, should those customers choose to adopt and standardize their production on the INTERCEPT Blood System, our ability to meet such significant demand may be constrained due to a variety of factors, including supply issues, manufacturing disruptions, availability of disposable kits manufactured from the obsolete plastic materials in jurisdictions that have not approved the alternate plastics, or other obsolescence of parts, among others. If we encounter such disruptions or supply shortages, we may have to allocate available products to customers, which could negatively impact our business and reputation or cause those customers to look for alternatives to the INTERCEPT Blood System.

We expect to continue to generate losses.

We may never achieve a profitable level of operations. Our cost of product sold, research and development and selling, general and administrative expenses have resulted in substantial losses since our inception. The platelet and plasma systems have been approved in the U.S. only since December 2014 and are not approved in many countries around the world. The red blood cell system is in the development stage and may never emerge from the development stage as a marketed product. We may be required to reduce the sales price for our products in order to make our products economically attractive to our customers and to governmental and private payors, or to compete favorably with other blood safety interventions or other pathogen reduction technologies, which may reduce or altogether eliminate any 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. We expect to incur additional research and development costs associated with the development of different configurations of existing products including our illuminator, development of new products, planning, enrolling and completing ongoing clinical and non-clinical studies, including the post-approval studies we are required to conduct in connection with the FDA approval of the platelet system, pursuing potential regulatory approvals in other geographies where we do not currently sell our platelet and plasma systems, planning and conducting in vitro studies and clinical development of our red blood cell system in Europe and the U.S., and completing activities to support a potential CE mark submission for our red blood cell system in Europe. These costs could be substantial and could extend the period during which we expect to operate at a loss, particularly if we experience any difficulties or delays in completing the activities.

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

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

Sales of our products are dependent on purchasing decisions of and/or reimbursement from government health administration authorities, distribution partners and other organizations. As a result of adverse conditions affecting the global economy and credit and financial markets, disruptions due to political instability or terrorist attacks, economies and currencies largely affected by declining commodity prices or otherwise, these organizations may defer purchases, may be unable to satisfy their purchasing or reimbursement obligations, or may delay payment for the INTERCEPT Blood System.

The sales of our products in Europe and CIS countries are denominated in Euros and other currencies. As a result, we are exposed to foreign exchange risk, and our results of operations have been and will continue to be impacted by fluctuations in the exchange rate between the U.S. dollar and other currencies, in particular the Euro. In addition, there have been concerns for the overall stability and

suitability of the Euro as a single currency given the economic and political challenges facing individual Eurozone countries. Continuing deterioration in the creditworthiness of Eurozone countries, the withdrawal of, or the announcement of the withdrawal of, one or more member countries from the European Union, or E.U., following the United Kingdom's, or U.K.'s, referendum in which voters approved an exit from the E.U., or the failure of the Euro as a common European currency or an otherwise diminished value of the Euro could materially and adversely affect our product revenue.

A meaningful amount of our product revenue has come from sales to our distributor in Russia and other CIS countries. Low worldwide oil prices and the ongoing civil, political and economic disturbances in Russia, Turkey and Ukraine, and their spillover effect on surrounding areas, along with the impact of sanctions imposed against Russia by certain European nations and the U.S., have significantly devalued the Russian Ruble and other CIS currencies and may continue to have a negative impact on the Russian and other CIS countries' economies, particularly if sanctions continue to be levied against Russia or are strengthened from those currently in place from either the E.U., U.S. or both. For example, in August 2017, President Trump signed into law new legislation which provides for additional sanctions against Russia. While our agreement with our Russian and other CIS distributors calls for sales, invoicing and collections to be denominated in Euros, if significant sanctions continue or are strengthened, if new sanctions are imposed in connection with Russia's alleged interference in the U.S. election or otherwise, if worldwide oil prices continue to remain low and/or if measures taken by the Russian government to support the Ruble fail, the Russian economy and value of the Ruble or other CIS currencies may further weaken or remain weak, and our business in Russia and other CIS countries may be negatively impacted further or never recover to historical levels. Similarly, low worldwide oil prices and current political conflicts may negatively impact potential future sales of our products in the Middle East and other oil producing exporters.

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

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

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

- development;
- testing;
- manufacturing;
- labeling;
- storage;
- clinical trials;
- product safety;
- pre-market clearance or approval;
- sales and distribution;
- use standards and documentation;
- conformity assessment procedures;
- product traceability and record keeping procedures;

- post-launch surveillance and post-approval studies;
- quality;
- advertising and promotion;
- product import and export; and
- reimbursement.

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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. In addition, jurisdictions may differ in the definition of what constitutes a transfusable unit of platelets. We have developed our products with the aim to standardize the volume of platelets treatable by our system, wherever possible, which may not be accepted by all regulators or customers, may require additional data to support approval or which may not produce optimal transfusable blood components. For example, in certain jurisdictions, our approved label claims and the definition of a viable platelet unit for transfusion may allow for a significantly lower or higher platelet count per volume than other jurisdictions may allow. This variability in platelet count per volume may result in differences in platelet quality once processed and stored using INTERCEPT, and if customers experience sub-optimal platelet quality following INTERCEPT treatment, they may limit their adoption of INTERCEPT or consider adoption of competing blood safety technologies over INTERCEPT. In addition, our approved labels from the FDA limit our current approvals to certain platelet collection platforms and a particular storage solution for the particular collection platform. For instance, our FDA approved claims permit apheresis collection of platelets on the Fresenius Amicus device while stored in an additive solution or for apheresis collection of platelets collected on the Terumo Trima device and stored in 100% plasma. Such discrepant collection methodologies and storage solutions and conditions also exist for red blood cells. We may be required to provide the FDA with data for each permutation for which blood banking treatment practices exist which may be time consuming, costly and limit the potential size of the U.S. market that can use our products. In addition, in order to generate data that would be satisfactory to the FDA, we need to test our products with different blood center production configurations producing otherwise saleable products for the blood center. As such, we will generally need to purchase blood components which are expensive and may be limited during periods of low availability. For example, we continue to experience such availability constraints for platelets. Any such inability to procure blood components at a reasonable price, or at all, to conduct studies in order to generate data sufficient for label claim expansions may negatively impact our business opportunities.

Clinical and Preclinical

Clinical trials are particularly expensive and have a high risk of failure. Any of our trials may fail or may not achieve results sufficient to attain market acceptance, which could prevent us from achieving profitability. We do not know whether we will begin or complete clinical trials on schedule, if at all. Clinical trials can be delayed for a variety of reasons, including delays in obtaining regulatory approval to commence a study, delays in reaching agreement on acceptable clinical study agreement terms with prospective clinical sites, delays in obtaining institutional review board, ministry of health or ethical committee approval to conduct a study at a prospective clinical site, delays in recruiting subjects to participate in a study, delays in the conduct of the clinical trial by personnel at the clinical site or due to our inability to actively and timely monitor clinical trial sites because of travel restrictions, political instability or terrorist activity or concerns over employee safety. We have in the past restricted and may again in the future need to restrict travel to certain clinical trial sites for monitoring site visits or to otherwise manage the trial due to state department issued travel warnings and restrictions. Significant delays in clinical testing could also materially impact our clinical trials. For example, the ReDeS study is ongoing in Puerto Rico which has seen massive destruction from the hurricanes of 2017. The blood centers and hospitals were significantly impacted, causing delays in enrollment and progress on the ReDeS study. To mitigate these delays, we are seeking to enroll patients in the U.S., including in Florida, though we cannot be certain if these mitigation steps will allow us to successfully enroll and complete the clinical trial. 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 were able to enroll patients in our European Phase 3 red blood cell system trial in chronic anemia patients and may impact other studies thus far. Consequently, we may be unable to recruit suitable patients into clinical trials on a timely basis, if at all, which may lead to higher costs or the inability to complete the clinical trials. We cannot rely on interim results of trials to predict their final results, and acceptable results in early trials might not be repeated in later trials. Any trial may fail to produce results satisfactory to the FDA or foreign regulatory authorities. In addition, preclinical and clinical data can be interpreted in different ways, which could delay, limit or prevent regulatory approval. Negative or inconclusive results from a preclinical study or

clinical trial, or adverse medical events during a clinical trial could cause a preclinical study or clinical trial to be repeated, require other studies to be performed or cause a program to be terminated, even if other studies or trials relating to a program are successful.

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

If any additional product candidates receive approval for commercial sale in the U.S., or if we obtain approval for expanded label claims for the platelet system or plasma system, the FDA may require one or more post-approval clinical or in vitro studies as a condition of approval, such as the post-approval clinical study we are required to conduct in connection with the approval of the platelet system and the additional post-approval study that we are required to conduct on recovery and survival of platelets suspended in 100% plasma in connection with the recent expanded label claim that we received for the platelet system. Each of these studies and any additional studies that the FDA may require could involve significant expense and may require us to secure adequate funding to complete. In addition, enrollment of post-marketing studies may be difficult to complete timely if customers of blood centers are reluctant to accept conventional, non-INTERCEPT treated products once INTERCEPT products become available to them. Other regulatory authorities outside of the U.S. may also require post-marketing studies. Governments or regulatory authorities may impose new regulations or other changes or we may discover that we are subject to additional regulations that could further delay or preclude regulatory approval and subsequent adoption of our potential products. We cannot predict the adoption, implementation or impact of adverse governmental regulation that might arise from future legislative or administrative action. Furthermore, any guidance document or mandate that prescribes use of INTERCEPT may impose a compliance requirement on blood centers that operate and process blood components in a manner for which we do not yet have approved label claims. Our inability to meet such operational or processing constraints may impair our potential results permanently or until we are able to obtain such claims.

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

submit applications, supplements or amendments for manufacturing and sale may face disapproval or delays in approval that could further delay or deter them from using our products. The regulatory impact on potential customers could slow or limit the potential sales of our products.

Red Blood Cell System

Our red blood cell system is currently in development and has not been commercialized anywhere in the world. Significant development and financial resources will be required to progress the red blood cell system into a commercially viable product and to obtain the necessary regulatory approvals for the product. Final development of the red blood cell system may never occur and failure can occur any time during the process. Any failure or delay in completing the development activities for the red blood cell system would prevent or delay its commercialization, which could materially and adversely affect our business, financial condition, results of operations, growth prospects and potential future market adoption of any of our products, including the red blood cell system. Many of the factors described above that can contribute to the failure or delay of a clinical trial could impact the trials we conduct for our red blood cell system. Even if we are successful in earlier clinical trials, the results of those early trials may not be predictive of results obtained in later and larger clinical trials of the red blood cell system or the results of routine use if we are able to commercialize the red blood cell system. In those cases, the FDA or foreign regulatory agencies may require we engage in additional clinical trials or

conduct further studies or analysis which may be costly and time-consuming. Furthermore, regulators may require clinical data for our red blood cell system under each collection and processing method using various additive or storage solutions before they would grant approval for any such configuration. If we were unable to collect data under each configuration or if we elect to pursue certain configurations over others for initial approval, our market opportunity may be limited. In some instances, we are relying on contract research organizations and other third parties to assist us in designing, managing, monitoring and otherwise carrying out our clinical trials and development activities for the red blood cell system. We do not control these third parties and, as a result, they may not treat our activities as their highest priority, or in the manner in which we would prefer, which could result in delays, inefficient use of our resources and could distract personnel from other activities. Additionally, if we, our contract research organizations or other third parties assisting us or our study sites fail to comply with applicable good clinical practices, the clinical data generated in our trials may be deemed unreliable and the FDA or foreign regulatory agencies may require us to perform additional clinical trials before approving the red blood cell system for commercialization. We cannot assure you that, upon inspection, regulatory agencies will determine that any of our clinical trials comply with good clinical practices. In addition, our clinical trials must be conducted with product produced under the FDA's cGMP regulations and similar regulations outside of the U.S. Our failure or the failure of our product manufacturers to comply with these regulations may require us to repeat or redesign clinical trials, which would delay the regulatory approval process. We must complete other prerequisites, including developing and validating an analytical method to test GMP manufactured compounds used in the red blood cell system to show that they consistently meet specifications and additional CMC activities in order to proceed with our planned CE mark submission. Developing a methodology and assay that is sufficiently sensitive and robust may be time consuming, and delays or failures in such development efforts could in-turn delay our ability to obtain regulatory approvals. In addition, existing lots of these red blood cell compounds manufactured under GMP may be dispositioned by regulators or ourselves as unsuitable for either commercial or clinical use which would impact our ability to produce INTERCEPT treated-red blood cells for ongoing and future clinical trials and may require changes to the manufacturing process of our red blood cell compounds or new production of the compounds, all of which would be costly and time consuming and impact our ability to perform under our contract with BARDA. We understand that one of our component suppliers for our red blood cell system is experiencing significant financial difficulties which may impact their ability to maintain standards suitable for GMP regulations or ability to exist as a going concern. While we are in the process of identifying alternate manufactures of the component, qualification of any alternate supplier will be time consuming and may cause delay in obtaining regulatory approval and will cause us to incur additional cost. Further, we are currently in the process of negotiating a commercial supply agreement with the manufacturer of the processing kits used in the red blood cell clinical trials. If we are unable to reach agreement on terms, our ability to complete the ReDeS and ReCePI studies and any future Phase 3 clinical trials may be adversely impacted. There can be no guarantee that we will reach agreement or that, if an agreement is reached, that it will be on terms favorable to us.

In 2003, we terminated Phase 3 clinical trials evaluating a prior generation of the red blood cell system in acute and chronic anemia patients. The trials were terminated due to the detection of antibody reactivity to INTERCEPT-treated red blood cells in two patients in the 2003 chronic anemia trial. Although the antibody reactivity was not associated with any adverse events, we developed process changes designed to diminish the likelihood of antibody reactivity in red blood cells treated with our modified process. In a subsequent Phase 1 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 3 clinical trials in Europe using the modified process in patients with acute and chronic anemia, respectively. We successfully completed the European Phase 3 acute anemia clinical trial and the European Phase 3 chronic anemia clinical trials, with the INTERCEPT Blood System for red blood cells meeting its primary efficacy and safety endpoints in both trials. However, we cannot assure you that the adverse events observed in the terminated 2003 Phase 3 clinical trials of our earlier red blood cell system will not be observed in the future. In addition, although our completed European Phase 3 clinical trials in acute anemia patients and chronic anemia patients using our modified process met their primary endpoints, we cannot assure you that the same or similar results will be observed in current

and potential future clinical trials using our modified process.

We will need to successfully conduct and complete each of the ReDeS and ReCePI studies as well as an additional Phase 3 clinical trial for chronic anemia in the U.S. before the FDA will consider our red blood cell product for approval. There can be no assurance that we will be able to successfully complete these perquisite Phase 3 clinical trials or otherwise generate sufficient Phase 3 clinical data, 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 an additional Phase 3 clinical trial. In part, we will seek to introduce supplemental clinical data we obtained from European clinical trials, though we cannot assure you that we will be able to demonstrate comparability or that the FDA will allow supplemental clinical European data. The FDA will require us to place a clinical hold on any clinical trial if we see a hemolytic reaction associated with treatment emergent antibodies with amustaline specificity in patients receiving INTERCEPT-treated red blood cells in that trial. Should we experience such an incident, we will need to investigate the underlying cause of the hemolytic reaction, which in many patient populations may be difficult for us to assess imputability which may lead to a complete halt of the clinical trial, may irreparably harm our red blood cell product's reputation and we may be forced to suspend or terminate development activities related to the red blood cell system in the U.S., which would have a material adverse effect on our business and business prospects. In addition, if we are unable to generate sufficient perquisite Phase 3 clinical data and/or reach agreement with the FDA on a Phase 3 clinical trial design for our red blood cell system, our agreement with BARDA will be severely limited in scope or could be

terminated altogether, and our ability to complete the development activities required for licensure in the U.S. may require additional capital beyond which we currently have. If alternative sources of funding are not available, we may be forced to suspend or terminate development activities related to the red blood cell system in the U.S.

We completed our European Phase 3 clinical trials of our red blood cell system for acute anemia patients and separately for chronic anemia patients. Although we plan to complete additional development activities to support an anticipated CE mark submission for the red blood cell system, such development activities could prolong development of our red blood cell system, and we do not expect to receive any regulatory approvals of our red blood cell system in the next twelve months, if ever. We understand that while the data generated from our European Phase 3 clinical trials may be sufficient to receive CE mark approval, we may need to generate additional safety data from commercial use in order to achieve broad market acceptance. In addition, the European Phase 3 clinical trials in acute, and separately, chronic anemia patients, may need to be supplemented by additional, successful Phase 3 clinical trials for approval in certain countries. If such additional Phase 3 clinical trials are required, they would likely need to demonstrate equivalency of INTERCEPT-treated red blood cells compared to conventional red blood cells and the significantly lower lifespan for INTERCEPT-treated red blood cells compared to non-treated red blood cells may limit our ability to obtain regulatory approval for the product. A number of trial design issues that could impact efficacy, regulatory approval and market acceptance will need to be resolved prior to the initiation of further clinical trials. In addition, if we are unable to secure the full amount of funding contemplated by the BARDA agreement for any reason, our ability to complete the development activities required for potential licensure in the U.S. may require additional capital beyond which we currently have, and we may be required to obtain additional capital in order to complete the development of and obtain any regulatory approvals for the red blood cell system. Further, while we believe that our available cash and cash equivalents and short-term investments, as well as cash to be received from product sales and under our agreement with BARDA, will be sufficient to meet our capital requirements for at least the next twelve months, if we are unable to generate sufficient product revenue, or access sufficient funds under our BARDA agreement or the public and private equity and debt capital markets, we may be unable to execute successfully on our operating plan. If alternative sources of funding are not available, we may be forced to suspend or terminate development activities related to the red blood cell system in the U.S. which would have a material adverse effect on our business and business prospects. If we are unsuccessful in advancing the red blood cell system through clinical trials, resolving process and product design issues or in obtaining subsequent regulatory approvals and acceptable reimbursement rates, we may never realize a return on our R&D expenses incurred to date for the red blood cell system program. Regulatory delays can also materially impact our product development costs. If we experience delays in testing, conducting trials or approvals, our product development costs will increase, which costs may not be reimbursable to us under the BARDA agreement. Even if we were to successfully complete and receive approval for our red blood cell system, potential blood center customers may object to working with a potent chemical, like amustaline, the active compound in the red blood cell system, or may require modifications to automate the process, which would result in additional development costs, any of which could limit any market acceptance of the red blood cell system. If the red blood cell system were to face such objections from potential customers, we may choose to pay for capital assets, specialized equipment or personnel for the blood center, which would have a negative impact on any potential contribution margin from red blood cell system sales. Additionally, the use of the red blood cell system may result in some processing loss of red blood cells. If the loss of red blood cells leads to increased costs, or the perception of increased costs for potential customers, or potential customers believe that the loss of red blood cells reduces the efficacy of the transfusion unit, or our process requires changes in blood center or clinical regimens, potential customers may not adopt our red blood cell system even if approved for commercial sale.

Platelet and Plasma Systems

In 2007, we obtained a CE mark approval from E.U. regulators for our platelet system, and have subsequently received a renewal in 2012 and again in 2017, in accordance with the five year renewal schedule. We or our customers have received approval for the sale and/or use of INTERCEPT-treated platelets within the Europe in France,

Switzerland, Germany and Austria. We or our customers may also be required to conduct additional testing in order to obtain regulatory approval in countries that do not recognize the CE mark as being adequate for commercializing the INTERCEPT Blood System in those countries. The level of additional product testing varies by country, but could be expensive or take a long time to complete. In addition, regulatory agencies are able to withdraw or suspend previously issued approvals due to changes in regulatory law, our inability to maintain compliance with regulations or other factors.

In 2006, we obtained a CE mark approval from E.U. regulators for our plasma system, and have subsequently received a renewal in 2011 and again in 2016, in accordance with the five year renewal schedule. We or our customers have received approval for the sale and/or use INTERCEPT-treated plasma within Europe in France, Switzerland, Austria and Germany. In some countries, including several in Europe, we or our customers may be required to perform additional clinical studies or submit manufacturing and marketing applications in order to obtain regulatory approval. If we or our customers are unable to obtain or maintain regulatory approvals for the use and sale or continued sale and use of INTERCEPT-treated platelets or plasma, market adoption of our products will be negatively affected and our growth prospects would be materially and adversely impacted.

The FDA has approved the platelet system for ex vivo preparation of pathogen-reduced apheresis platelet components collected and stored in InterSol and 100% plasma 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. Additionally, the FDA approved the plasma system for ex vivo preparation of plasma in order to reduce the risk of TTI when treating patients requiring therapeutic plasma transfusion. We have conducted and are conducting additional in vitro studies for our platelet system to potentially expand our label claims to include, among others, platelets collected from pooled random donors, storage of INTERCEPT-treated platelets for up to seven days rather than five days, and a new processing set for triple dose collections. Failure to obtain any of these label expansion claims may negatively affect market adoption and our growth prospects would be materially and adversely affected.

As a condition to the initial FDA approval of the platelet system, we are required to conduct a post-approval clinical study of the platelet system. Successful enrollment and completion of this study requires that we develop sufficient INTERCEPT production capabilities with U.S. blood center customers. Delays in delivering INTERCEPT systems to blood centers that can supply INTERCEPT-treated platelets to hospitals involved in the study may lead to increased costs to us and may jeopardize our ability to complete the study in a timeframe acceptable to the FDA. Furthermore, blood centers' ability to produce INTERCEPT-treated platelets and supply hospitals enrolled in the study may be negatively impacted by a shortage of overall platelet availability, constraints in producing platelets in compliance with our approved claims or operational inefficiencies experienced as a result of INTERCEPT treatment. In addition, we must identify and contract with hospitals that have the desire and ability to participate and contribute to the study in a timely manner and who are willing to purchase INTERCEPT-treated platelets from our blood center customers. If we are unable to complete this study, in a timely manner or at all, or the results of this study reveal unacceptable safety risks, we could be required to perform additional studies, which may be costly, and even lose U.S. marketing approval of the platelet system. Further, we are required to conduct a post-approval recovery and survival clinical study in connection with the recent label expansion approval for the use of the platelet system to treat platelets suspended in 100% plasma. Successful enrollment and completion of this additional study will also require that we identify and contract with hospitals that have the desire and ability to participate and contribute to the study in a timely manner and who are willing to purchase INTERCEPT-treated platelets from our blood center customers. If we are unable to complete this study, in a timely manner or at all, or the results of this study reveal unacceptable safety risks, we could be required to perform additional studies, which may be costly. In addition to these studies, the FDA may also require us to commit to perform other lengthy post-marketing studies, for which we would have to expend significant additional resources, which could have an adverse effect on our operating results, financial condition and stock price. In addition, there is a risk that these studies will show results inconsistent with our previous studies. Should this happen, potential customers may delay or choose not to adopt the INTERCEPT Blood System and existing customers may cease use of the INTERCEPT Blood System.

The execution and completion of the ReDeS and ReCePI studies and planned or required clinical trials or studies will continue to result in additional costs, and will continue to require attention and resources from our clinical, regulatory and management teams, which may adversely affect our commercialization efforts and other regulatory and clinical programs.

Post-Marketing Approval

We are also required to continue to comply with applicable FDA and other regulatory requirements now that we have obtained approval for the INTERCEPT Blood System for platelets and plasma. These requirements relate to, among other things, labeling, packaging, storage, advertising, promotion, record-keeping and reporting of safety and other information. In addition, our manufacturers and their facilities are required to comply with extensive FDA and foreign regulatory agency requirements, including, in the U.S., ensuring that quality control and manufacturing procedures conform to cGMP and current QSR requirements. As such, we and our contract manufacturers are subject to continual

review and periodic inspections. Accordingly, we and others with whom we work must continue to expend time, money and effort in all areas of regulatory compliance, including manufacturing, production and quality control. We are also required to report certain adverse events and production problems, if any, to the FDA and foreign regulatory authorities, when applicable, and to comply with requirements concerning advertising and promotion for our products. For example, our promotional materials and training methods must comply with FDA and other applicable laws and regulations, including the prohibition of the promotion of unapproved, or off-label, use. If the FDA determines that our promotional materials or training constitutes promotion of an off-label use, it could request that we modify our training or promotional materials or subject us to regulatory or enforcement actions, including the issuance of an untitled letter, a warning letter, injunction, seizure, civil fine or criminal penalties. It is also possible that other federal, state or foreign enforcement authorities might take action if they consider our promotional or training materials to constitute promotion of an off-label use, or a violation or any other federal or state law that applies to us, such as laws prohibiting false claims for reimbursement. Any enforcement action brought by a federal, state or foreign authority could result in significant civil, criminal and/or administrative penalties, damages, fines, disgorgement, individual imprisonment, additional reporting obligations and oversight if we become subject to a corporate integrity agreement or other agreement to resolve allocations of non-compliance with these laws, exclusion from participation in government programs, such as Medicare and Medicaid, injunctions, private “qui tam” actions brought by individual whistleblowers in the name of the government, or refusal to allow us to enter into government contracts, contractual damages, administrative burdens, and diminished profits and future earnings. In addition, 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, divert our management's attention, result in substantial damage awards against us and harm our reputation.

Should a regulatory agency question a reported adverse event, we may not be able to rule out product failure as the cause, whether or not product failure is the cause of the reported adverse event. If a regulatory agency suspects or discovers problems with a product, such as adverse events of unanticipated severity or frequency, or problems with the facility or the manufacturing process at the facility where the product is manufactured, or problems with the quality of product manufactured, or disagrees with the promotion, marketing, or labeling of a product, a regulatory agency may impose restrictions on use of that product, including requiring withdrawal of the product from the market. Our failure to comply with applicable regulatory requirements could result in enforcement action by regulatory agencies, which may include any of the following sanctions:

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

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

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

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

We anticipate that a significant portion of the funding for the development of the red blood cell system will come from our agreement with BARDA. In this regard, in June 2016, we entered into an agreement with BARDA that is worth up to approximately $186.2 million to support the development of the red blood cell system. However, our agreement with BARDA only reimburses certain specified development and clinical activities that have been authorized by BARDA pursuant to the base period and certain options of the agreement and the potential exercise of subsequent option periods. To date, BARDA has committed approximately $88.2 million under the base period of the

agreement and options exercised in 2016. Accordingly, our ability to receive any of the additional $98.0 million in funding provided for under the BARDA agreement is dependent on BARDA exercising additional options under the agreement, which it may do or not do at its sole discretion. In addition, BARDA is entitled to terminate our BARDA agreement for convenience at any time, in whole or in part, and is not required to provide continued funding beyond reimbursement of amounts currently incurred and obligated by us as a result of contract performance. Moreover, the continuation of our BARDA agreement depends in large part on our ability to meet development milestones previously agreed to with BARDA and on our compliance with certain operating procedures and protocols. BARDA may suspend or terminate the agreement should we fail to achieve key milestones, or fail to comply with the operating procedures and processes approved by BARDA and its audit agency. There can be no assurance that we will be able to achieve these milestones or continue to comply with these procedures and protocols. For instance, our ReDeS study, which is being funded as part of our agreement with BARDA, is currently being conducted in Puerto Rico and Florida. Given the recent hurricanes and destruction to Puerto Rico, our ability to enroll patients and make meaningful progress with

the ReDeS study has been negatively impacted and the successful completion of the ReDeS study will likely depend on increasing enrollment through sites outside of Puerto Rico. Our ability to meet the expectations of BARDA under our contract is largely dependent on our ability to attract, hire and retain personnel with competencies that are in short supply. In addition, in many instances we must identify third-party suppliers, negotiate terms acceptable to us and BARDA and ensure ongoing compliance by these suppliers with the obligations covered by our BARDA contract. If we are unable to provide adequate supplier oversight or if suppliers are unable to comply with the requirements of the contract, our ability to meet the anticipated milestones may be impaired. There can also be no assurance that our BARDA agreement will not be terminated, that our BARDA agreement will be extended through the exercise of subsequent option periods, that any such extensions would be on terms favorable to us, or that we will otherwise obtain the funding that we anticipate to obtain under our agreement with BARDA. Moreover, changes in government budgets and agendas may result in a decreased and deprioritized emphasis on supporting the development of pathogen reduction technology. If our BARDA agreement is terminated or suspended, if there is any reduction or delay in funding under our BARDA agreement, or if BARDA determines not to exercise some or all of the options provided for under the agreement, our revenues and cash flows could be significantly and negatively impacted and we may be forced to seek alternative sources of funding, which may not be available on non-dilutive terms, terms favorable to us or at all. If alternative sources of funding are not available, we may be forced to suspend or terminate development activities related to the red blood cell system in the U.S.

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

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

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

- audit and object to any BARDA agreement-related costs and fees on grounds that they are not allowable under the Federal Acquisition Regulation, or FAR, and require us to reimburse all such costs and fees;
- suspend or prevent us for a set period of time from receiving new contracts or grants or extending our existing agreement based on violations or suspected violations of laws or regulations;
- claim nonexclusive, nontransferable rights to product manufactured and intellectual property developed under the BARDA agreement and may, under certain circumstances involving public health and safety, license such inventions to third parties without our consent;
- cancel, terminate or suspend our BARDA agreement based on violations or suspected violations of laws or regulations;
- terminate our BARDA agreement in whole or in part for the convenience of the government for any reason or no reason, including if funds become unavailable to the U.S. Department of Health and Human Services' Office of the Assistant Secretary for Preparedness and Response;
- reduce the scope and value of our BARDA agreement;
- decline to exercise an option to continue the BARDA agreement;
- direct the course of the development of the red blood cell system in a manner not chosen by us;
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require us to perform the option periods provided for under the BARDA agreement even if doing so may cause us to forego or delay the pursuit of other red blood cell program opportunities with greater commercial potential;

- take actions that result in a longer development timeline than expected;
- limit the government's financial liability to amounts appropriated by the U.S. Congress on a fiscal-year basis, thereby leaving some uncertainty about the future availability of funding for the red blood cell program even after it has been funded for an initial period; and
- change certain terms and conditions in our BARDA agreement.

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

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

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

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

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

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

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

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

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

In addition, as a U.S. government contractor, we are required to comply with applicable laws, regulations and standards relating to our accounting practices and are subject to periodic audits and reviews. As part of any such audit or review, the U.S. government may review the adequacy of, and our compliance with, our internal control systems and policies, including those relating to our purchasing, property, estimating, compensation and management information systems. Based on the results of its audits, the U.S. government may

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

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

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

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

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

Any of the foregoing actions could have a material adverse effect on our reputation, business, financial condition and operating results. Furthermore, our key suppliers may not continue to be in compliance with all applicable regulatory requirements, which could result in our failure to produce our products on a timely basis and in the required quantities,

if at all. In addition, before any additional products would be considered for marketing approval in the U.S. or elsewhere, our suppliers will have to pass an audit by the FDA or other regulatory agencies. We are dependent on our suppliers' cooperation and ability to pass such audits. Such audits and any audit remediation may be costly. Failure to pass such audits by any of our suppliers would affect our ability to obtain licensure in the U.S. or elsewhere.

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

Any modifications to the platelet and plasma systems that could significantly affect their safety or effectiveness, including significant design and manufacturing changes, or that would constitute a major change in their intended use, manufacture, design, components, or technology requires approval of a new PMA or PMA supplement. However, certain changes to a PMA-approved device do not require submission and approval of a new PMA or PMA supplement and may only require notice to FDA in a PMA Annual Report. The FDA requires every supplier to make this determination in the first instance, but the FDA may review any supplier's decision. The FDA may not agree with our decisions regarding whether new clearances or approvals are necessary. Our products could be subject to recall if the FDA determines, for any reason, that our products are not safe or effective or that appropriate regulatory submissions were not made. If new regulatory approvals are required, this could delay or preclude our ability to market the modified system. For example, due to the obsolescence of certain parts, we have redesigned the illuminators used in the platelet and plasma systems and we are qualifying new plastics for use in our disposable kits, and we will need to receive approval of both of these changes from the FDA. In addition, in order to address the entire market in the U.S., we will need to obtain approval for additional configurations of the platelet system, including triple dose collections and random donor platelets. Our approved labels from the FDA limit our current approvals to certain platelet collection platforms and a particular storage solution for the particular collection platform. For instance, our approved claims permit apheresis collection of platelets on the Fresenius Amicus device while stored in an additive solution or for apheresis collection of platelets collected on the Terumo Trima device and stored in 100% plasma. Such discrepant collection methodologies and storage solutions and conditions also exist for red blood cells. We may be required to provide the FDA with data for each permutation for which blood banking treatment practices exist which may be time consuming, costly and limit the potential size of the U.S. market that can use our products. We have conducted and may conduct additional in vitro studies for our platelet system to potentially expand our label claims to include, among others, platelets collected from pooled random donors, storage of INTERCEPT-treated platelets for up to seven days rather than five days, and a new processing set for triple dose collections. Our failure to obtain FDA and foreign regulatory approvals of new platelet and plasma product configurations could significantly limit product revenues from sales of the platelet and plasma systems. In any event, delays in receipt or failure to receive approvals, the loss of previously received approvals, or the failure to comply with any other existing or future regulatory requirements, could reduce our sales and negatively impact our profitability potential and future growth prospects. In addition, if the FDA or other regulatory or accrediting body were to mandate safety interventions, including the option of pathogen reduction technology, when we had not received approval for all operational configurations, the market to which we could sell our products may be limited until we obtain such approvals, if ever, or may be permanently impaired if competing options are more broadly available. In addition, we may seek to expand use of our products under new PMA approvals or PMA supplements. For instance, we plan to perform additional studies and seek regulatory approval for INTERCEPT-treated extended storage cryoprecipitate from plasma and we may develop, test and seek approval for other biological plasma products. Such products may require or we may choose to pursue a change in business model whereby we are selling the finished component to hospitals rather than an illuminator and disposable kit to blood centers. We have no experience selling to hospitals nor do we have experience or expertise complying with regulations governing finished biologics. If we are unable to successfully market such products to hospitals or comply with unique regulations, our ability to monetize and deliver such products will be negatively impacted.

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

We are responsible for worldwide sales, marketing, distribution, maintenance and regulatory support of the INTERCEPT Blood System. If we fail in our efforts to develop or maintain such internal competencies or establish

acceptable relationships with third parties to support us in these areas on a timely basis, our ability to commercialize the INTERCEPT Blood System may be irreparably harmed.

We have a wholly-owned subsidiary, headquartered in the Netherlands, dedicated primarily to selling and marketing the platelet and plasma systems in Europe, the CIS and the Middle East. Our commercial activities for the U.S., Latin and South America and Asia are based out of our headquarters in Concord, California with certain support from our European headquarters in the Netherlands, with certain individuals servicing Latin and South America and Asia, domiciled outside of the U.S. Our commercial organization focused on the U.S. market has limited resources and is relatively inexperienced, and as a result, has limited to no experience selling and marketing our platelet and plasma systems. Given the large relative size of the American Red Cross, should they deploy INTERCEPT rapidly under our commercial agreement, our resources may be inadequate to fulfill the American Red Cross' and other customers' demands, which could result in a loss of product revenues or customer contracts, or both. We will need to maintain and may need to increase our competence and size in a number of functions, including sales, deployment and product support, marketing, regulatory, inventory and logistics, customer service, credit and collections, risk management, and quality assurance systems in order to successfully support our commercialization activities in all of the jurisdictions we currently sell and market, or anticipate selling and marketing, our products. Many of these competencies require compliance with U.S., E.U., South American, Asian and local standards

and practices, including regulatory, legal and tax requirements, with some of which we have limited experience. In this regard, should we obtain regulatory approval in an increased number of geographies, we will need to ensure that we maintain a sufficient number of personnel or develop new business processes to ensure ongoing compliance with the multitude of regulatory requirements in those territories. Hiring, training and retaining new personnel is costly, time consuming and distracting to existing employees and management. We have limited experience operating on a global scale and we may be unsuccessful complying with the variety and complexity of laws and regulations in a timely manner, if at all. In addition, in some cases, the cost of obtaining approval and maintaining compliance with certain regulations and laws may exceed the product revenue that we recognize from such a territory, which would adversely affect our results of operations and could adversely affect our financial condition. Furthermore, we may choose to seek alternative ways to sell or treat blood components with our products. These may include new business models, which may include selling kits to blood centers, performing inactivation ourselves, staffing blood centers or selling services or other business model changes. We have no experience with these types of business models, or the regulatory requirements or licenses needed to pursue such new business models. Additionally, such business models may be viewed as a threat to existing customers. We cannot assure you that we will pursue such business models or if we do, that we will be successful or that our existing customers will not feel threatened.

Further, in June 2016, the U.K. held a referendum in which voters approved an exit from the E.U., commonly referred to as “Brexit,” and the U.K. government delivered a notice of withdrawal in March 2017, with the U.K. scheduled to exit the E.U. by April 2019. The withdrawal could, among other outcomes, disrupt the free movement of goods, services and people between the U.K. and the E.U., undermine bilateral cooperation in key policy areas and significantly disrupt trade between the U.K. and the E.U. We may also face new regulatory costs and challenges as result of Brexit that could have a material adverse effect on our operations. In addition, Brexit could lead to legal uncertainty and potentially divergent national laws and regulations as the U.K. determines which E.U. laws to replace or replicate. Altered regulations could add time and expense to the process by which our product candidates receive regulatory approval in the E.U. Given the lack of comparable precedent, it is unclear what financial, regulatory, trade and legal implications the withdrawal of the U.K. from the E.U. will have and how such withdrawal will affect us.

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

We have entered into distribution agreements, generally on a geographically exclusive basis, with distributors in certain regions. We rely on these distributors to obtain and maintain any necessary in-country regulatory approvals, as well as market and sell the INTERCEPT Blood System, provide customer and technical product support, maintain inventories, and adhere to our quality system in all material respects, among other activities. Generally, our distribution agreements require distributors to purchase minimum quantities in a given year over the term of the agreement. Failure by our distributors to meet these minimum purchase obligations may impact our financial results. In addition, failure by our distributors to provide an accurate forecast impacts our ability to predict the timing of product revenue and our ability to accurately forecast our product supply needs. While our contracts generally require distributors to exercise diligence, these distributors may fail to commercialize the INTERCEPT Blood System in their respective territories. For example, our distributors may fail to sell product inventory they have purchased from us to end customers or may sell competing products ahead of or in conjunction with INTERCEPT. In addition, initial purchases of illuminators or INTERCEPT disposable kits by these third parties may not lead to follow-on purchases of platelet and plasma systems’ disposable kits. 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 product revenue and we may have little recourse, short of termination, in the event that a distributor fails to execute according to our expectations and contractual provisions. In the past, we have experienced weaker than expected growth due to declining performance by certain of our distributors. Periodically, we transition certain territories to new distribution partners or our direct sales force where we believe we can improve performance relative to the distributor. Because new distribution partners or our direct sales force may have limited experience marketing and selling our products in certain territories, or at all, we cannot be certain that they will perform better than the predecessor distributor. In certain cases, our distributors hold the regulatory approval to sell INTERCEPT for their particular geography. Termination, loss of exclusivity or transitioning from these distributors would require us to negotiate a transfer of the applicable regulatory approvals to us or new distributors which may be difficult to do in a timely manner, or at all. We expect that our product revenue will be adversely impacted with the loss or transition of one or more of these distributors. If we choose to terminate distributor agreements, we would either need to reach agreement with, qualify, train and supply a replacement distributor or supply

and service end-user customer accounts in those territories ourselves. Although our distribution agreements generally provide that the distributor will promptly and efficiently transfer its existing customer agreements to us, there can be no assurance that this will happen in a timely manner or at all or that the distributor will honor its outstanding commitments to us. In addition, terminated distributors may own illuminators placed at customer sites and may require us to repurchase those devices or require end-user customers to purchase new devices from us. Additionally, we may need terminated distributors to cooperate with us or a new distributor in transitioning sub-distributor relationships and contracts, hospital contracts, public tenders, or regulatory certificates or licenses held in their name. These factors may be disruptive for our customers and our reputation may be damaged as a result. Our distribution partners may have more established relationships with potential end user customers than a new distributor or we may have in particular territory, which could adversely impact our ability to successfully commercialize our products in these territories. In addition, it may take longer for us to be paid if payment timing and terms in these new arrangements are less favorable to us than those in our existing distributor arrangements. As we service end-user accounts directly rather than through distributors, we incur additional expense, our working capital is negatively impacted due to longer periods from cash collection from direct sales customers when compared to the timing of cash collection from our former distribution partners and we may be exposed to additional complexity including local statutory and tax compliance. Current or transitioning distributors may irreparably harm relationships with local existing and prospective customers and our standing with the blood banking community in general. In the event that we are unable to find alternative distributors or mobilize our own sales efforts in the territories in which a particular distributor operates, customer supply, our reputation and our operating results may be adversely affected. In addition, in territories where new distributors are responsible for servicing end-user accounts, there will be a period of transition in order to properly qualify and train these new distributors, which may disrupt the operations of our customers and adversely impact our reputation and operating results.

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

Our ability to generate significant product revenue from our platelet and plasma systems depends in part on our ability to achieve market acceptance of, and to otherwise effectively market, our platelet and plasma systems in the U.S. Even if we are able to achieve market acceptance in the U.S. or newly commercialized markets, we have provided and may continue to provide adoption incentives which may negatively impact our reported sales. Successfully commercializing our products in the U.S. may take considerable time during which we will need to build relationships, additional routine-use data and trust from the industry. As a company, we have no prior experience in commercializing any products in the U.S., and we still need to attract, retain, train and support sales, marketing and scientific affairs personnel and other commercial talent. For example, we need to attract and retain 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 and employment market for MSLs is highly competitive. As such, we need to commit significant additional management and other resources in order to maintain and expand our MSL team and sales and marketing functions. We may be unable to develop and maintain adequate MSL, sales and marketing capabilities for the U.S. market and we also may not be able to devote sufficient resources to the advertising, promotion and sales efforts for the platelet and plasma systems in the U.S. We will also have to compete with other life sciences and medical device companies to recruit, hire, train and retain the MSL, sales and marketing personnel that we anticipate we need. For these and other reasons, we may be unable to develop and maintain an effective and qualified U.S.-based commercial organization in a cost-effective manner or realize a positive return on our investment. If we are unable to develop and maintain an effective and qualified U.S.-based commercial organization in a timely manner or at all, we may fail to realize the full sales potential of our platelet and plasma systems in the U.S. In addition, should we seek and obtain approval for unique biological products created by

use of the INTERCEPT blood system, including extended storage cryoprecipitate, we may choose to sell the treated end product directly to hospitals using our commercial organization. We have no experience selling biological end products directly to hospitals which may cause a distraction for our commercial organization or we may be viewed as a competitive threat to our blood center customers.

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 gross margins will be negatively impacted.

In October 2015, we amended and restated our manufacturing and supply agreement with Fresenius. Under the amended agreement, Fresenius is obligated to sell, and we are obligated to purchase finished disposable kits for the platelet, plasma and red blood cell kits

from Fresenius with certain exceptions permitted. The initial term of the amended agreement extends through July 1, 2025, and is automatically renewed thereafter for additional two year renewal terms, subject to termination by either party upon (i) two years written notice prior to the expiration of the initial term or (ii) one year written notice prior to the expiration of any renewal term. We and Fresenius each have normal and customary termination rights, including termination for material breach. Fresenius is our sole supplier for the manufacture of these products. Fresenius may fail to manufacture an adequate supply of INTERCEPT disposable kits which would harm our business. Disruptions to our supply chain as a result of any potential ensuing protests, strikes or other work-stoppages would be detrimental to our business and operating results. While we and Fresenius recently entered into the amended agreement, in the event Fresenius refuses or is unable to continue operating under the amended agreement, we may be unable to maintain inventory levels or otherwise meet customer demand, and our business and operating results would be materially and adversely affected.

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

Our manufacturing and supply agreement with Ash Stevens automatically extended at the end of 2017 and now continues until December 31, 2019, and will continue to automatically renew 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. We have not been notified by Ash Stevens of their intention to terminate the agreement. 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.

In April 2017, we entered into an amended and restated manufacturing and supply agreement with Porex for the continued supply of the compound adsorption. Porex is our sole supplier for certain components of and manufacturing of the compound adsorption devices. Under the amended and restated Porex agreement, we are no longer subject to a minimum annual purchase requirement; however, Porex has the right to terminate the agreement, upon twelve months' prior written notice, if annual production falls below a mutually agreed threshold. If not sooner terminated, the amended and restated Porex agreement expires on December 31, 2019. In addition, we entered into an amended and restated supply agreement with Brotech Corporation d/b/a Purolite Company, or Purolite, for the supply of raw materials used to make the compound adsorption devices. The amended supply agreement expires in April 2021 and will automatically renew for an additional year unless either party has provided notice not to renew at least two years prior to the expiration. Under the terms of the amended agreement, pricing is volume based and is subject to annual, prospective adjustments based on a Producer Price Index subject to an annual cap. Our agreement with Nova, which manufacturers our illuminators, currently extends through September 2018 and is automatically renewable for one year terms, but may be terminated by Nova on at least twelve months' prior written notice. We have not been notified by Nova of their intention to terminate the agreement.

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

certain plastics used to make INTERCEPT disposable kits are no longer available. As a result, we and our manufacturers have identified alternate plastics and we have received CE Mark approval for our platelet product using the alternate plastics but will need to qualify and validate those plastics in the U.S. and for our plasma product in Europe before we can utilize them in commercial manufacturing. In addition, we understand that a compound adsorbent housing component is no longer available and an alternate housing will need to be qualified by Fresenius. Identification and qualification of alternate suppliers is time consuming and costly, and there can be no assurance that we will be able to demonstrate equivalency of alternate components or suppliers or that we will receive regulatory approval in the U.S. or other jurisdictions. If we conclude that supply of the INTERCEPT Blood System or components from suppliers is uncertain, we may choose to build and maintain inventories of raw materials, work-in-process components, or finished goods, which would consume capital resources faster than we anticipate and may cause our supply chain to be less efficient.

Currently Nova is manufacturing illuminators to meet customer demand and maintain our own inventory levels. Subject to obsolescence, we may be required to identify and qualify replacement components for illuminators and in doing so, we may be required to conduct additional studies, which could include clinical trials to demonstrate equivalency or validate any required design or component changes. We and our customers rely on the availability of spare parts to ensure that customer platelet and plasma

production is not interrupted. If we are not able to supply spare parts for the maintenance of customer illuminators, our ability to keep existing customers or sign up new customers may be negatively impacted. Due to the obsolescence of certain parts, we have redesigned the illuminators used in the platelet and plasma systems, and we will need to receive approval of this redesign from the FDA. Our failure to obtain FDA and foreign regulatory approvals of a new illuminator could constrain our ability to penetrate the U.S. market and may otherwise significantly limit product revenue 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. Furthermore, we understand that components used in the redesigned illuminator are no longer commercially available beyond what we and Nova have stockpiled or to which we have access under final buy transactions. We will need to continue investing in subsequent versions of the illuminator to enhance functionality and manage obsolescence. In addition, our illuminators contain embedded proprietary software that runs on software code we have developed and that we own. Changes to certain components due to obsolescence, illuminator redesign or market demand, may require us to modify the existing software code or to develop new illuminator software. Our ability to develop new illuminator software, correct coding flaws and generally maintain the software code is reliant on third-party contractors who, in some cases, have sole knowledge of the software code. Our ability to develop and maintain the illuminator software may be impaired if we are not able to continue contracting with those key third-party contracted developers or if we are unable to source alternate employees or consultants to do so. Software development is inherently risky and may be time consuming and costly.

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

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

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

We may encounter unforeseen manufacturing difficulties which, at a minimum, may lead to higher than anticipated costs, scrap rates, or delays in manufacturing products. In addition, we may not receive timely or accurate demand information from distributors or customers, or may not accurately forecast demand ourselves for the INTERCEPT Blood System. Further, certain distributors and customers require, and potential future distributors or customers may require, product with a minimum shelf life. If customers requiring minimum shelf-lives order smaller quantities or do not purchase product as we anticipate, or at all, we may have elevated inventory levels with relatively short shelf-lives which may lead to increased write-offs and inefficient use of our cash. Should we choose not to fulfill smaller orders with minimum shelf lives, our product sales may be harmed. We will need to destroy or consume

outdated inventory in product demonstration activities, which may in turn lead to elevated product demonstration costs and/or reduced gross margins. In order to meet minimum shelf-life requirements, we may need to manufacture sufficient product to meet estimated forecasted demand. As a result, we may carry excess work-in-process or finished goods inventory, which would consume capital resources and may become obsolete, or our inventory may be inadequate to meet customer demand. Our platelet and plasma systems' disposable kits have 18 to 24 months shelf lives from the date of manufacture. Should we change or modify any of our product configurations or components, such future configurations of our products may not achieve the same shelf life that existing products have. We and our distributors may be unable to ship product to customers prior to the expiration of the product shelf life, a risk that is heightened if we elect to increase our inventory levels in order to mitigate supply disruptions. We have entered into certain public tenders, 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. In addition, certain large national customers, like those in France or the U.K. may choose to convert all of their operation to INTERCEPT. Should we or our suppliers encounter any manufacturing issues, we may not be able to satisfy all of the global demand or may have to allocate available product to certain customers which may negatively impact our customers operations and consequently, our reputation. Conversely, we may choose to overstock inventory in order to mitigate any unforeseen potential disruption to manufacturing which could consume our cash resources faster than we anticipate and may cause our supply chain to be less efficient.

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

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

With respect to the manufacture of our products, our third party manufacturers source components and raw materials for the manufacture of the INTERCEPT processing sets. Certain of these components are no longer commercially available, are nearing end-of-life or are available only from a limited number of suppliers. We and our third party manufacturers do not have guaranteed supply contracts with all of the raw material or component suppliers for our products, which magnify the risk of shortage and obsolescence and decreases our manufacturers' ability to negotiate pricing with their suppliers. Any shortage or obsolescence of raw materials, components or accessories or our inability to control costs associated with raw materials, components or accessories, could increase our costs to manufacture our products. Further, if any supplier to our third party manufacturers is unwilling or unable to provide high quality raw materials in required quantities and at acceptable prices, our manufacturers may be unable to find alternative sources or may fail to find alternative suppliers at commercially acceptable prices, on satisfactory terms, in a timely manner, or at all. If any of these events were to occur, our product quality, competitive position, reputation and business could suffer, we could experience cancellations of customer orders, refusal by customers to accept deliveries or a reduction in our prices and margins to the detriment of our financial performance and results of operations.

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

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

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

Medicaid programs, additional reporting requirements and/or oversight if we become subject to a corporate integrity agreement or similar agreement to resolve allegations of non-compliance with these laws, and the curtailment of our operations. Healthcare fraud and abuse regulations are complex, and even minor irregularities can potentially give rise to claims that a statute or prohibition has been violated. The laws that may affect our ability to operate include, but are not limited to:

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

We are also subject to foreign laws and regulations covering data privacy and the protection of health-related and other personal information. In this regard, E.U. member states and other foreign jurisdictions, including Switzerland, have adopted data protection laws and regulations which impose significant compliance obligations. For example, the E.U. Data Protection Directive, as implemented into national laws by the E.U. member states, imposes strict obligations and restrictions on the ability to collect, analyze and transfer personal data, including health data from clinical trials and adverse event reporting. The E.U. Data Protection Directive prohibits the transfer of personal data to countries outside of the European Economic Area, or EEA, such as the U.S., which are not considered by the European Commission, or EC, to provide an adequate level of data protection. Switzerland has adopted similar restrictions. Although there are legal mechanisms to allow for the transfer of personal data from the EEA and Switzerland to the U.S., a judgment of the European Court of Justice that invalidated the EC decision on the U.S. safe harbor has increased uncertainty around the adequacy of these legal mechanisms. This means that it will no longer be possible to transfer personal data from the E.U. to entities in the U.S. that rely on safe harbor certification as a legal

basis for the transfer of such data. In addition, data protection authorities from the different E.U. member states may interpret the E.U. Data Protection Directive and national laws differently, and guidance on implementation and compliance practices are often updated or otherwise revised, which adds to the complexity of processing personal data in the E.U. If we fail to comply with applicable data privacy laws, or if the legal mechanisms we rely upon to allow for the transfer of personal data from the EEA or Switzerland to the U.S. (or other countries not considered by the EC to provide an adequate level of data protection) are not considered adequate, we could be subject to government enforcement actions and significant penalties against us, and our business could be adversely impacted if our ability to transfer personal data outside of the EEA or Switzerland is restricted, which could adversely impact our operating results. Further, the European Commission has approved a new data protection regulation, known as the General Data Protection Regulation, or GDPR, which was officially adopted in April 2016 and will be applicable in May, 2018. This GDPR is intended to replace the current E.U. Data Protection Directive, and will

introduce new data protection requirements and substantial fines for breaches of the data protection rules. The GDPR will increase our responsibility and liability in relation to personal data that we process, and we may be required to put in place additional compliance mechanisms.

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 United States Patient Protection and Affordable Care Act, or the ACA, 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 ACA provides that the government may assert that a claim including items or services resulting from a violation of the federal Anti-Kickback Statute constitutes a false or fraudulent claim for purposes of the federal False Claims Act. Moreover, while we do not submit claims and our customers make the ultimate decision on how to submit claims, from time-to-time, we may provide reimbursement guidance to our customers. If a government authority were to conclude that we provided improper advice to our customers or encouraged the submission of false claims for reimbursement, we could face action against us by government authorities. Any violations of these laws, or any action against us for violation of these laws, even if we successfully defend against it, could result in a material adverse effect on our reputation, business, results of operations and financial condition.

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

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

In addition, there has been a recent trend of increased U.S. federal and state regulation of payments and transfers of value provided to healthcare professionals or entities. Section 6002 of the ACA, known as the Physician Payments Sunshine Act, 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 $165,786 per year, and up to an aggregate of $1,105,241 per year for "knowing failures." Manufacturers must submit reports by the 90th day of each subsequent calendar year. Due to the difficulty in complying with the Physician Payments Sunshine Act, we cannot assure you that we will successfully report all payments and transfers of value provided by us, and any failure to comply could result in significant fines and penalties. Some states, such as California and Connecticut, also mandate implementation of commercial compliance programs, and other states, such as Massachusetts and Vermont, impose restrictions on device manufacturer marketing practices and tracking and reporting of gifts, compensation and other remuneration to healthcare professionals and entities. The shifting commercial compliance environment and the need to build and maintain robust and expandable systems to comply with different compliance and reporting requirements in multiple jurisdictions increase the possibility that we may fail to comply fully with one or more of these requirements.

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

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

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

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

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

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

- imposes an annual excise tax of 2.3% on entities that manufacture or import eligible medical devices offered for sale in the U.S.;
- establishes a new Patient-Centered Outcomes Research Institute to oversee and identify priorities in comparative clinical effectiveness research in an effort to coordinate and develop such research; and
- 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.

Since its enactment, there have been judicial and Congressional challenges to numerous provisions of the ACA, as well as recent efforts by the Trump administration to repeal or replace certain aspects of the ACA. Since January 2017, President Trump has signed two Executive Orders and other directives designed to delay the implementation of certain provisions of the ACA or otherwise circumvent some of the requirements for health insurance mandated by the ACA. Concurrently, Congress has considered legislation that would repeal or repeal and replace all or part of the ACA. While Congress has not passed comprehensive repeal legislation, two bills affecting the implementation of certain taxes under the ACA have been signed into law. The Tax Cuts and Jobs Act of 2017, or the Tax Act, includes a provision repealing, effective January 1, 2019, the tax-based shared responsibility payment imposed by the ACA on certain individuals who fail to maintain qualifying health coverage for all or part of a year that is commonly referred to as the “individual mandate”. Additionally, on January 22, 2018, President Trump signed a continuing resolution on appropriations for fiscal year 2018 that delayed the implementation of certain ACA-mandated fees, including delaying imposition of the medical device excise tax on non-exempt medical devices through December 31, 2019. Congress may consider additional legislation to repeal or repeal and replace other elements of the ACA. Any repeal and replace legislation may have the effect of limiting the amounts that government agencies will pay for healthcare products and

services, which could result in reduced demand for our products or additional pricing pressure, or may lead to significant deregulation, which could make the introduction of competing products and technologies much easier. Policy changes, including potential modification or repeal of all or parts of the ACA or the implementation of new health care legislation could result in significant changes to the health care system, which could have a material adverse effect on our business, results of operations and financial condition.

In addition, other legislative changes have been proposed and adopted since the ACA was enacted. On August 2, 2011, President Obama signed into law the Budget Control Act of 2011, which, among other things, created the Joint Select Committee on Deficit Reduction to recommend to Congress proposals in spending reductions. The Joint Select Committee did not achieve a targeted deficit reduction of at least $1.2 trillion for the years 2013 through 2021, triggering the legislation's automatic reduction to several government programs. This includes reductions to Medicare payments to providers of 2% per fiscal year, which went into effect in April 2013 and, due to subsequent legislative amendments to the statute, including the Bipartisan Budget Act of 2018, will stay in effect through 2027, 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. More recently, there has been heightened governmental scrutiny in the United States to control the rising cost of healthcare. For example, such scrutiny has resulted in several recent congressional inquiries and proposed and enacted federal and state legislation designed to, among other things, bring more transparency to pricing and reform government program reimbursement methodologies for pharmaceutical products, some of which are included in the Trump administration's budget proposal for fiscal year 2019.

The Trump administration has publicly stated a core goal is to deregulate wherever possible. It is unclear if this contraction in regulation would also apply to guidance documents that would impact our industry. For example, the FDA has indicated that they will finalize guidance prescribing steps blood centers would have to comply with to safeguard platelet products from bacterial contamination. The initial draft guidance prescribed our technology as an option. Should the administration remove such guidance documentation, market uptake for INTERCEPT platelets may be impaired. Conversely, any significant deregulation could make the introduction of competing products and technologies much easier than the burden faced by us in order to receive FDA approval. 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 and plasma products and product candidates are not compatible with some collection, production and storage methods or combinations thereof. Further, blood centers using INTERCEPT must have access to those certain devices, blood bags, assays or platelet additive solutions that are compatible with our products.

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

In order to address the entire market in the U.S., Japan, and potentially elsewhere, we will need to develop and test additional configurations of the platelet system. For example, in the U.S., we understand a significant number of platelet concentrates are derived from larger volumes collected from apheresis donors split into three therapeutic transfusable doses. Future configurations of the platelet system will be needed to treat platelet donations with such processing parameters. We estimate that the majority of platelets used in the U.S. are collected by apheresis, though a

significant minority is prepared from pooled random donor platelets derived from whole blood collections. In addition, many blood centers may view pooled random donor platelets treated with INTERCEPT as an economically optimal approach. In order to gain regulatory approvals for a pathogen reduction system compatible with triple dose collections, and random donor platelets, we will need to perform additional product development and testing, including additional clinical trials. We have conducted and may conduct additional in vitro studies for our platelet system to potentially expand our label claims to include, among others, platelets collected from pooled random donors, storage of INTERCEPT-treated platelets for up to seven days rather than five days, and a new processing set for triple dose collections. In the U.S, our approved labels for the platelet system from the FDA limit our current approvals to certain platelet collection platforms and a particular storage solution for the particular collection platform. For instance, our approved claims permit apheresis collection of platelets on the Fresenius Amicus device while stored in an additive solution or for apheresis collection of platelets collected on the Terumo Trima device and stored in 100% plasma. We may be required to provide the FDA with data for each permutation for which blood banking treatment practices exist which may be time consuming, costly and limit the potential size of the U.S. market that can use our products. Our failure to obtain FDA and foreign regulatory approvals of any new configurations could significantly limit product revenue from sales of the platelet system. In addition, given that there is some loss of platelets using our product, blood centers may need to increase collection volumes in order to use our product and maintain an adequate concentration for a triple therapeutic dose. In any event, delays in receipt or failure to receive approval could reduce our sales and

negatively impact our profitability potential and future growth prospects. Similarly, to achieve market acceptance in certain geographies, we may be required to design, develop and test new product configurations for the platelet and plasma systems. In addition, if the FDA or other regulatory or accrediting body were to mandate safety interventions, including the option of pathogen reduction technology, when we had not received approval for all operational configurations, the market to which we could sell our products may be limited until we obtain such approvals, if ever, or may be permanently impaired if competing options are more broadly available. In addition, we will need to continue to generate acceptable data in order to conform with the evolving collection practices such as automated whole-blood collection. If we are unable to conform to evolving collection practices our ability to address those portions of the market may be compromised. These development activities will increase our costs significantly and may not be successful. We may need to demonstrate the safety and efficacy of our platelet system using a variety of configurations before our platelet system would be approved for such configurations. Delays in obtaining any future approvals would adversely affect our ability to introduce new or enhanced products in a timely manner, which in turn would harm our product revenue and potential future profitability.

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

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

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

These alternative strategies may be more effective in reducing certain types of pathogens from blood products, including certain non-lipid-enveloped viruses, such as hepatitis A and E viruses, which our products have not demonstrated an ability to inactivate, or human parvovirus B-19, which is also a non-lipid-enveloped virus, for which our products have not demonstrated a high level of inactivation. While studies have demonstrated that our products can effectively inactivate a broad spectrum of pathogens in blood components, market adoption of our products may be reduced if customers determine that competitors' products inactivate a broader range of pathogens that are of particular interest to the transfusion medicine community. In addition, customers and prospective customers may believe that our competitors' products are safer, more cost effective or easier to implement and incorporate into existing blood processing procedures than INTERCEPT Blood System products. In Europe, several companies, including Grifols S.A., Octapharma AG, MacoPharma International and Kedrion Biopharma, are developing or selling commercial pathogen reduction systems or services to treat fresh frozen plasma.

MacoPharma has received CE Mark for a UVC-based product for pathogen reduced platelets. MacoPharma currently has a Phase 3 clinical trial underway in Germany to generate additional data for expanded approvals. In addition, Terumo BCT, a subsidiary of Terumo Corporation, has developed a pathogen reduction system for blood products and

has been issued CE marks for its system for both platelets and plasma. We further understand that Terumo BCT developed a pathogen reduction system for whole blood and has recently completed a clinical trial of its whole blood system in Ghana, receiving a Class II CE mark. Terumo BCT's products may offer competitive advantages over our INTERCEPT Blood System. Terumo Corporation is a large Japanese-based, multinational corporation with more mature products and relationships than we have. Our ability to commercialize our products in certain markets, particularly in Japan, may be negatively affected by Terumo BCT's resources and their pre-existing relationships with regulators and customers. Should Terumo BCT's product be approved for use and commercialized in Japan, our products would likely directly compete with their products and we believe we would likely either need to establish operations in Japan or partner with a local Japanese company.

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

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

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

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

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

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

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

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

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

The FDA and similar foreign governmental authorities have the authority to require the recall of commercialized products in the event of material deficiencies or defects in design or manufacture of a product or in the event that a product poses an unacceptable risk to health. The FDA's authority to require a recall must be based on an FDA finding that there is reasonable probability that the device would cause serious injury or death. Manufacturers may also, under their own initiative, recall a product if any material deficiency in a device is found or withdraw a product to improve device performance or for other reasons. The FDA requires that certain classifications of recalls be reported to the FDA within ten working days after the recall is initiated. A government-mandated or voluntary recall by us or one of our distributors could occur as a result of an unacceptable risk to health, component failures,

malfunctions, manufacturing errors, design or labeling defects or other deficiencies and issues. Regulatory agencies in other countries have similar authority to recall devices because of material deficiencies or defects in design or manufacture that could endanger health. Any recall would divert management attention and financial resources and could cause the price of our stock to decline, expose us to product liability or other claims and harm our reputation with customers. Such events could impair our ability to supply our products in a cost-effective and timely manner in order to meet our customers' demands. Companies are required to maintain certain records of recalls, even if they are not reportable to the FDA or similar foreign governmental authorities. We may initiate voluntary recalls involving our products in the future that we determine do not require notification of the FDA or foreign governmental authorities. If the FDA or foreign governmental authorities disagree with our determinations, they could require us to report those actions as recalls. A future recall announcement could harm our reputation with customers and negatively affect our sales. In addition, the FDA or a foreign governmental authority could take enforcement action for failing to report the recalls when they were conducted.

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

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

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

Our near-term capital requirements are dependent on various factors, including operating costs and working capital investments associated with commercializing the INTERCEPT Blood System, including in connection with the continuing U.S. commercial launch of our platelet and plasma systems, costs to develop different configurations of existing products and new products, including our illuminator, costs associated with planning, enrolling and completing ongoing studies, and the post-approval studies we are required to conduct in connection with the FDA approval of the platelet system, costs associated with pursuing potential regulatory approvals in other geographies where we do not currently sell our platelet and plasma systems, costs associated with conducting in vitro studies and clinical development of our red blood cell system in Europe and the U.S., costs associated with performing the agreed-upon activities under our BARDA agreement, and costs related to creating, maintaining and defending our intellectual property. Our long-term capital requirements will also be dependent on the success of our sales efforts, competitive developments, the timing, costs and magnitude of our longer-term clinical trials and other development activities related to our platelet, plasma and red blood cell systems, including required post-approval studies for the platelet system, market preparedness and product launch activities for any of our products in geographies where we do not currently sell our products, and regulatory factors. Until we are able to generate a sufficient amount of product revenue and generate positive net cash flows from operations, which we may never do, meeting our long-term capital

requirements is in large part reliant on continued access to funds under our BARDA agreement and the public and private equity and debt capital markets, as well as on collaborative arrangements with partners, augmented by cash generated from operations and interest income earned on the investment of our cash balances. While we believe that our available cash and cash equivalents and short-term investments, as well as cash received from product sales and under our agreement with BARDA, will be sufficient to meet our capital requirements for at least the next twelve months, if we are unable to generate sufficient product revenue, or access sufficient funds under our BARDA agreement or the public and private equity and debt capital markets, we may be unable to execute successfully on our operating plan. We have based our cash sufficiency estimate on assumptions that may prove to be incorrect. If our assumptions prove to be incorrect, we could consume our available capital resources sooner than we currently expect or in excess of amounts than we currently expect, which could adversely affect our commercialization and clinical development activities.

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 amended and restated loan and security agreement, or the Amended Credit 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, financial performance covenants and repayment provisions that reduce cash resources and limit future access to capital markets. In addition, we expect to continue to opportunistically seek access to the equity capital markets to support our development efforts and

operations. To the extent that we raise additional capital by issuing equity securities, our stockholders may experience substantial dilution. To the extent that we raise additional funds through collaboration or partnering arrangements, we may be required to relinquish some of our rights to our technologies or rights to market and sell our products in certain geographies, grant licenses on terms that are not favorable to us, or issue equity that may be substantially dilutive to our stockholders.

While we expect to receive significant funding under our five-year agreement with BARDA, our ability to obtain the funding we expect to receive under the agreement is subject to various risks and uncertainties, including with respect to BARDA's ability to terminate the agreement for convenience at any time and our ability to achieve the required milestones under the agreement. In addition, access to federal contracts is subject to the authorization of funds and approval of our research plans by various organizations within the federal government, including the U.S. Congress. The general economic environment, coupled with tight federal budgets, has led to a general decline in the amount available for government funding. If BARDA were to eliminate, reduce or delay funding under our agreement, this would have a significant negative impact on the programs associated with such funding and could have a significant negative impact on our revenues and cash flows. In addition, if we are unable to generate sufficient perquisite Phase 3 clinical data and/or reach agreement with the FDA on a Phase 3 clinical trial design for our red blood cell system, our agreement with BARDA will be severely limited in scope or could be terminated altogether, and our ability to complete the development activities required for licensure in the U.S. may require additional capital beyond which we currently have. If alternative sources of funding are not available, we may be forced to suspend or terminate development activities related to the red blood cell system in the U.S.

As a result of economic conditions, general global economic uncertainty, political change, and other factors, we do not know whether additional capital will be available when needed, or that, if available, we will be able to obtain additional capital on reasonable terms. If we are unable to raise additional capital due to the volatile global financial markets, general economic uncertainty or other factors, we may need to curtail planned development or commercialization activities. In addition, we may need to obtain additional funds to complete development activities for the red blood cell system necessary for potential regulatory approval in Europe, if costs are higher than anticipated or we encounter delays. We may need to obtain additional funding to conduct additional randomized controlled clinical trials for existing or new products, particularly if we are unable to access any additional portions of the funding contemplated by our BARDA agreement, and we may choose to defer such activities until we can obtain sufficient additional funding or, at such time, our existing operations provide sufficient cash flow to conduct these trials.

Covenants in our Amended Credit 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 Amended Credit Agreement.

Our Amended Credit Agreement with Oxford Finance provides $40.0 million of term loan funds, due July 1, 2022, of which $30.0 million 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 Amended Credit Agreement. The Amended Credit 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. In addition, receipt of a qualified audit opinion (other than as to going concern or a qualification resulting solely from the scheduled maturity of term loans occurring within one year from the date such opinion is delivered) would be a violation of an affirmative covenant under the Amended

Credit Agreement. While we believe that our available cash and cash equivalents and short-term investments, as well as cash to be received from product sales and under our agreement with BARDA, will be sufficient to meet our capital requirements for at least the next twelve months, if we are unable to generate sufficient product revenue, or access sufficient funds under our BARDA agreement or the public and private equity and debt capital markets, we may be unable to execute successfully on our operating plan. Our failure to comply with any of the covenants could result in a default under the Amended Credit Agreement, which could permit the lenders to declare all or part of any outstanding borrowings to be immediately due and payable, or to refuse to permit additional borrowings under the Amended Credit Agreement. If we are unable to repay those amounts, the lenders under the Amended Credit Agreement could proceed against the collateral granted to them to secure that debt, which would seriously harm our business. In addition, should we be unable to comply with these covenants or if we default on any portion of our outstanding borrowings, the lenders can also impose a 5% penalty. Moreover, our ability to access the final $10.0 million under the Amended Credit Agreement is subject to our ability to achieve a certain revenue threshold, which condition we may not be able to meet and which could adversely affect our liquidity. Before we would consider accessing the final $10.0 million under the Amended Credit Agreement, if available, 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.

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. As use of information technology systems has increased, deliberate attacks and attempts to gain unauthorized access to computer systems and networks have increased in frequency and sophistication. Our information technology, systems and networks 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. We are also potentially vulnerable to data security breaches—whether by employees or others—which may expose sensitive data to unauthorized persons. For example, we have in the past and may in the future be subject to “phishing” attacks in which third parties send emails purporting to be from reputable sources. Phishing attacks may attempt to obtain personal information, infiltrate our systems to initiate wire transfers or otherwise obtain proprietary or confidential information. Although we have not experienced any losses as a result of such attacks or any other breaches of data security, such breaches could lead to the loss of trade secrets or other intellectual property, or could lead to the public exposure of personal information (including sensitive personal information) of our employees, clinical trial patients, distributors, customers and others. Breaches and other inappropriate access can be difficult to detect and any delay in identifying them could increase their harm. While we have implemented security measures to protect our data security and information technology systems, such measures may not prevent such events. Any such breaches of security and inappropriate access could disrupt our operations, harm our reputation or otherwise have a material adverse effect on our business, financial condition and results of operations.

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, ability to perform under our BARDA agreement, or results of operations and growth prospects could be adversely affected. Even if we are able to identify and hire qualified personnel commensurate with our growth objectives and opportunities, the process of integrating new employees is time consuming, costly and distracting to existing employees and management. Such disruptions may have an adverse impact on our operations, our ability to service existing markets and customers, or our ability to comply with regulations and laws.

All of the employees of our subsidiary, Cerus Europe B.V., are employed outside the U.S., including in France, where labor and employment laws are relatively stringent and, in many cases, grant significant job protection to certain employees, including rights on termination of employment. In addition, one of our manufacturing partners that we are dependent on is located in France and may

have employees that are members of unions or represented by a works council as required by law. These more stringent labor and employment laws to the extent that they are applicable, coupled with the requirement to consult with the relevant unions or works' councils, could increase our operational costs with respect to our own employees and could result in passed through operational costs by our manufacturing partner. If the increased operational costs become significant, our business, financial condition and results of operations could be adversely impacted.

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

Our ability to use our federal and state net operating loss, or NOL, carryforwards to offset potential future taxable income and related income taxes that would otherwise be due is dependent upon our generation of future taxable income before the expiration dates of the NOL carryforwards, and we cannot predict with certainty when, or whether, we will generate sufficient taxable income to use all of our NOL carryforwards. On December 22, 2017, President Trump signed into law the Tax Act. Under the Tax Act, federal net operating losses incurred in 2018 and in future years may be carried forward indefinitely, but the deductibility of such federal net operating losses is limited. It is uncertain if and to what extent various states will conform to the Tax Act. In addition, utilization of NOL carryforwards to offset potential future taxable income and related income taxes that would otherwise be due is subject to annual limitations under the "ownership change" provisions of Sections 382 of the Internal Revenue Code of 1986, as amended, or the Code, and similar state provisions, which may result in the expiration of NOL carryforwards before future utilization. In general, under the Code, if a corporation undergoes an "ownership change," generally defined as a greater than 50% change (by value) in its equity ownership over a three-year period, the corporation's ability to use its pre-change NOL carryforwards and other pre-change tax attributes (such as research and development credit carryforwards) to offset its post-change taxable income or taxes may be limited. Our equity offerings and other changes in our stock ownership, some of which are outside of our control, may have resulted or could in the future result in an ownership change. Although we have completed studies to provide reasonable assurance that an ownership change limitation would not apply, we cannot be certain that a taxing authority would reach the same conclusion. If, after a review or audit, an ownership change limitation were to apply, utilization of our domestic NOL and tax credit carryforwards could be limited in future periods and a portion of the carryforwards could expire before being available to reduce future income tax liabilities.

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

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

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

We cannot be certain that our patents or patents that we license from others will be enforceable and afford protection against competitors. Our patents or patent applications, if issued, may be challenged, invalidated or circumvented. Our patent rights may not provide us with proprietary protection or competitive advantages against competitors with similar technologies. Others may independently develop technologies similar to ours or independently duplicate our technologies. For example, we are aware of a recently expired U.S. patent issued to a third-party that covers methods to remove psoralen compounds from blood products. We have reviewed the patent and believe there exist substantial questions concerning its validity. We cannot be certain, however, that a court would hold the patent to be invalid or not infringed by our platelet or plasma systems. In this regard, whether or not we have infringed this patent will not be

known with certainty unless and until a court interprets the patent in the context of litigation. In the event that we are found to have infringed any valid claim of this patent, we may, among other things, be required to pay damages. Our patents expire at various dates between 2018 and 2031. Recent patent applications will, if granted, result in patents with later expiration dates. In addition, we have a license from Fresenius to U.S. and foreign patents relating to the INTERCEPT Blood System, which expire at various dates between 2018 and 2024. Due to the extensive time required for development, testing and regulatory review of our potential products, our patents may expire or remain in existence for only a short period following commercialization. This would reduce or eliminate any advantage of the patents.

We cannot be certain that we were the first to make the inventions covered by each of our issued patents or pending patent applications or that we were the first to file patent applications for such inventions. We may need to license the right to use third-party patents and intellectual property to continue development and commercialization of our products, including in connection with our

planned commercialization of the platelet and plasma systems in the U.S. We may not be able to acquire such required licenses on acceptable terms, if at all. If we do not obtain such licenses, we may need to design around other parties' patents, or we may not be able to proceed with the development, manufacture or sale of our products.

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

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

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

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

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

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

Additionally, the Trump administration has called for substantial changes to foreign trade policy and has raised the possibility of imposing significant increases in tariffs on international trade. We also rely on various U.S. corporate tax provisions related to international commerce. If we are subject to new regulations, including those under the Tax Act, or if restrictions and tariffs increase our operating costs in the future, and we are not able to recapture those costs from our customers, or if such initiatives, regulations, restrictions or tariffs make it more difficult for us to compete in overseas markets, our business, financial condition and results of operations could be adversely impacted.

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

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

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

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

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

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

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

The recently passed comprehensive tax reform bill could adversely affect our business and financial condition.

The Tax Act significantly changes the Internal Revenue Code of 1986, as amended. The Tax Act, among other things, contains significant changes to corporate taxation, including reduction of the corporate tax rate on future earnings to 21%, limitation of the future tax deduction for net interest expense, limitation of the deduction for future net operating losses to 80% of current year taxable income and elimination of net operating loss carrybacks, changes in the treatment of offshore earnings regardless of whether they are repatriated, mandatory capitalization of research and development expenses, further deduction limits on executive compensation and modifying, repealing and creating many other business deductions and credits. Our federal net operating loss carryovers generated in 2018 and thereafter will be carried forward indefinitely pursuant to the Tax Act. We continue to examine the impact this tax reform legislation may have on our business. Notwithstanding the reduction in the corporate income tax rate, the overall impact of the Tax Act is uncertain and our business and financial condition could be adversely affected. In addition, it is uncertain if and to what extent various states will conform to the Tax Act. The impact of the Tax Act on holders of our common stock is also uncertain and could be adverse. We urge our stockholders to consult with their legal and tax advisors with respect to such legislation and the potential tax consequences of investing in our common stock.

Item 1B. Unresolved Staff Comments
None.

Item 2. Properties
Our corporate headquarters, which includes our principal executive offices, is located in Concord, California. This leased facility includes laboratory space for blood safety research and supports general administrative, marketing and

technical support functions. We also lease a facility in Amersfoort, the Netherlands, which is used for selling and administrative functions. In February 2018, we entered into a lease arrangement for our new corporate headquarters in Concord, California. The lease term commences upon completion of the buildout of the space and continues for 133 full calendar months. We believe that our current and future facilities will be adequate for the foreseeable future. The following table summarizes the properties we lease and their location, size, term and primary functions as of December 31, 2017.

Locations	Square Footage	Lease Expiration Date	Primary Functions
Concord, CA, United States	36,029	November 2019	Administrative and research
Concord, CA, United States	7,702	September 2019	Administrative and warehouse
Concord, CA, United States	6,655	December 2019	Administrative and research
Concord, CA, United States	21,440	July 2019	Sales, administrative, marketing and technical support
Amersfoort, Netherlands	7,300	January 2023	Sales and administrative

Item 3. Legal Proceedings
None.

Item 4. Mine Safety Disclosures
Not applicable.

PART II

Item 5. Market for Registrant's Common Equity, Related Stockholder Matters and Issuer Purchases of Equity Securities

Our common stock is traded on the Nasdaq Global Market under the symbol "CERS." The following table sets forth, for the periods indicated, the high and low intra-day sales prices for our common stock as reported by the Nasdaq Global Market:

	High	Low
Year Ended December 31, 2017:		
First Quarter	$4.58	$3.91
Second Quarter	4.61	2.02
Third Quarter	2.73	2.15
Fourth Quarter	3.95	2.76
Year Ended December 31, 2016:		
First Quarter	$6.66	$4.81
Second Quarter	6.89	4.90
Third Quarter	7.64	5.79
Fourth Quarter	6.34	4.17

On February 22, 2018, the last reported sale price of our common stock on the Nasdaq Global Market was $4.27 per share. On February 22, 2018, we had 139 holders of record of our common stock.

Dividends

We have not declared or paid dividends on our common stock and do not intend to pay cash dividends on our common stock in the foreseeable future. Additionally, any cash dividends declared or paid would require prior written consent under the terms of the amended and restated loan and security agreement entered on July 31, 2017, with Oxford Finance LLC.

Stock Performance Graph [1]

The following graph shows the total stockholder return of an investment of $100 in cash (and the reinvestment of any dividends thereafter) on December 31, 2012, and tracked the performance through December 31, 2017, for (i) our common stock, (ii) the Nasdaq Biotechnology Index, (iii) the NYSE ARCA Biotechnology Index, and (iv) the Nasdaq Stock Market (United States) Index. Our stock price performance shown in the graph below is based upon historical data and is not indicative of future stock price performance.

Comparison of 5-year Cumulative Total Return on Investment

	December 31,					
	2012	2013	2014	2015	2016	2017
Cerus Corporation	$100.00	$204.11	$197.47	$200.00	$137.66	$106.96
Nasdaq Biotech Index	100.00	165.61	222.08	247.44	193.79	234.60
NYSE ARCA Biotech Index	100.00	150.64	222.30	246.53	198.77	272.92
Nasdaq	100.00	138.32	156.85	165.84	178.28	228.63

[1] The graph and the other information furnished in this section is not “soliciting material,” is not deemed “filed” with the SEC and is not to be incorporated by references to any filing of Cerus Corporation under the Securities Act of 1933 or the Securities Act of 1934, whether made before or after the date hereof and irrespective of any general incorporation language in such filing.

Item 6. Selected Financial Data

The following table summarizes certain selected financial data for the five years ended December 31, 2017, which has been derived from audited consolidated financial statements. The information presented below may not be indicative of future results and should be read in conjunction with "Item 7—Management's Discussion and Analysis of Financial Condition and Results of Operations," and the consolidated financial statements and notes thereto included elsewhere in this Annual Report on Form 10-K.

	Year Ended December 31,				
(in thousands, except per share amounts)	2017	2016	2015	2014	2013
Consolidated Statements of Operations Data:					
Product revenue	$43,568	$37,183	$34,223	$36,416	$39,657
Cost of product revenue	22,531	20,295	23,464	21,188	22,602
Gross profit on product revenue	21,037	16,888	10,759	15,228	17,055
Government contract revenue	7,758	2,092	—	—	—
Loss from operations	(57,530)	(61,447)	(61,075)	(44,503)	(28,299)
Net loss	(60,585)	(62,906)	(55,868)	(38,755)	(43,337)
Net loss per share:					
Basic	$(0.56)	$(0.62)	$(0.58)	$(0.52)	$(0.64)
Diluted	$(0.56)	$(0.62)	$(0.61)	$(0.61)	$(0.64)
Weighted average shares outstanding used for calculating loss per share:					
Basic	108,221	101,826	96,068	74,767	67,569
Diluted	108,221	101,826	96,905	76,534	67,569

	December 31,				
(in thousands)	2017	2016	2015	2014	2013
Consolidated Balance Sheets Data:					
Cash, cash equivalents, short-term investments and investment in marketable equity securities	$60,696	$71,628	$107,879	$51,294	$57,676
Working capital	66,767	67,217	108,544	45,736	38,730
Total assets	98,244	103,476	139,402	81,669	83,381
Long-term obligations	36,173	18,801	22,775	10,998	1,162
Total stockholders' equity	38,940	57,787	94,765	41,521	42,795

Item 7. Management's Discussion and Analysis of Financial Condition and Results of Operations

This discussion and analysis should be read in conjunction with our audited consolidated financial statements and the accompanying notes thereto included in this Annual Report on Form 10-K for the year ended December 31, 2017. Operating results for the year ended December 31, 2017, are not necessarily indicative of results that may occur in future periods.

Overview

Since our inception in 1991, we have devoted substantially all of our efforts and resources to the research, development, clinical testing and commercialization of the INTERCEPT Blood System. The INTERCEPT Blood System is designed for three blood components: platelets, plasma and red blood cells. The INTERCEPT Blood System for platelets, or platelet system, and the INTERCEPT Blood System for plasma, or plasma system, have received CE marks and U.S. Food and Drug Administration, or FDA, approval and are being marketed and sold in a number of countries around the world. We sell both the platelet and plasma systems using our direct sales force and through distributors.

The platelet system is approved in the U.S. for ex vivo preparation of pathogen-reduced apheresis platelet components collected and stored in 100% plasma or InterSol in order to reduce the risk of transfusion-transmitted infection, or TTI, including sepsis, and to potentially reduce the risk of transfusion-associated graft versus host disease or TA-GVHD. As part of the FDA's approval of the platelet system, we are required to successfully conduct and complete two post-approval studies - a haemovigilance study to evaluate the incidence of acute lung injury following transfusion of INTERCEPT treated platelets; and a recovery study of platelets treated with the platelet system that is currently in discussion with FDA. The plasma system is approved in the U.S. for ex vivo preparation of plasma in order to reduce the risk of TTI when treating patients requiring therapeutic plasma transfusion.

The INTERCEPT Blood System for red blood cells, or the red blood cell system, is currently in development and has not been commercialized anywhere in the world. We announced the successful completion of our European Phase 3 clinical trial of our red blood cell system for acute anemia patients in January 2015, and in January 2018, we reported that the primary efficacy and safety endpoints were successfully achieved in our European Phase 3 clinical trial for chronic anemia patients. Based on the results of those trials, we plan to submit for CE mark approval in the European Union in the second half of 2018. In the U.S., we successfully completed a Phase 2 recovery and lifespan study in 2014. In 2017, we initiated a Phase 3 clinical, double-blind study, known as the ReDeS study, to assess the safety and efficacy of INTERCEPT-treated red blood cells when compared to conventional red blood cells in regions impacted by the Zika virus epidemic. Also in 2017, we received investigational device exemption, or IDE, approval from the FDA to initiate a Phase 3 clinical trial, known as the ReCePI study, that is designed to evaluate the efficacy and safety of INTERCEPT-treated red blood cells in patients requiring transfusion for acute blood loss during surgery. In addition to successfully conducting and completing the ReDeS and ReCePI studies, we will need to successfully conduct and complete an additional Phase 3 clinical trial for chronic anemia in the U.S. before the FDA will consider our red blood cell product for approval. We also understand that one or more additional in vitro studies will be required to be successfully completed and submitted to the FDA prior to any initiation of a potential Phase 3 clinical trial. There can be no assurance that we will be able to successfully satisfy any such in vitro studies, nor can there be any assurance that we and the FDA will agree to any trial protocol we propose or that we will otherwise obtain FDA clearance to initiate a potential Phase 3 clinical trial. Although we plan to complete additional development activities to support an anticipated CE mark submission for the red blood cell system, such development activities could prolong development of our red blood cell system, and we do not expect to receive any regulatory approvals of our red blood cell system in the next twelve months, if ever. We must demonstrate an ability to define, test and meet acceptable specifications for our GMP manufactured compounds used to prepare INTERCEPT-treated red blood cells before we can submit and seek regulatory approval of our red blood cell system. Developing a methodology and assay that is sufficiently sensitive and robust may be time consuming, and delays or failures in such development efforts

could in-turn delay our ability to obtain regulatory approvals. We understand that while the data generated from our European Phase 3 clinical trials may be sufficient to receive CE mark approval, we may need to generate additional safety data from commercial use in order to achieve broad market acceptance. In addition, these trials may need to be supplemented by additional, successful Phase 3 clinical trials for approval in certain countries. If such additional Phase 3 clinical trials are required, they would likely need to demonstrate equivalency of INTERCEPT-treated red blood cells compared to conventional red blood cells and significantly lower lifespan for INTERCEPT-treated red blood cells compared to non-treated red blood cells may limit our ability to obtain any regulatory approvals for the red blood cell system. As part of our development activities, we will need to successfully complete a number of in vitro studies prior to receiving any regulatory approvals in Europe and certain additional activities, including the ReDeS and ReCePI studies and an additional Phase 3 clinical trial for chronic anemia in the U.S., prior to receiving any regulatory approvals in the U.S. Successful completion of these activities may require capital beyond that which we currently have or that may be available to us under our agreement with the Biomedical Advanced Research and Development Authority, or BARDA, and we may be required to obtain additional capital in order to complete the development of and obtain any regulatory approvals for the red blood cell system. In addition, if we are unable to develop sufficient quantities of the active compounds for our products meeting defined quality and regulatory specifications or if our suppliers are not able to maintain regulatory compliance, we may experience delays in testing, conducting trials or obtaining approvals, and our product development costs would likely increase.

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

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

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 amended and restated loan and security agreement, or Amended Credit 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, financial performance covenants and repayment provisions that reduce cash resources and limit future access to capital markets. In addition, we expect to continue to opportunistically seek access to the equity capital markets to support our development efforts and operations. To the extent that we raise additional capital by issuing equity securities, our stockholders may experience substantial dilution. To the extent that we raise additional funds through collaboration or partnering arrangements, we may be required to relinquish some of our rights to our technologies or rights to market and sell our products in certain geographies, grant licenses on terms that are not favorable to us, or issue equity that may be substantially dilutive to our stockholders.

As a result of economic conditions, general global economic uncertainty, political change, and other factors, we do not know whether additional capital will be available when needed, or that, if available, we will be able to obtain additional capital on reasonable terms. If we are unable to raise additional capital due to the volatile global financial markets, general economic uncertainty or other factors, we may need to curtail planned development or commercialization activities. In addition, we may need to obtain additional funds to complete development activities for the red blood cell system necessary for potential regulatory approval in Europe, if costs are higher than anticipated or we encounter delays. We may need to obtain additional funding to conduct additional randomized controlled clinical trials for existing or new products, particularly if we are unable to access any additional portions of the funding contemplated by our BARDA agreement, and we may choose to defer such activities until we can obtain sufficient additional funding or, at such time, our existing operations provide sufficient cash flow to conduct these trials.

Although we received FDA approval of our platelet and plasma systems in December 2014, our U.S. commercial efforts in 2017 continued to be, and in 2018 will continue to be, largely focused on implementing INTERCEPT to customers with whom we have previously signed agreements and continuing to develop awareness of INTERCEPT's product profile relative to other platelet and plasma products, including conventional, un-treated components. Significant product revenue from customers in the U.S. may not occur, if at all, until we have been able to successfully implement the platelet and plasma systems and demonstrate that they are economical, safe and efficacious for potential customers.

Outside of the U.S., we recognize product revenues from the sale of our platelet and plasma systems in a number of countries around the world including those in Europe, the Commonwealth of Independent States, or CIS, and the Middle East. In 2018, we plan to focus commercial efforts on supporting continued use of INTERCEPT by existing customers and supporting the national adoption of the platelet system in France. However, since no purchase volume commitments have been made by the Établissement Français du Sang, or EFS, for the French market significant product revenue from the French market may not occur or may not consistently occur quarter-over-quarter. National deployment of the INTERCEPT Blood System for platelets throughout France will require a coordinated and highly managed roll-out and any set back or failure could negatively impact the timing and success of adoption. We cannot provide any assurance that national deployment of INTERCEPT in France would be sustainable, should it occur, or that we will be able to secure any subsequent contracts with EFS or that the terms, including the pricing or committed volumes, if any, of any future contract will be equivalent or superior to the terms under our current contract.

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

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

Fresenius

Fresenius Kabi AG, or Fresenius, manufactures and supplies the platelet and plasma systems to us under a supply agreement, or Supply Agreement. Fresenius is obligated to sell, and we are obligated to purchase, finished disposable kits for our platelet, plasma and red blood cell systems. The Supply Agreement permits us to purchase platelet, plasma and red blood cell systems from third parties to the extent necessary to maintain supply qualifications with such third parties or where local or regional manufacturing is needed to obtain product registrations or sales. Pricing terms are initially fixed and decline at specified annual production levels, and are subject to certain adjustments after the initial pricing term.

The Supply Agreement requires us to make certain payments totaling €8.6 million, or the Manufacturing and Development Payments, to Fresenius in 2016 and on December 31 of the earlier of (a) the year of achievement of certain production volumes or (b) 2022. In 2016, we paid €3.1 million to Fresenius. Because these payments represent unconditional payment obligations, we recognize our liability for these payments at their net present value at discount rate of 9.72% based on our effective borrowing rate at that time. The Manufacturing and Development Payments liability is accreted through interest expense based on the estimated timing of its ultimate settlement. As of December 31, 2017, we had accrued $5.8 million (€4.8 million) related to the Manufacturing and Development Payments.

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

The initial term of the Supply Agreement extends through July 1, 2025, or the Initial Term, and is automatically renewed thereafter for additional two year terms, or Renewal Terms, subject to termination by either party upon (i) two years written notice prior to the expiration of the Initial Term or (ii) one year written notice prior to the expiration of any Renewal Term. Under the Supply Agreement, we have the right, but not the obligation, to purchase certain assets and assume certain liabilities from Fresenius. In the event that Fresenius refuses or is unable to continue operating under the Supply Agreement, we may be unable to maintain inventory levels or otherwise meet customer demand, and our business and operating results would be materially and adversely affected.

Likewise, if we conclude that supply of the INTERCEPT Blood System or components from Fresenius and others is uncertain, we may choose to build and maintain inventories of raw materials, work-in-process components, or finished goods, which would consume capital resources faster than we anticipate and may cause our supply chain to be less efficient. Like most regulated manufacturing processes, our ability to produce our products is dependent on our or our suppliers' ability to source components and raw materials which may at times be in short demand or obsolete. In such cases, we and/or Fresenius or other suppliers may need to source, qualify

and obtain approval for replacement materials or components which would likely prove to be disruptive and consume capital resources sooner than we anticipate.

BARDA

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

The five-year agreement with BARDA provides for the reimbursement of certain amounts incurred by us in connection with our satisfaction of certain contractual milestones. Under the agreement, we are reimbursed and recognize revenue as qualified direct contract costs are incurred plus allowable indirect costs, based on approved provisional indirect billing rates, which permit recovery of fringe benefits, overhead and general and administrative expenses. BARDA has exercised its option to provide reimbursement of our expenses during a base period, or the Base Period, and has exercised options, or Option Periods, of up to $88.2 million for expenses related to the clinical development of the red blood cell system. If we were to satisfy subsequent milestones and BARDA were to exercise additional Option Periods, the total funding opportunity under the BARDA agreement could reach up to $186.2 million over the five-year agreement period. If exercised by BARDA in its sole discretion, each subsequent Option Period would fund activities related to broader implementation of the platelet and plasma system or the red blood cell system in areas of Zika virus risk, clinical and regulatory development programs in support of the potential licensure of the red blood cell system in the U.S., and development, manufacturing and scale-up activities for the red blood cell system. We are currently responsible for co-investment of approximately $5.0 million, and would be responsible for an additional $9.6 million, if certain additional Option Periods were exercised by BARDA. BARDA will make periodic assessments of our progress and the continuation of the agreement is based on our success in completing the required tasks under the Base Period and each exercised Option Period. BARDA has rights under certain contract clauses to terminate the agreement, including the ability to terminate for convenience at any time.

Although BARDA has committed to reimburse us for up to $88.2 million in expenses to date, we may not receive all of these funds if BARDA were to terminate the agreement. Amounts invoiced and currently payable under the BARDA agreement are subject to future audits at the discretion of the government. These audits could result in an adjustment to revenue previously reported, which potentially could be significant.

Equity and Debt Agreements

Cantor

On May 5, 2016, we entered into Amendment No. 2 to the Controlled Equity Offering^{SM} Sales Agreement, dated August 31, 2012, as previously amended on March 21, 2014, which together we refer to as the Prior Cantor Agreement, with Cantor Fitzgerald & Co., or Cantor, that provided for the issuance and sale of shares of our common stock over the term of the Cantor Agreement having an aggregate offering price of up to $132.2 million, $70.0 million of which was available at May 5, 2016, through Cantor. During the years ended December 31, 2017 and 2016, 11.0 million and 3.5 million shares, respectively, of our common stock were sold under the Prior Cantor Agreement for aggregate net proceeds of $30.3 million and $22.0 million, respectively.

On August 4, 2017, we entered into Amendment No. 3 to the Prior Cantor Agreement (together, the “Amended Cantor Agreement”). The Amended Cantor Agreement became effective on January 8, 2018, and provides for the issuance and sale of shares of our common stock having an aggregate offering price of up to $70.0 million through Cantor, which

amount includes the $31.4 million of unsold shares of common stock available for sale under the Prior Cantor Agreement immediately prior to the effectiveness of the Amended Cantor Agreement. Under the Amended Cantor Agreement, Cantor also acts as our sales agent and receives compensation based on an aggregate of 2% of the gross proceeds on the sale price per share of its common stock. The issuance and sale of these shares by us pursuant to the Amended Cantor Agreement are deemed an “at-the-market” offering and are registered under the Securities Act of 1933, as amended.

Debt Agreement

Prior to December 31, 2016, we maintained a five year loan and security agreement with Oxford Finance, or the Term Loan Agreement, under which we borrowed $20.0 million. We received $10.0 million from the first tranche, or Term Loan A, in June 2014. In June 2015, we received $10.0 million from the second tranche, or Term Loan B. Term Loan A bore an interest rate of 6.95%, and Term Loan B bore an interest rate of 7.01%. Term Loans A and B were set to mature on June 1, 2019, with various interest only periods.

On April 27, 2017, the Oxford Term Loan Agreement was amended to include an additional interest-only period for all advances under the Term Loan Agreement. As amended, we were required to make interest only payments from May 2017 through December 2017 followed by eighteen months of equal principal and interest payments thereafter. We were also required to make a final payment equal to 7% of the principal amounts of the Term Loans drawn payable on the earlier to occur of maturity or prepayment.

On July 31, 2017, we entered into an amended and restated loan and security agreement, or the Amended Credit Agreement, which amended and restated the Term Loan Agreement in its entirety. The Amended Credit Agreement provides for secured growth capital term loans, or 2017 Term Loans, of up to $40.0 million. All of our current and future assets, excluding our intellectual property and 35% of our investment in Cerus Europe B.V., are secured for the borrowings under the Amended Credit Agreement. The 2017 Term Loans are available in two tranches. The first tranche of $30.0 million, or 2017 Term Loan A, was drawn by us on July 31, 2017, with the proceeds in part to repay in full all of the outstanding the term loans under the Term Loan Agreement of $17.6 million and the final payment of the Term Loan Agreement of $1.4 million. The second tranche of $10.0 million, or 2017 Term Loan B, will be made available to us upon our achieving consolidated trailing six-month revenues as defined in the agreement, or the Revenue Milestone. If the Revenue Milestone is achieved, we may draw the 2017 Term Loan B through the earlier of (i) January 31, 2019, and (ii) the date which is 60 days after the achievement of the Revenue Milestone. The 2017 Term Loans require interest-only payment through February 1, 2019, followed by 42 months of equal principal payments plus declining interest payments. However, if we draw the 2017 Term Loan B, then the interest-only period will be extended through August 1, 2019, and the amortization period will be reduced to 36 months. Interest on 2017 Term Loan A and 2017 Term Loan B will bear interest at a rate equal to the greater of (i) 8.01% and (ii) the three-month U.S. LIBOR rate plus 6.72%. The interest rate of Term Loan A at December 31, 2017, was approximately 8.4%.We will also be required to make a final payment fee of 8.00% of the principal amounts of the 2017 Term. As of December 31, 2017, our indebtedness under Term Loan A was approximately $29.8 million. The Amended Credit Agreement contains certain nonfinancial covenants, with which we were in compliance at December 31, 2017.

Critical Accounting Policies and Management Estimates

The preparation of financial statements requires us to make estimates, assumptions and judgments that affect the reported amounts of assets, liabilities, revenues and expenses, and related disclosures of contingent assets and liabilities. On an ongoing basis, we evaluate our estimates, including those related to revenue recognition, inventory valuation, certain accrued liabilities, valuation and impairment of purchased intangibles and goodwill, valuation of stock options under share-based payments, valuation allowance of our deferred tax assets and uncertain income tax positions. We base our estimates on historical experience and on various other assumptions that we believe to be reasonable under the circumstances, the results of which form our basis for making judgments about the carrying value of assets and liabilities that are not readily apparent from other sources. Actual results may differ from those estimates under different assumptions or conditions.

We believe the following critical accounting policies require us to make significant judgments and estimates used in the preparation of our financial statements:

• Revenue—Revenue is recognized when (i) persuasive evidence of the agreement exists; (ii) delivery has occurred or services have been rendered; (iii) pricing is fixed or determinable; and (iv) collection is reasonably assured.

Revenue related to product sales is generally recognized when we fulfill our obligations for each element of an agreement. For all sales of our INTERCEPT Blood System products, we use a binding purchase order or signed sales contract as evidence of a written agreement. We sell our platelet and plasma systems directly to blood banks, hospitals, universities, government agencies, as well as to distributors in certain regions. Generally, our contracts with

our customers do not provide for open return rights, except within a reasonable time after receipt of goods in the case of defective or non-conforming product. For revenue arrangements with multiple elements, we determine whether the delivered elements meet the criteria as separate units of accounting. Such criteria require that the deliverable have stand-alone value to the customer and that if a general right of return exists relative to the delivered item, delivery or performance of the undelivered item(s) is considered probable and substantially in the control. Once we determine if the deliverable meets the criteria for a separate unit of accounting, we must determine how the consideration should be allocated between the deliverables and how the separate units of accounting should be recognized as revenue. Consideration received is allocated to elements that are identified as discrete units of accounting. Because we have no vendor specific objective evidence or third party evidence for our systems, the allocation of revenue is based on best estimated selling price for the platelet and plasma systems sold. The objective of best estimated selling price is to determine the price at which we would transact a sale, had the product been sold on a stand-alone basis. We determine best estimated selling price for our platelet and plasma systems by considering multiple factors.

• Government contract revenue—Revenue related to the cost reimbursement provisions under our BARDA agreement is recognized as the allowable direct contract costs plus allowable indirect costs are incurred based on approved provisional indirect billing rates, which permit recovery of fringe benefits, overhead and general and administrative expenses. Direct costs incurred under cost reimbursable contracts are recorded as research and development expenses or general and administrative expenses. Payments to us

pursuant to our BARDA agreement are provisional payments subject to adjustment upon audit by the government. These audits could result in an adjustment to revenue previously reported, which adjustments potentially could be significant. Management believes that revenue for periods not yet audited has been recorded in amounts that are expected to be realized upon final audit and settlement. When the final determination of the allowable costs for any year has been made, revenue and billings may be adjusted accordingly in the period that the adjustment is known.

• Inventories—We own certain components of INTERCEPT disposable kits in the form of work-in-process inventory and finished goods, UVA illuminators, and certain replacement parts for our illuminators. While it is not customary for our inventory production cycle to exceed twelve months, our supply chain for certain of these components, held as work-in-process on our consolidated balance sheets, could potentially take in excess of one year to complete production before being utilized in finished INTERCEPT disposable kits. We maintain an inventory balance based on our current sales projections, and at each reporting period, we evaluate whether our work-in-process inventory will be consumed in production of finished units in order to sell to existing and prospective customers within the next twelve-month period. We use judgment to factor in lead times for the production of our finished units to meet forecasted demands. If actual results differ from those estimates, work-in-process inventory could potentially accumulate for periods exceeding one year.

Inventory is recorded at the lower of cost, determined on a first in, first-out basis, or net realizable value. Our platelet and plasma systems' disposable kits generally have 18 to 24 months shelf lives from the date of manufacture.

Illuminators and replacement parts do not have regulated expiration dates. We use significant judgment to analyze and determine if the composition of our inventory is obsolete, slow-moving, or unsalable and frequently review such determinations. We write-down specifically identified unusable, obsolete, slow-moving, or known unsalable inventory that has no alternative use in the period that it is first recognized by using a number of factors including product expiration dates, open and unfulfilled orders, and sales forecasts. Any write-down of our inventory to net realizable value establishes a new cost basis and will be maintained even if certain circumstances suggest that the inventory is recoverable in subsequent periods. Costs associated with the write-down of inventory are recorded in "Cost of product revenue" on our consolidated statements of operations.

• Accrued liabilities—We record accrued liabilities for expenses related to certain contract research activities and development services, including those related to clinical trials, preclinical safety studies and external laboratory studies, as well as development activities being performed by third parties. Some of those accrued liabilities are based on estimates because billings for these activities may not occur on a timely basis consistent with the performance of the services. Specifically, accruals for clinical trials require us to make estimates surrounding costs associated with patients at various stages of the clinical trial, pass through costs to clinical sites, contract research organization costs including fees, database development, and reporting costs, among others.

• Goodwill and intangible assets—In August 2010, we accounted for the acquisition of certain assets as a business combination. In connection with the acquisition, we used significant judgment, including, but not limited to, judgments as to cash flows, discount rates, and economic lives, in identifying the assets acquired and in determining the fair values to record the purchased assets on our consolidated balance sheets. In addition, we assessed the fair value of the non-controlling interest that we held prior to the acquisition. We determined that a considerable amount of the purchase consideration was goodwill, which represents value unique to us as the holder of worldwide rights to the INTERCEPT Blood System. We may be unable to realize the recorded value of the acquired assets and our assumptions may prove to be incorrect, which may require us to write-down or impair the value of the assets if and when facts and circumstances indicate a need to do so. We perform an impairment test on our goodwill annually on August 31 of each fiscal year or more frequently if indicators of impairment exist. The test for goodwill impairment may be addressed using qualitative factors to determine whether it is more likely than not that the fair value of a reporting unit is less than the carrying amount. If we determine that it is more likely than not that the fair value of a

reporting unit is less than the carrying amount, we must then proceed with performing the quantitative goodwill impairment test. We may choose not to perform the qualitative assessment to test goodwill for impairment and proceed directly to the quantitative impairment test; however, we may revert to the qualitative assessment to test goodwill for impairment in any subsequent period. The quantitative goodwill impairment test compares the fair value of each reporting unit with the respective carrying amount, including goodwill. We have determined that we operate in one reporting unit and estimate the fair value of our one reporting unit using the enterprise approach under which we consider our quoted market capitalization as reported on the Nasdaq Global Market. We consider quoted market prices that are available in active markets to be the best evidence of fair value. We also consider other factors, which include future forecasted results, the economic environment and overall market conditions. If the fair value of the reporting unit exceeds the carrying amount, goodwill of the reporting unit is not considered. If the carrying amount of the reporting unit's goodwill exceeds the implied fair value of that goodwill, an impairment loss is recognized in an amount equal to that excess, limited to the carrying amount of goodwill in our one reporting unit. On August 31, 2017, we performed our annual review of goodwill as described above and determined that goodwill was not impaired during the year ended December 31, 2017. We will continue to monitor events and changes in circumstances that could indicate carrying amounts of our intangible assets may not be recoverable. When such events or changes in circumstances occur, we assess recoverability by determining whether the carrying value of such assets will be recovered through the undiscounted expected future cash flows. If the expected undiscounted

future cash flows are less than the carrying amount of these assets, we then measure the amount of the impairment loss based on the excess of the carrying amount over the fair value of the assets. No events or changes in circumstances arose during the year ended December 31, 2017 which would require us to test the recoverability of our intangible assets.

• Stock-based compensation—We issue stock-based awards to our employees, contractors and members of our Board of Directors, as strategic, long-term incentives. We also maintain an active employee stock purchase plan within the meaning of Section 423(b) of the Internal Revenue Code. We use the Black-Scholes option pricing model to determine the grant-date fair value of stock-based awards. The Black-Scholes option pricing model requires that we use assumptions regarding a number of complex and subjective variables to determine appropriate inputs to the model, which include the expected term of the grants, actual and projected employee stock option exercise behaviors, including forfeitures, our expected stock price volatility, the risk-free interest rate and expected dividends. The grant-date fair value of stock-based awards is then recognized as stock-based compensation expense on a straight-line basis over the requisite service period, which is the vesting period, and is adjusted for estimated forfeitures. To the extent that stock options contain performance criteria for vesting, stock-based compensation is recognized once the performance criteria are probable of being achieved.

For our stock-based awards issued to non-employees, the measurement date at which the fair value of the stock-based award is measured is the earlier of (i) the date at which a commitment for performance by the grantee to earn the equity instrument is reached or (ii) the date at which the grantee’s performance is complete.

• Income taxes—Since our inception, we have accumulated significant net operating losses and research and development credits that may be used in future periods to offset future taxable income. We currently estimate that we may not be able to utilize all of our deferred tax assets. In addition, we may not generate future taxable income prior to the expiration of our net operating loss carry forwards and research and development credits. Timing and significance of any estimated future taxable income is highly subjective and is beyond the control of management due to uncertainties in market conditions, economic environments in which we operate, and timing of regulatory approval of our products. We do not recognize tax positions that do not have a greater than 50% likelihood of being recognized upon review by a taxing authority having full knowledge of all relevant information. Use of a valuation allowance is not an appropriate substitute for the derecognition of a tax position. We recognize accrued interest and penalties related to unrecognized tax benefits in our income tax expense. To date, we have not recognized any interest and penalties in our consolidated statements of operations, nor have we accrued for or made payments for interest and penalties. We continue to carry a full valuation allowance on substantially all of our deferred tax assets. Although we believe it more likely than not that a taxing authority would agree with our current tax positions, there can be no assurance that the tax positions we have taken will be substantiated by a taxing authority if reviewed. Our U.S. federal tax returns from 1998 through 2016 and all our California tax returns through 2016 remain subject to examination by the taxing jurisdictions due to unutilized net operating losses and research credits.

Results of Operations

Years Ended December 31, 2017, 2016 and 2015

Revenue

	Year Ended December 31,			% Change	
(in thousands, except percentages)	2017	2016	2015	2017	2016

				to 2016	to 2015
Product revenue	$43,568	$37,183	$34,223	17 %	9 %
Government contract revenue	7,758	2,092	—	271%	N/A
Total revenue	$51,326	$39,275	$34,223	31 %	15 %

Product revenue increased by $6.4 million during the year ended December 31, 2017, compared to the year ended December 31, 2016, primarily due to the year-over-year increased demand of our disposable kits for our platelet system as a result of growth in EMEA, including the commencement of the national rollout of INTERCEPT in France, and sales to U.S. customers that are entering routine use of the platelet system, and, to a lesser extent, due to improved foreign exchange rates for the Euro. The year-over-year growth in sales of disposable kits for our platelet system was partially offset by decreased sales of disposable kits for our plasma products.

Product revenue increased by $3.0 million during the year ended December 31, 2016, compared to the year ended December 31, 2015, attributable mainly to increased illuminator sales primarily in the U.S market and increased sales volume of disposable platelet and plasma system kits in our European and Middle Eastern markets.

We anticipate product revenue for INTERCEPT disposable kits will increase in future periods as the INTERCEPT Blood System gains market acceptance in geographies where commercialization efforts are underway, and as national adoption of the platelet system

continues in France, as well as from expected continued contribution from U.S. sales and newly accessible geographies. However, a deterioration of the Euro relative to the U.S. dollar has in the past and could in the future have a material impact on our product revenues, as the majority of our product revenue is expected to come from Euro denominated markets over the near term. As a result of these and other factors, the historical results may not be indicative of INTERCEPT Blood System product revenue in the future.

We recognized $7.8 million, $2.1 million and zero revenue from our BARDA agreement during the years ended December 31, 2017, 2016 and 2015, respectively, as a result of the direct and indirect contract costs incurred under the BARDA agreement. As our ReDeS study and anticipated ReCePI study enroll and as the other qualified clinical and development activities increase under the Option Periods exercised, we anticipate reported BARDA revenue will increase.

Cost of Product Revenue

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

	Year Ended December 31,			% Change	
				2017 to 2016	2016 to 2015
(in thousands, except percentages)	2017	2016	2015		
Cost of product revenue	$22,531	$20,295	$23,464	11%	(14 %)

Cost of product revenue increased by $2.2 million during the year ended December 31, 2017, compared to the year ended December 31, 2016. The increase was primarily due to the increase of sales in the current year compared to the prior year. Cost of product revenue was also impacted by the quantity of disposable kits sold during the reported periods and the quantity of illuminators sold, all with generally offsetting effects.

Cost of product revenue decreased by $3.2 million during the year ended December 31, 2016, compared to the year ended December 31, 2015. The decrease was primarily the result of the elimination of the royalty to Fresenius in the fourth quarter of 2015 and decreased obsolescence and manufacturing charges in 2016 compared to the prior year.

Our gross margin on product sales was 48% during the year ended December 31, 2017, up from 45% during the year ended December 31, 2016. The increase in gross margins on product sales was primarily due to increased demand for disposable kits for the platelet system and favorable Euro foreign exchange rates.

Our gross margin on product sales was 45% during the year ended December 31, 2016, up from 31% during the year ended December 31, 2015. The increase in gross margins on product sales was primarily due to the elimination of the royalty to Fresenius in the fourth quarter of 2015, decreased obsolescence and manufacturing charges, increased illuminator sales, and efficiencies realized related to inventory management during the year ended December 31, 2016, compared to the year ended December 31, 2015.

Changes in our gross margins on product sales are affected by various factors, including the volume of product manufactured and the relative per unit pricing in our agreement with Fresenius, exchange rate of the Euro relative to the U.S dollar, manufacturing and supply chain costs, the mix of product sold, and the mix of customers to which products are sold. We may encounter unforeseen manufacturing difficulties which, at a minimum, may lead to higher than anticipated costs, scrap rates, or delays in manufacturing products. In addition, we may face competition which may limit our ability to maintain existing selling prices for our products which in turn would negatively affect our reported gross margins on product sales. Our gross margins on product sales may be impacted in the future based on all of these and other criteria.

We expect to maintain inventory levels that will be sufficient to meet forecasted demand and plan to continue to manufacture at levels above those produced in 2017.

Research and Development Expenses

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

	Year Ended December 31,			% Change 2017 to 2016	% Change 2016 to 2015
(in thousands, except percentages)	2017	2016	2015		
Research and development	$33,710	$31,322	$25,643	8%	22%

Research and development expenses increased $2.4 million during the year ended December 31, 2017, compared to the year ended December 31, 2016, primarily due to the increased headcount costs and costs associated with clinical development of our INTERCEPT red blood cell system, our pursuit of supplemental approvals for the platelet and plasma systems, and activities related to the BARDA agreement.

Research and development expenses increased by $5.7 million during the year ended December 31, 2016, compared to the year ended December 31, 2015, primarily due to increased costs associated with clinical development of our red blood cell system, our pursuit of PMA supplement approvals for the platelet and plasma systems, and the initial activities under the BARDA agreement.

We expect to incur additional research and development costs associated with planning, enrolling and completing our required post-approval studies for the platelet system, pursuing potential regulatory approvals in other geographies where we do not currently sell our platelet and plasma systems, planning and conducting in vitro studies and clinical development of our red blood cell system in Europe and the U.S., completing activities to support a potential CE mark submission for our red blood cell system in Europe, new product development and product enhancements, including potential new label claims, and costs associated with performing the activities under our BARDA agreement. Due to the inherent uncertainties and risks associated with developing biomedical products, including, but not limited to, intense and changing government regulation, uncertainty of future preclinical studies and clinical trial results and uncertainty associated with manufacturing, it is not possible to reasonably estimate the costs to complete these research and development projects. We face numerous risks and uncertainties associated with the successful completion of our research and development projects, which risks and uncertainties are discussed in further detail under “Item 1A—Risk Factors” in Part I of this Annual Report on Form 10-K.

Selling, General, and Administrative Expenses

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

	Year Ended December 31,			% Change 2017 to 2016	% Change 2016 to 2015
(in thousands, except percentages)	2017	2016	2015		
Selling, general and administrative	$52,413	$48,753	$45,989	8%	6%

Selling, general, and administrative expenses increased by $3.7 million during the year ended December 31, 2017, compared to the year ended December 31, 2016, primarily due to increased commercial activity in the U.S. and to a lesser extent, the costs associated with administering the contract with BARDA for INTERCEPT red blood cell development.

Selling, general, and administrative expenses increased by $2.8 million during the year ended December 31, 2016, compared to the year ended December 31, 2015, primarily due to increased spending related to general corporate activities associated with the increased commercial activities targeting and servicing new and potential U.S. customers and the development activities under BARDA agreement.

We anticipate our selling, general, and administrative spending to remain relatively consistent over the coming year.

Amortization of Intangible Assets

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

	Year Ended December 31,			% Change 2017 to 2016	% Change 2016 to 2015
(in thousands, except percentages)	2017	2016	2015		
Amortization of intangible assets	$202	$202	$202	0%	0%

Amortization of intangible assets remained flat during the year ended December 31, 2017, compared to the years ended December 31, 2016 and 2015, as there were no changes to the composition of our intangible assets or the assumptions used to determine the useful lives. In addition, no impairment charges were recognized related to our intangible assets during the years ended December 31, 2017, 2016 and 2015.

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

Non-Operating Income (Expense), Net

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

	Year Ended December 31,			% Change 2017 to 2016	% Change 2016 to 2015
(in thousands, except percentages)	2017	2016	2015		
Gain from revaluation of warrant liability	$—	$—	$3,566	N/A	(100%)
Foreign exchange (loss) gain	(10)	21	(396)	(148%)	(105%)
Interest expense	(3,022)	(2,445)	(1,705)	24%	43%
Other income, net	3,864	1,140	71	239%	1,506%
Total non-operating income (expense), net	$832	$(1,284)	$1,536	(165%)	(184%)

Warrant liability

In August 2009 and November 2010, we issued warrants to purchase an aggregate of 2.4 million and 3.7 million shares of common stock, respectively, in connection with offerings of our common stock. In August 2014 and

November of 2015, all of the outstanding August 2009 and November 2010 warrants, respectively, were exercised. The fair value of the outstanding warrants, which used the Black-Scholes model, was classified as a liability on our consolidated balance sheet and was adjusted at each subsequent reporting period, until such time the warrants were exercised. Upon exercise, the fair value of the warrants was reclassified from liabilities to stockholders' equity. We had no outstanding warrants during the years ended December 31, 2017 and 2016. We recorded a non-cash gain from the revaluation of the warrant liability of $3.6 million for the year ended December 31, 2015.

Foreign exchange gain (loss)

Foreign exchange loss remained relatively flat during the year ended December 31, 2017, compared to the year ended December 31, 2016.

We recorded a foreign exchange gain of less than $0.1 million during the year ended December 31, 2016, compared to a foreign exchange loss of $0.4 million during the year ended December 31, 2015, primarily attributable to favorable foreign currency variations between the Euro and U.S. dollar during the year 2016 compared to unfavorable variations in the prior year.

Interest expense

Interest expense increased by $0.6 million for the year ended December 31, 2017, compared to the year ended December 31, 2016, primarily due to the increased average outstanding debt balance under our Amended Credit Agreement with Oxford (see discussion under the heading “Debt” below).

Interest expense increased by $0.7 million for the year ended December 31, 2016, compared to the year ended December 31, 2015, primarily due to a higher effective interest rate and larger average outstanding debt balance under our Term Loan Agreement (see discussion under the heading “Debt” below), resulting from the drawdown of Term Loan B of $10.0 million in June 2015.

Other income, net

Other income, net increased by $2.7 million during the year ended December 31, 2017, compared to the year ended December 31, 2016, primarily due to the realized gain from the sale of our remaining shares of Aduro Biotech, Inc., or Aduro, common stock of approximately $3.5 million.

Other income, net increased by $1.1 million during the year ended December 31, 2016, compared to the year ended December 31, 2015, primarily due to the realized gain from the sale of 50,000 shares of Aduro common stock, and the increased interest income from our investments in marketable securities.

Provision for Income Taxes

	Year Ended December 31,			% Change	
				2017 to 2016	2016 to 2015
(in thousands, except percentages)	2017	2016	2015		
Provision (benefit) for income taxes	$3,887	$175	$(3,671)	2,121%	(105%)

For the year ended December 31, 2017, we recorded a tax expense of $3.9 million, which was primarily due to the sale of our shares of Aduro. For the year ended December 31, 2016, we recorded a tax expense of $0.2 million, which was a result of our Cerus Europe B.V. subsidiary’s operating profit. For the year ended December 31, 2015, we recorded a tax benefit of $3.7 million, which was the result of the increased value of our investment in Aduro common stock.

Due to our history of cumulative operating losses, management has concluded that, after considering all of the available objective evidence, it is not likely that all our net deferred tax assets will be realized. Accordingly, substantially all of our U.S. deferred tax assets continue to be subject to a valuation allowance as of December 31, 2017.

On December 22, 2017, new tax legislation, Tax Cuts and Jobs Act, or the Tax Act, was signed into law, which significantly changes the Internal Revenue Code of 1986, as amended. The Tax Act did not impact the tax expense

recorded for 2017 due to our continuing operating losses and the valuation allowance against all of our deferred tax assets, but did have other tax related effects. One component of the Tax Act is a provision which required the deemed distribution of the accumulated earnings of Cerus Europe B.V. As a result, we realized a deemed income inclusion of $3.2 million associated permanently reinvested earnings in our subsidiary. This deemed inclusion reduced the net operating loss for the year but did not result in any cash outlays. We did not make any actual distribution of accumulated earnings and continue to maintain the funds as permanently reinvested outside the U.S.

Liquidity and Capital Resources

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

At December 31, 2017, we had cash, cash equivalents, and restricted cash of $13.9 million, compared to $22.7 million at December 31, 2016. Our cash equivalents primarily consist of money market instruments, which are classified for accounting purposes as available-for-sale. In addition, we had $47.0 million of short-term investments and investments in marketable equity securities at December 31, 2017, and $49.1 million at December 31, 2016. We also had total indebtedness of approximately $29.8 million under our Amended Credit Agreement at December 31, 2017, and approximately $19.4 million under our Term Loan Agreement at December 31, 2016 . Excess cash is typically invested in highly liquid instruments of short-term investments with high-quality credit rated corporate and government agency fixed-income securities in accordance with our investment policy.

Operating Activities

Net cash used in operating activities was $52.2 million for the year ended December 31, 2017, compared to $53.5 million during the year ended December 31, 2016. The decrease in net cash used in operating activities was primarily related to the Manufacturing and Development Payments to Fresenius during the year ended December 31, 2016, which did not reoccur in the current period. The decrease in net cash used in operating activities was also related to the increased product sales and reimbursements from the BARDA agreement, partially offset by the increase in our accounts receivables as a result of the timing of cash receipts, during the year ended December 31, 2017, as compared to the same period in 2016.

Net cash used in operating activities was $53.5 million for the year ended December 31, 2016, compared to $51.1 million during the year ended December 31, 2015. The increase in net cash used in operating activities was primarily related to the increased cash spent for development activities for our red blood cell program and selling and administrative expenses related to our continuing U.S. commercial launch of our platelet and plasma systems, partially offset by a net increase in the combined total for our accounts payable and accrued liabilities as a result of the timing of payments during the year ended December 31, 2016, as compared to the corresponding period in 2015. The increase in net cash used in operating activities was also impacted by payments to Fresenius related to the Manufacturing and Development Payments, and an increased inventory build during the year ended December 31, 2016, as compared to the corresponding period in 2015.

Investing Activities

Net cash provided by investing activities was $0.4 million for the year ended December 31, 2017, compared to $19.9 million of net cash used during the year ended December 31, 2016. The change period over period was primarily the result of lower purchases of investments, and higher proceeds from the sale of our Aduro common stock and maturities of investments in marketable securities, during the year ended December 31, 2017, as compared to the same period in 2016.

Net cash used in investing activities was $19.9 million for the year ended December 31, 2016, compared to $1.5 million of net cash provided during the year ended December 31, 2015. The change period over period was primarily the result of lower proceeds from maturities of investments in marketable securities during the year ended December 31, 2016, as compared to the same period in 2015, partially offset by the proceeds from the sale of 50,000 shares of Aduro common stock.

Financing Activities

Net cash provided by financing activities was $43.0 million during the year ended December 31, 2017, compared to $24.6 million net cash provided during the year ended December 31, 2016. The change was primarily due to the proceeds received from the 2017 Term Loans described in more detail below, and an increase in public offering proceeds, partially offset by the repayment of Term Loans A and B under the original Term Loan Agreement, during the year ended December 31, 2017.

Net cash provided by financing activities was $24.6 million during the year ended December 31, 2016, compared to $98.0 million during the year ended December 31, 2015. The decrease in net cash provided by financing activities was primarily due to the decrease of proceeds received from public offerings. In January 2015, we issued 14.6 million shares of our common stock in an underwritten public offering for approximately $75.3 million. This was further impacted by our drawdown of Term Loan B of $10.0 million in June 2015 and the proceeds from the exercise of

warrants in 2015.

Working Capital

Working capital decreased to $66.8 million at December 31, 2017, from $67.2 million at December 31, 2016, primarily due to the cash used to support ongoing operations which resulted in lower cash and cash equivalent balances, and timing of payments related to accounts payable. This was partially offset by the increased product sales and accounts receivable collections. Working capital decreased to $67.2 million at December 31, 2016, from $108.5 million at December 31, 2015, primarily due to the cash used to support ongoing operations which resulted in lower cash and cash equivalent balances, and the decline of the market value of our investment in Aduro.

Capital Requirements

Our near-term capital requirements are dependent on various factors, including operating costs and working capital investments associated with commercializing the INTERCEPT Blood System, including in connection with the continuing our U.S. commercial launch of our platelet and plasma systems, costs to develop different configurations of existing products and new products, including our illuminator, costs associated with planning, enrolling and completing ongoing studies, and the post-approval studies we are required to conduct in connection with the FDA approval of the platelet system, costs associated with pursuing potential regulatory

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

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 Amended Credit Agreement with Oxford Finance, as described above under “Equity and Debt Agreements—Debt Agreement,” or potentially pursuant to new arrangements with different lenders. We may borrow funds on terms that may include restrictive covenants, including covenants that restrict the operation of our business, liens on assets, high effective interest rates 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.

While we expect to receive significant funding under our five-year agreement with BARDA, our ability to obtain the funding we expect to receive under the agreement is subject to various risks and uncertainties, including with respect to BARDA’s ability to terminate the agreement for convenience at any time and our ability to achieve the required milestones under the agreement. In addition, access to federal contracts is subject to the authorization of funds and approval of our research plans by various organizations within the federal government, including the U.S. Congress. The general economic environment, coupled with tight federal budgets, has led to a general decline in the amount available for government funding. If BARDA were to eliminate, reduce or delay funding under our agreement, this would have a significant negative impact on the programs associated with such funding and could have a significant negative impact on our revenues and cash flows. In addition, if we are unable to generate sufficient perquisite Phase 3 clinical data and/or reach agreement with the FDA on an additional Phase 3 clinical trial for chronic anemia in the U.S. for our red blood cell system, our agreement with BARDA will be severely limited in scope or could be terminated altogether, and our ability to complete the development activities required for licensure in the U.S. may require additional capital beyond which we currently have. If alternative sources of funding are not available, we may be forced to suspend or terminate development activities related to the red blood cell system in the U.S.

As a result of economic conditions, general global economic uncertainty, political change, and other factors, we do not know whether additional capital will be available when needed, or that, if available, we will be able to obtain additional capital on reasonable terms. If we are unable to raise additional capital due to the volatile global financial markets, general economic uncertainty or other factors, we may need to curtail planned development or commercialization activities. In addition, we may need to obtain additional funds to complete development activities for the red blood cell system necessary for potential regulatory approval in Europe, if costs are higher than anticipated or we encounter delays. We may need to obtain additional funding to conduct additional randomized controlled clinical trials for existing or new products, particularly if we are unable to access any additional portions of the funding contemplated by our BARDA agreement, and we may choose to defer such activities until we can obtain sufficient additional funding or, at such time, our existing operations provide sufficient cash flow to conduct these trials.

Other Information

On August 4, 2017, we entered into the Amended Cantor Agreement. In connection with the Amended Cantor Agreement, we filed a new shelf registration statement on Form S-3, which was declared effective by the SEC on January 8, 2018, and which we refer to as the New Registration Statement. The Amended Cantor Agreement became effective upon the effectiveness of the New Registration Statement, and provides for the issuance and sale of shares of our common stock having an aggregate offering price of up to $70.0 million through Cantor, which amount includes the $31.4 million of unsold shares of common stock available for sale under the Prior Cantor Agreement immediately prior to the effectiveness of the Amended Cantor Agreement. Under the Amended Cantor Agreement, Cantor also acts as our sales agent and receives compensation based on an aggregate of 2% of the gross proceeds on the sale price per share of its common stock. The issuance and sale of these shares by us pursuant to the Amended Cantor Agreement are deemed an "at-the-market" offering and are registered under the Securities Act of 1933, as amended. See "Equity and Debt Agreements—Cantor" above for more information on the Amended Cantor Agreement and the Prior Cantor Agreement.

In January 2018, we issued and sold 14,030,000 shares of our common stock, at $4.10 per share in an underwritten public offering. The total proceeds to us from this offering were $57.5 million before deducting estimated offering expenses payable by us.

Commitments and Off-Balance Sheet Arrangements

Off-balance sheet arrangements

We did not have any off-balance sheet arrangements as of December 31, 2017 and 2016.

Contractual Commitments

The following summarizes our contractual commitments at December 31, 2017:

(in thousands)	Total	1 year	2 - 3 years	4 - 5 years	After 5 years
Debt	$39,756	$2,554	$20,266	$16,936	$ —
Minimum purchase requirements	19,535	9,607	5,004	4,924	—
Manufacturing and development obligations	6,588	—	6,588	—	—
Operating leases	3,189	1,387	1,408	377	17
Other commitments	825	693	132	—	—
Total contractual obligations	$69,893	$14,241	$33,398	$22,237	$ 17

Debt

On July 31, 2017, we entered into Amended Credit Agreement with Oxford. The Amended Credit Agreement provides for secured growth capital term loans of up to $40.0 million. For more information on the Amended Credit Agreement, see "Equity and Debt Agreements—Debt Agreement" above.

Minimum purchase requirements

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

Manufacturing and development obligations

The Supply Agreement with Fresenius calls for a payment of €5.5 million on December 31 of the year in which certain production volumes are achieved, or December 31, 2022, whichever occurs first.

Operating leases

We generally lease our office facilities and certain equipment and automobiles under non-cancelable operating leases with initial terms in excess of one year that require us to pay operating costs, property taxes, insurance and maintenance. The operating leases expire at various dates through 2023, with certain of the leases providing for renewal options, provisions for adjusting future lease payments, which is based on the consumer price index and the right to terminate the lease early. Our leased facilities qualify as operating leases and as such, are not included on our consolidated balance sheets.

Other commitments

Our other commitments primarily consist of obligations for business insurance financing and our landlord financed leasehold improvements, which are in addition to the operating leases we have for office and laboratory space. We pay for the financed

leasehold improvements as a component of rent and are required to reimburse our landlords over the remaining life of the respective leases.

Financial Instruments

Our investment policy is to manage our marketable securities portfolio to preserve principal and liquidity while maximizing the return on the investment portfolio to assist us in funding our operations. We currently invest our cash and cash equivalents in money market funds and interest-bearing accounts with financial institutions. Our money market funds are classified as Level 1 in the fair value hierarchy, in which quoted prices are available in active markets, as the maturity of money market funds are relatively short and the carrying amount is a reasonable estimate of fair value. Our available-for-sale securities related to corporate debt and U.S. government agency securities are classified as Level 2 in the fair value hierarchy, which uses observable inputs to quoted market prices, benchmark yields, reported trades, broker/dealer quotes or alternative pricing sources with reasonable levels of price transparency. We maintain portfolio liquidity by ensuring that the securities have active secondary or resale markets. We did not record any other-than-temporary impairment losses during the years ended December 31, 2017, 2016 and 2015. Adverse global economic conditions have had, and may continue to have, a negative impact on the market values of potential investments.

Item 7A. Quantitative and Qualitative Disclosures about Market Risk

Interest Rate Risk

At December 31, 2017, we held cash, cash equivalents, short-term investments and investments in marketable equity securities of $60.7 million. We do not believe our exposure to interest rate risk to be material given we held cash in interest-bearing accounts with financial institutions and the short-term nature of our investment portfolio consisted of highly liquid money market instruments and corporate debt and U.S. government agency securities with short-term maturities. The weighted average interest rates of our cash and cash equivalents at December 31, 2017 were 1.56%.

Our exposure to market rate risk for changes in interest rates relates primarily to our money market instruments, corporate debt securities and the amounts borrowed pursuant to the Amended Credit Agreement. We do not use derivative financial instruments. By policy, we may place investments with high quality debt security issuers, limit the amount of credit exposure to any one issuer and limit duration by restricting the term for single securities and for the portfolio as a whole. Our investments are held and managed by a third-party capital management adviser that in turn, utilizes a combination of active market quotes and where necessary, proprietary pricing models as well as a subscribed pricing service, in order to estimate fair value. While we believe that we will be able to recognize the fair value of our money market instruments when they mature or are sold, or if we purchase investments in securities in the future, there can be no assurance that the markets for these securities will not deteriorate further or that the institutions that these securities are with will be able to meet their debt obligations.

With respect to the Amended Credit Agreement, we are exposed to risks associated with changes in interest rates in connection with our borrowings under the Amended Credit Agreement. Based on our indebtedness under the Amended Credit Agreement of $29.8 million as of December 31, 2017, and the interest rate on such borrowings then in effect, a 1.0% increase in interest rates would increase our net interest expense in 2018 by approximately $0.3 million.

Foreign Currency Risk

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 impacted by changes in these or other factors.

Product sales for our blood safety products are predominantly made in Europe and generally are invoiced to customers in Euro. In addition, we incur operating expenses, including payment for finished goods inventory of disposable kits for the platelet and plasma systems. These inventory purchases and operating expenses are generally paid in Euro and, to a much lesser degree, other foreign currencies. Our exposure to foreign exchange rate volatility is a direct result of our product sales, cash collection and expenses to support our international operations. Foreign exchange rate fluctuations are recorded as a component of non-operating income (expense), net on our consolidated statements of operations. Significant fluctuations in the volatility of foreign currencies relative to the United States dollar may materially impact our results of operations. An unfavorable 10% change in foreign currency exchange rates for our cash, accounts receivable, accounts payable and accrued liabilities that are denominated in foreign currencies at December 31, 2017, would have negatively impacted our annual financial results by $0.3 million. Currently we do not have any near-term plans to enter into a formal hedging program to mitigate the effects of foreign currency volatility.

Item 8. Financial Statements and Supplementary Data

Our consolidated financial statements, together with related notes and reports of Ernst & Young LLP, independent registered public accounting firm, are listed in Item 15(a) and included herein.

Item 9. Changes in and Disagreements with Accountants on Accounting and Financial Disclosure

None.

Item 9A. Controls and Procedures

Evaluation of Disclosure Controls and Procedures

We have carried out an evaluation under the supervision and with the participation of management, including our principal executive officer and principal financial officer, of our disclosure controls and procedures (as defined in Rule 13a-15(e) of the Securities Exchange Act of 1934, as amended) as of the end of the period covered by this Annual Report on Form 10-K. Based on their evaluation, our principal executive officer and principal financial officer concluded that our disclosure controls and procedures were effective as of December 31, 2017.

Limitations on the Effectiveness of Controls

A control system, no matter how well conceived and operated, can provide only reasonable, not absolute, assurance that the objectives of the control system are met. Because of the inherent limitations in all control systems, no evaluation of controls can provide absolute assurance that all control issues, if any, within a company have been detected. Accordingly, our disclosure controls and procedures are designed to provide reasonable assurance, not absolute assurance, that the objectives of our disclosure control system are met and, as set forth above, our principal executive officer and principal financial officer have concluded, that based on their evaluation as of the end of the period covered by this Annual Report on Form 10-K, our disclosure controls and procedures were effective to provide reasonable assurance that the objective of our disclosure control system were met.

Management’s Report on Internal Control over Financial Reporting

Our management is responsible for establishing and maintaining adequate internal control over financial reporting, as defined in Rules 13a-15(f) under the Securities Exchange Act of 1934, as amended. Internal control over financial reporting is a process designed to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles in the United States of America.

Under the supervision and with the participation of our management, including our Chief Executive Officer and Chief Financial Officer, we conducted an evaluation of the effectiveness of our internal control over financial reporting as of December 31, 2017. Management based its assessment on the criteria set forth by the Committee of Sponsoring Organizations of the Treadway Commission (2013 framework) in Internal Control—Integrated Framework. Based on this evaluation, our management concluded that as of December 31, 2017, our internal control over financial reporting was effective.

The effectiveness of our internal control over financial reporting as of December 31, 2017, has been audited by Ernst & Young LLP, our independent registered public accounting firm, as stated in their attestation report, which is included below.

Changes in Internal Control over Financial Reporting

There were no changes in our internal control over financial reporting which occurred during our fiscal quarter ended December 31, 2017, which have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

Report of Independent Registered Public Accounting Firm

To the Shareholders and the Board of Directors of Cerus Corporation

Opinion on Internal Control over Financial Reporting

We have audited Cerus Corporation’s internal control over financial reporting as of December 31, 2017, based on criteria established in Internal Control — Integrated Framework issued by the Committee of Sponsoring Organizations of the Treadway Commission (2013 framework) (the COSO criteria). In our opinion, Cerus Corporation (the Company) maintained, in all material respects, effective internal control over financial reporting as of December 31, 2017, based on the COSO criteria.

We also have audited, in accordance with the standards of the Public Company Accounting Oversight Board (United States) (PCAOB), the consolidated balance sheets of the Company as of December 31, 2017 and 2016, and the related consolidated statements of operations, comprehensive loss, stockholders’ equity and cash flows for each of the three years in the period ended December 31, 2017, and the related notes and our report dated March 8, 2018 expressed an unqualified opinion thereon.

Basis for Opinion

The Company's management is responsible for maintaining effective internal control over financial reporting and for its assessment of the effectiveness of internal control over financial reporting included in the accompanying Management’s Report on Internal Control over Financial Reporting. Our responsibility is to express an opinion on the Company’s internal control over financial reporting based on our audit. We are a public accounting firm registered with the PCAOB and are required to be independent with respect to the Company in accordance with the U.S. federal securities laws and the applicable rules and regulations of the Securities and Exchange Commission and the PCAOB.

We conducted our audit in accordance with the standards of the PCAOB. Those standards require that we plan and perform the audit to obtain reasonable assurance about whether effective internal control over financial reporting was maintained in all material respects.

Our audit included obtaining an understanding of internal control over financial reporting, assessing the risk that a material weakness exists, testing and evaluating the design and operating effectiveness of internal control based on the assessed risk, and performing such other procedures as we considered necessary in the circumstances. We believe that our audit provides a reasonable basis for our opinion.

Definition and Limitations of Internal Control over Financial Reporting

A company’s internal control over financial reporting is a process designed to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles. A company’s internal control over financial reporting includes those policies and procedures that (1) pertain to the maintenance of records that, in reasonable detail, accurately and fairly reflect the transactions and dispositions of the assets of the company; (2) provide reasonable assurance that

transactions are recorded as necessary to permit preparation of financial statements in accordance with generally accepted accounting principles, and that receipts and expenditures of the company are being made only in accordance with authorizations of management and directors of the company; and (3) provide reasonable assurance regarding prevention or timely detection of unauthorized acquisition, use, or disposition of the company's assets that could have a material effect on the financial statements.

Because of its inherent limitations, internal control over financial reporting may not prevent or detect misstatements. Also, projections of any evaluation of effectiveness to future periods are subject to the risk that controls may become inadequate because of changes in conditions, or that the degree of compliance with the policies or procedures may deteriorate.

/s/ Ernst & Young LLP

Redwood City, California

March 8, 2018

Item 9B. Other Information

None.

PART III

Certain information required by Part III is omitted from this Annual Report on Form 10-K since we intend to file our definitive proxy statement for our 2018 annual meeting of stockholders, or the Proxy Statement, pursuant to Regulation 14A of the Securities Exchange Act of 1934, as amended, not later than 120 days after the end of the fiscal year covered by this Annual Report on Form 10-K, and certain information to be included in the proxy statement is incorporated herein by reference.

Item 10. Directors, Executive Officers and Corporate Governance
Information required by this item regarding executive officers, directors and nominees for directors, including information with respect to our audit committee and audit committee financial expert, and the compliance of certain reporting persons with Section 16(a) of the Securities Exchange Act of 1934, as amended, will be included in the Proxy Statement and is incorporated herein by reference.

Code of Ethics

We have adopted the Cerus Corporation Code of Business Conduct and Ethics, or Ethics Code, that applies to all of our officers, directors and employees. The Ethics Code is available on our website at www.cerus.com on the "Corporate Governance" page of the section titled "Investors." If we make any substantive amendments to the Ethics Code or grant any waiver from a provision of the Ethics Code to any executive officer or director, we intend to promptly disclose the nature of the amendment or waiver as required by applicable laws. To satisfy our disclosure requirements, we may post any waivers of or amendments to the Ethics Code on our website in lieu of filing such waivers or amendments on a Form 8-K.

Our employees are required to report any conduct that they believe in good faith to be an actual or apparent violation of the Ethics Code. The Audit Committee of our Board of Directors has established procedures to receive, retain and address complaints regarding accounting, internal accounting controls or auditing matters and to allow for the confidential and anonymous submission by employees of related concerns.

Item 11. Executive Compensation
The information required by this item is incorporated herein by reference to our Proxy Statement.

Item 12. Security Ownership of Certain Beneficial Owners and Management and Related Stockholder Matters
The information required by this item is incorporated herein by reference to our Proxy Statement.

Item 13. Certain Relationships and Related Transactions, and Director Independence
The information required by this item is incorporated herein by reference to our Proxy Statement.

Item 14. Principal Accountant Fees and Services
The information required by this item is incorporated herein by reference to our Proxy Statement.

PART IV

Item 15. Exhibits and Financial Statement Schedules
The following documents are being filed as part of this Annual Report on Form 10-K:

(a) Financial Statements.

Other information is omitted because it is either presented elsewhere, is inapplicable or is immaterial as defined in the instructions.

(b) Exhibits.

Exhibit Number	Description of Exhibit
3.1(20)	Amended and Restated Certificate of Incorporation of Cerus Corporation.
3.2(20)	Certificate of Amendment to the Amended and Restated Certificate of Incorporation of Cerus Corporation.
3.3(20)	Certificate of Designation of Series C Junior Participating Preferred Stock of Cerus Corporation.
3.4(25)	Certificate of Amendment to the Amended and Restated Certificate of Incorporation of Cerus Corporation.
3.5(6)	Amended and Restated Bylaws of Cerus Corporation.
4.1(1)	Specimen Stock Certificate.
4.2(12)	Rights Agreement, dated as of November 3, 1999, as amended as of August 6, 2001, between Cerus Corporation and Wells Fargo Bank, N.A. (formerly known as Norwest Bank Minnesota, N.A.).
4.3(13)	Amendment to Rights Agreement, dated as of October 28, 2009, between Cerus Corporation and Wells Fargo Bank, N.A. (which includes the form of Rights Certificate as Exhibit B thereto).

Supply and/or Manufacturing Agreements

10.1(26)†	Amended and Restated Supply Agreement, dated April 21, 2014, by and between Cerus Corporation and Purolite Corporation.
10.2(34)†	Amended and Restated Supply and Manufacturing Agreement, dated April 1, 2017, by and between Cerus Corporation and Porex Corporation.
10.3(30)†	Amended and Restated Manufacturing and Supply Agreement, dated October 19, 2015, by and between Cerus Corporation and Fresenius Kabi Deutschland GmbH.
10.4(8)†	Manufacturing and Supply Agreement, dated September 30, 2008, by and between Cerus Corporation and NOVA Biomedical Corporation.
10.5(31)†	Amendment #1 to the Manufacturing and Supply Agreement, dated March 15, 2016, by and between NOVA Biomedical Corporation and Cerus Corporation.

Exhibit Number	Description of Exhibit
10.6(17)†	Amended and Restated Supply Agreement, dated as of September 1, 2011, between Cerus Corporation and Ash
	Stevens Inc.
10.7(22)†	Addendum 1 to Amended and Restated Supply Agreement, dated August 1, 2013, by and between Cerus Corporation and Ash Stevens, Inc.
	Loan and Security Agreements
10.8(35)†	Amended and Restated Loan and Security Agreement, dated July 31, 2017, by and among Cerus Corporation and Oxford Finance LLC, as collateral agent and a lender.
10.9(35)	First Amendment to Loan and Security Agreement, effective July 31, 2017, by and among Cerus Corporation and Oxford Finance LLC, as collateral agent and a lender.
	Real Estate Lease Agreements
10.10(4)	Standard Industrial/Commercial Single-Tenant Lease-Net, dated October 12, 2001 between Cerus Corporation and California Development, Inc.
10.11(7)	Second Amendment to Standard Industrial/Commercial Single-Tenant Lease-Net, dated as of September 18, 2008 between Cerus Corporation and California Development, Inc.
10.12(14)	Letter to California Development, Inc. exercising option to extend the lease term from the Second Amendment to Standard Industrial/Commercial Single-Tenant Lease-Net, dated as of September 18, 2008 between Cerus Corporation and California Development, Inc.
10.13(23)	Real Property Lease, dated June 20, 2013, between Cerus Corporation and S. P. Cuff as Managing Partner of the Redwoods Business Center LP.
10.14(27)	Letter, dated March 13, 2015 to Cuff Property Management exercising option to extend the lease term under the Real Property Lease, dated June 20, 2013, between Cerus Corporation and S. P. Cuff as Managing Partner of the Redwoods Business Center LP.
10.15(34)	Letter, dated April 25, 2017, to Cuff Property Management exercising option to extend the lease term under the Real Property Lease, dated June 20, 2013, between Cerus Corporation and S.P. Cuff as Managing Partner of the Redwoods Business Center L.P.
	Employment Agreements or Offer Letters
10.16(16)*	Employment Letter, by and between Cerus Corporation and William M. Greenman, dated May 12, 2011.
10.17(21)*	Addendum to Employment Agreement for William M. Greenman, dated December 5, 2012.

10.18(23)*	Employment Letter, by and between Cerus Corporation and Laurence Corash, dated July 30, 2009.
10.19(15)*	Employment Letter, by and between Cerus Corporation and Laurence Corash, dated March 2, 2010.
10.20(12)*	Employment Letter for Kevin D. Green, dated May 1, 2009.
10.21(21)*	Employment Letter, by and between Cerus Corporation and Chrystal Menard, dated October 19, 2012.
10.22(23)*	Employment Letter, by and between Cerus Corporation and Carol Moore, dated December 14, 2007.
10.23(29)*	Employment Letter, by and between Cerus Corporation and Richard J. Benjamin MBChB, PhD, FRCPath, dated May 12, 2015.
10.24(30)*	Consulting Agreement, by and between Cerus Corporation and Caspar Hogeboom, dated December 23, 2015.

Exhibit Number	Description of Exhibit
10.25(32)*	Employment Letter, by and between Cerus Corporation and Vivek Jayaraman, dated May 31, 2016.
	Stock Plans and Related Forms
10.26(1)*	1996 Equity Incentive Plan.
10.27(1)*	Form of Incentive Stock Option Agreement under the 1996 Equity Incentive Plan.
10.28(1)*	Form of Nonstatutory Stock Option Agreement under the 1996 Equity Incentive Plan.
10.29(28)*	Amended and Restated 1996 Employee Stock Purchase Plan, effective June 10, 2015.
10.30(2)*	1998 Non-Officer Stock Option Plan.
10.31(3)*	1999 Equity Incentive Plan, adopted April 30, 1999, approved by stockholders July 2, 1999.
10.32(5)*	1999 Non-Employee Directors' Stock Option Sub-Plan, amended December 4, 2002.
10.33(34)*	Amended and Restated 2008 Equity Incentive Plan, effective June 7, 2017.
10.34(18)*	Form of Option Agreement for employees under the Amended and Restated 2008 Equity Incentive Plan.
10.35(18)*	Form of Option Agreement for non-employee directors under the Amended and Restated 2008 Equity Incentive Plan.
10.36(18)*	Form of Restricted Stock Unit Agreement under the Amended and Restated 2008 Equity Incentive Plan.
	Other Compensatory Plans or Agreements
10.37(21)*	Bonus Plan for Senior Management of Cerus Corporation, as amended December 5, 2012.
10.38(9)*	Cerus Corporation Change of Control Severance Benefit Plan, as amended.
10.39(11)*	Form of Severance Benefits Agreement.
10.40(33)*	Amended and Restated Non-Employee Director Compensation Policy, effective April 19, 2017.
10.41(33)*	2016 and 2017 Executive Officer Compensation Arrangements.
	Other Material Agreements

10.42(1)	Form of Indemnity Agreement entered into between Cerus Corporation and each of its directors and executive officers.
10.43(10)	Form of Amended and Restated Indemnity Agreement, adopted April 24, 2009.
10.44(19)	Controlled Equity OfferingSM Sales Agreement, dated August 31, 2012, by and between Cerus Corporation and Cantor Fitzgerald & Co.
10.45(24)	Amendment No 1. to Controlled Equity OfferingSM Sales Agreement, dated March 21, 2014, by and between Cerus Corporation and Cantor Fitzgerald & Co.
10.46(31)	Amendment No. 2 to Controlled Equity OfferingSM Sales Agreement, dated May 5, 2016, by and between Cerus Corporation and Cantor Fitzgerald & Co.
10.47(34)	Amendment No. 3 to Controlled Equity OfferingSM Sales Agreement, dated August 4, 2017, by and between Cerus Corporation and Cantor Fitzgerald & Co.

Exhibit Number	Description of Exhibit
10.48(14)†	License Agreement, dated as of February 2, 2005, by and between Cerus Corporation and Fresenius Kabi AG (successor-in-interest to Baxter Healthcare S.A. and Baxter Healthcare Corporation).
12.1	Computation of Earnings to Fixed Charges.
21.1	List of Registrant's subsidiaries.
23.1	Consent of Independent Registered Public Accounting Firm.
24.1	Power of Attorney (see signature page).
31.1	Certification of the Principal Executive Officer of Cerus Corporation pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.
31.2	Certification of the Principal Executive Officer of Cerus Corporation pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.
32.1(36)	Certification of the Principal Financial Officer and Principal Financial Officer pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.
101.INS	XBRL Instance Document.
101.SCH	XBRL Taxonomy Extension Schema Document.
101.CAL	XBRL Taxonomy Extension Calculation Linkbase Document.
101.DEF	XBRL Taxonomy Extension Definition Linkbase Document.
101.LAB	XBRL Taxonomy Extension Label Linkbase Document.
101.PRE	XBRL Taxonomy Extension Presentation Linkbase Document.

† Certain portions of this exhibit are subject to a confidential treatment order.
* Compensatory Plan.

(1) Incorporated by reference to the like-described exhibit to the Registrant's Registration Statement on Form S-1 (File No. 333-11341) and amendments thereto.

(2) Incorporated by reference to the like-described exhibit to the Registrant's Registration Statement on Form S-8, dated March 24, 1999.

(3)

Incorporated by reference to the like-described exhibit to the Registrant's Registration Statement on Form S-8, dated August 4, 1999.

(4) Incorporated by reference to the like-described exhibit to the Registrant's Annual Report on Form 10-K, for the year ended December 31, 2001.

(5) Incorporated by reference to the like-described exhibit to the Registrant's Quarterly Report on Form 10-Q, for the quarter ended March 31, 2003.

(6) Incorporated by reference to the like-described exhibit to the Registrant's Current Report on Form 8-K, filed with the SEC on June 19, 2008.

(7) Incorporated by reference to the like-described exhibit to the Registrant's Quarterly Report on Form 10-Q, for the quarter ended September 30, 2008.

(8) Incorporated by reference to the like-described exhibit to the Registrant's Annual Report on Form 10-K, for the year ended December 31, 2008.

(9) Incorporated by reference to the like-described exhibit to the Registrant's Quarterly Report on Form 10-Q, for the quarter ended March 31, 2009.

(10) Incorporated by reference to the like-described exhibit to the Registrant's Current Report on Form 8-K, filed with the SEC on April 30, 2009.

(11) Incorporated by reference to the like-described exhibit to the Registrant's Current Report on Form 8-K, filed with the SEC on June 1, 2009.

(12) Incorporated by reference to the like-described exhibit to the Registrant's Quarterly Report on Form 10-Q, for the quarter ended June 30, 2009.

(13) Incorporated by reference to the like-described exhibit to the Registrant's Current Report on Form 8-K, filed with the SEC on October 30, 2009.

(14) Incorporated by reference to the like-described exhibit to the Registrant's Annual Report on Form 10-K, for the year ended December 31, 2009.

(15) Incorporated by reference to the like-described exhibit to the Registrant's Current Report on Form 8-K, filed with the SEC on March 8, 2010.

(16) Incorporated by reference to the like-described exhibit to the Registrant's Current Report on Form 8-K, filed with the SEC on May 18, 2011.

(17) Incorporated by reference to the like-described exhibit to the Registrant's Quarterly Report on Form 10-Q, for the quarter ended September 30, 2011.

(18) Incorporated by reference to the like-described exhibit to the Registrant's Quarterly Report on Form 10-Q, for the quarter ended March 31, 2012.

(19) Incorporated by reference to the like-described exhibit to the Registrant's Current Report on Form 8-K, filed with the SEC on August 31, 2012.

(20) Incorporated by reference to the like-described exhibit to the Registrant's Quarterly Report on Form 10-Q, for the quarter ended September 30, 2012.

(21) Incorporated by reference to the like-described exhibit to the Registrant's Annual Report on Form 10-K, for the year ended December 31, 2012.

(22) Incorporated by reference to the like-described exhibit to the Registrant's Quarterly Report on Form 10-Q, for the quarter ended September 30, 2013.

(23) Incorporated by reference to the like-described exhibit to the Registrant's Annual Report on Form 10-K, for the year ended December 31, 2013.

(24) Incorporated by reference to the like-described exhibit to the Registrant's Current Report on Form 8-K, filed with the SEC on March 21, 2014.

(25) Incorporated by reference to the like-described exhibit to the Registrant's Quarterly Report on Form 10-Q, for the quarter ended June 30, 2014.

(26) Incorporated by reference to the like-described exhibit to Amendment No. 1 to the Registrant's Quarterly Report on Form 10-Q/A, for the quarter ended June 30, 2014.

(27) Incorporated by reference to the like-described exhibit to Registrant’s Quarterly Report on Form 10-Q, for the quarter ended March 31, 2015.

(28) Incorporated by reference to the like-described exhibit to Registrant’s Quarterly Report on Form 10-Q, for the quarter ended June 30, 2015.

(29) Incorporated by reference to the like-described exhibit to Registrant’s Quarterly Report on Form 10-Q, for the quarter ended September 30, 2015.

(30) Incorporated by reference to the like-described exhibit to Registrant's Annual Report on Form 10-K, for the year ended December 31, 2015.

(31) Incorporated by reference to the like-described exhibit to Registrant's Quarterly Report on Form 10-Q, for the quarter ended March 31, 2016.

(32) Incorporated by reference to the like-described exhibit to Registrant's Quarterly Report on Form 10-Q, for the quarter ended September 30, 2016.

(33) Incorporated by reference to the like-described exhibit to Registrant’s Quarterly Report on Form 10-Q, for the quarter ended March 31, 2017.

(34) Incorporated by reference to the like-described exhibit to Registrant’s Quarterly Report on Form 10-Q, for the quarter ended June 30, 2017.

(35) Incorporated by reference to the like-described exhibit to Registrant’s Quarterly Report on Form 10-Q, for the quarter ended September 30, 2017.

(36) This certification accompanies the Form 10-K to which it relates, is not deemed filed with the Securities and Exchange Commission, and is not incorporated by reference into any filing of the Registrant’s under the Securities Act of 1933, as amended, or the Securities Exchange Act of 1934, as amended (whether made before or after the date of the Form 10-K), irrespective of any general incorporation language contained in such filing.

Item 16. Form 10-K Summary

None.

Report of Independent Registered Public Accounting Firm

To the Shareholders and the Board of Directors of Cerus Corporation

Opinion on the Financial Statements

We have audited the accompanying consolidated balance sheets of Cerus Corporation (the Company) as of December 31, 2017 and 2016, the related consolidated statements of operations, comprehensive loss, stockholders' equity and cash flows for each of the three years in the period ended December 31, 2017, and the related notes (collectively referred to as the "consolidated financial statements"). In our opinion, the consolidated financial statements present fairly, in all material respects, the financial position of the Company at December 31, 2017 and 2016, and the results of its operations and its cash flows for each of the three years in the period ended December 31, 2017, in conformity with U.S. generally accepted accounting principles.

We also have audited, in accordance with the standards of the Public Company Accounting Oversight Board (United States) (PCAOB), the Company's internal control over financial reporting as of December 31, 2017, based on criteria established in Internal Control — Integrated Framework issued by the Committee of Sponsoring Organizations of the Treadway Commission (2013 Framework) and our report dated March 8, 2018 expressed an unqualified opinion thereon.

Basis for Opinion

These financial statements are the responsibility of the Company's management. Our responsibility is to express an opinion on the Company's financial statements based on our audits. We are a public accounting firm registered with the PCAOB and are required to be independent with respect to the Company in accordance with the U.S. federal securities laws and the applicable rules and regulations of the Securities and Exchange Commission and the PCAOB.

We conducted our audits in accordance with the standards of the PCAOB. Those standards require that we plan and perform the audit to obtain reasonable assurance about whether the financial statements are free of material misstatement, whether due to error or fraud. Our audits included performing procedures to assess the risks of material misstatement of the financial statements, whether due to error or fraud, and performing procedures that respond to those risks. Such procedures included examining, on a test basis, evidence regarding the amounts and disclosures in the financial statements. Our audits also included evaluating the accounting principles used and significant estimates made by management, as well as evaluating the overall presentation of the financial statements. We believe that our audits provide a reasonable basis for our opinion.

/s/ ERNST & YOUNG LLP

We have served as the Company's auditor since 1991.

Redwood City, California

March 8, 2018

CERUS CORPORATION

CONSOLIDATED BALANCE SHEETS

(in thousands, except per share amounts)

	December 31,	
	2017	2016
ASSETS		
Current assets:		
Cash and cash equivalents	$13,683	$22,560
Short-term investments	47,013	45,116
Investment in marketable equity securities	—	3,952
Accounts receivable	12,415	6,868
Inventories	14,457	12,531
Prepaid expenses	1,221	1,274
Other current assets	1,109	1,804
Total current assets	89,898	94,105
Non-current assets:		
Property and equipment, net	2,119	2,985
Goodwill	1,316	1,316
Intangible assets, net	536	738
Restricted cash	247	184
Other assets	4,128	4,148
Total assets	$98,244	$103,476
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities:		
Accounts payable	$10,974	$8,587
Accrued liabilities	11,712	11,218
Debt - current	—	6,934
Deferred product revenue - current	445	149
Total current liabilities	23,131	26,888
Non-current liabilities:		
Debt - non-current	29,798	12,441
Manufacturing and development obligations - non-current	5,766	4,770
Other non-current liabilities	609	1,590
Total liabilities	59,304	45,689
Commitments and contingencies		
Stockholders' equity:		
Preferred stock, $0.001 par value; 5,000 shares authorized, issuable in series; zero shares issued and outstanding at December 31, 2017 and 2016, respectively	—	—
Common stock, $0.001 par value; 225,000 shares authorized; 115,555 and 103,475 shares issued and outstanding at December 31, 2017 and 2016, respectively	115	103
Additional paid-in capital	760,225	718,299

Accumulated other comprehensive (loss) income	(97)	103
Accumulated deficit	(721,303)	(660,718)
Total stockholders' equity	38,940	57,787
Total liabilities and stockholders' equity	$98,244	$103,476

See accompanying Notes to Consolidated Financial Statements.

CERUS CORPORATION

CONSOLIDATED STATEMENTS OF OPERATIONS

(in thousands, except per share amounts)

	Year Ended December 31,		
	2017	2016	2015
Product revenue	$43,568	$37,183	$34,223
Cost of product revenue	22,531	20,295	23,464
Gross profit on product revenue	21,037	16,888	10,759
Government contract revenue	7,758	2,092	—
Operating expenses:			
Research and development	33,710	31,322	25,643
Selling, general and administrative	52,413	48,753	45,989
Amortization of intangible assets	202	202	202
Impairment of long-lived assets	—	150	—
Total operating expenses	86,325	80,427	71,834
Loss from operations	(57,530)	(61,447)	(61,075)
Non-operating income (expense), net:			
Gain from revaluation of warrant liability	—	—	3,566
Foreign exchange (loss) gain	(10)	21	(396)
Interest expense	(3,022)	(2,445)	(1,705)
Other income, net	3,864	1,140	71
Total non-operating income (expense) , net	832	(1,284)	1,536
Loss before income taxes	(56,698)	(62,731)	(59,539)
Provision (benefit) for income taxes	3,887	175	(3,671)
Net loss	$(60,585)	$(62,906)	$(55,868)
Net loss per share:			
Basic	$(0.56)	$(0.62)	$(0.58)
Diluted	(0.56)	(0.62)	(0.61)
Weighted average shares outstanding used for calculating net loss per share:			
Basic	108,221	101,826	96,068
Diluted	108,221	101,826	96,905

See accompanying Notes to Consolidated Financial Statements.

CERUS CORPORATION

CONSOLIDATED STATEMENTS OF COMPREHENSIVE LOSS

(in thousands)

	Year Ended December 31,		
	2017	2016	2015
Net loss	$(60,585)	$(62,906)	$(55,868)
Other comprehensive (loss) income:			
Unrealized (losses) gains on available-for-sale investments, net of taxes of zero, zero and $3,825 for 2017, 2016, and 2015, respectively	(200)	(7,186)	7,320
Comprehensive loss	$(60,785)	$(70,092)	$(48,548)

See accompanying Notes to Consolidated Financial Statements.

CERUS CORPORATION

CONSOLIDATED STATEMENTS OF STOCKHOLDERS' EQUITY

(in thousands)

	Common Stock		Additional Paid-in	Accumulated Other Comprehensive Income		Total Stockholders'
	Shares	Amount	Capital	(Loss)	Accumulated Deficit	Equity
Balance at December 31, 2014	80,404	$ 80	$ 583,416	$ (31)	$ (541,944)	$ 41,521
Net loss	—	—	—	—	(55,868)	(55,868)
Other comprehensive income	—	—	—	7,320	—	7,320
Issuance of common stock from public offering, net of offering costs	14,636	15	75,361	—	—	75,376
Issuance of common stock from exercise of stock options and warrants, and purchases from ESPP	4,055	4	19,682	—	—	19,686
Stock-based compensation	—	—	6,730	—	—	6,730
Balance at December 31, 2015	99,095	99	685,189	7,289	(597,812)	94,765
Net loss	—	—	—	—	(62,906)	(62,906)
Other comprehensive loss	—	—	—	(7,186)	—	(7,186)
Issuance of common stock from public offering, net of offering costs	3,526	3	21,978	—	—	21,981
Issuance of common stock from exercise of stock options and purchases from ESPP	854	1	3,067	—	—	3,068
Stock-based compensation	—	—	8,065	—	—	8,065
Balance at December 31, 2016	103,475	103	718,299	103	(660,718)	57,787
Net loss	—	—	—	—	(60,585)	(60,585)
Other comprehensive loss	—	—	—	(200)	—	(200)
Issuance of common stock from public offering, net of offering costs	10,986	11	30,145	—	—	30,156
Issuance of common stock from exercise of stock	1,094	1	2,426	—	—	2,427

options, vesting of restricted stock units, and purchases from ESPP						
Stock-based compensation	—	—	9,355	—	—	9,355
Balance at December 31, 2017	115,555	$ 115	$ 760,225	$ (97)	$ (721,303)	$ 38,940

See accompanying Notes to Consolidated Financial Statements.

CERUS CORPORATION

CONSOLIDATED STATEMENTS OF CASH FLOWS

(in thousands)

	Year Ended December 31,		
	2017	2016	2015
Operating activities			
Net loss	$(60,585)	$(62,906)	$(55,868)
Adjustments to reconcile net loss to net cash used in operating activities:			
Depreciation and amortization	1,811	1,817	1,699
Stock-based compensation	9,355	8,065	6,730
Changes in valuation of warrant liability	—	—	(3,566)
Non-cash interest expense	551	1,017	508
Non-cash deferred manufacturing and development expense	—	—	434
Deferred income taxes	(119)	28	7
Impairment of long-lived assets	—	150	—
Non-cash tax expense (benefit) from other unrealized gain on available-for-sale securities	3,825	—	(3,825)
Gain on sale of investment in marketable equity securities	(3,466)	(750)	—
Changes in operating assets and liabilities:			
Accounts receivable	(5,547)	(1,074)	(301)
Inventories	(2,092)	(1,781)	3,991
Other assets	1,107	1,327	1,379
Accounts payable	2,487	3,261	(3,866)
Accrued liabilities and other non-current liabilities	(507)	1,330	1,359
Manufacturing and development obligations	680	(3,568)	—
Deferred product revenue	265	(445)	190
Net cash used in operating activities	(52,235)	(53,529)	(51,129)
Investing activities			
Capital expenditures	(353)	(563)	(722)
Purchases of investments	(68,792)	(82,811)	(90,407)
Proceeds from maturities and sale of investments	69,566	63,450	92,645
Net cash provided by (used in) investing activities	421	(19,924)	1,516
Financing activities			
Net proceeds from equity incentives and warrants	2,428	3,068	12,767
Net proceeds from public offering	30,197	22,121	75,300
Proceeds from loans	30,000	—	10,000
Repayment of debt	(19,625)	(622)	(113)
Net cash provided by financing activities	43,000	24,567	97,954
Net (decrease) increase in cash, cash equivalents and restricted cash	(8,814)	(48,886)	48,341
Cash, cash equivalents and restricted cash, beginning of year	22,744	71,630	23,289
Cash, cash equivalents and restricted cash, end of year	$13,930	$22,744	$71,630
Supplemental disclosures:			
Cash paid for interest	$2,034	$1,366	$1,087

Cash paid for income taxes	160	157	153
Unpaid manufacturing and development obligation	—	—	7,051

See accompanying Notes to Consolidated Financial Statements.

CERUS CORPORATION

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

December 31, 2017

Note 1. Nature of Operations and Basis of Presentation

Cerus Corporation (the "Company") was incorporated in September 1991 and is developing and commercializing the INTERCEPT Blood System, which is designed to enhance the safety of blood components through pathogen reduction. The Company has worldwide commercialization rights for the INTERCEPT Blood System for platelets, plasma and red blood cells.

The Company sells its INTERCEPT platelet and plasma systems in the United States of America ("U.S."), Europe, the Commonwealth of Independent States ("CIS") countries, the Middle East and selected countries in other regions around the world. The Company conducts significant research, development, testing and regulatory compliance activities on its product candidates that, together with anticipated selling, general, and administrative expenses, are expected to result in substantial additional losses, and the Company may need to adjust its operating plans and programs based on the availability of cash resources. The Company's ability to achieve a profitable level of operations will depend on successfully completing development, obtaining additional regulatory approvals and achieving widespread market acceptance of its products. There can be no assurance that the Company will ever achieve a profitable level of operations.

Note 2. Summary of Significant Accounting Policies

Principles of Consolidation

The accompanying consolidated financial statements include those of Cerus Corporation and its subsidiary, Cerus Europe B.V. (together with Cerus Corporation, hereinafter "Cerus" or the "Company") after elimination of all intercompany accounts and transactions. These consolidated financial statements have been prepared in accordance with accounting principles generally accepted in the U.S. ("GAAP") and pursuant to the rules and regulations of the Securities and Exchange Commission ("SEC").

Use of Estimates

The preparation of financial statements requires management to make estimates, assumptions and judgments that affect the reported amounts of assets, liabilities, revenue and expenses, and related disclosures of contingent assets and liabilities. On an ongoing basis, management evaluates its estimates, including those related to the accounts receivable, inventory reserves, fair values of investments, stock-based compensation, intangible assets and goodwill, useful lives of intangible assets and property and equipment, income taxes, and accrued liabilities, among others. The Company bases its estimates on historical experience, future projections, and on various other assumptions that are believed to be reasonable under the circumstances. Actual results may differ from those estimates under different assumptions or conditions.

Revenue

Revenue is recognized when (i) persuasive evidence of the arrangement exists; (ii) delivery has occurred or services have been rendered; (iii) pricing is fixed or determinable; and (iv) collectability is reasonably assured. The Company's main sources of revenues for the years ended December 31, 2017, 2016 and 2015, were product revenue from sales of the INTERCEPT Blood System for platelets and plasma ("platelet and plasma systems" or "disposable kits") and UVA illumination devices ("illuminators").

Revenue related to product sales is generally recognized when the Company fulfills its obligations for each element of an agreement. For all sales of the Company's INTERCEPT Blood System products, the Company uses a binding purchase order or signed sales contract as evidence of an arrangement. The Company sells its platelet and plasma systems directly to blood banks, hospitals, universities, government agencies, as well as to distributors in certain regions. Generally, the Company's contracts with its customers do not provide for open return rights, except within a reasonable time after receipt of goods in the case of defective or non-conforming product. Deliverables and the units of accounting vary according to the provisions of each purchase order or sales contract. For revenue arrangements with multiple elements, the Company determines whether the delivered elements meet the criteria as separate units of accounting. Such criteria require that the deliverable have stand-alone value to the customer and that if a general right of return exists relative to the delivered item, delivery or performance of the undelivered item(s) is considered probable and substantially in the control of the Company. Once the Company determines if the deliverable meets the criteria for a separate unit of accounting, the Company must determine how the consideration should be allocated between the deliverables and how the separate units of accounting should be recognized as product revenue. Consideration received is allocated to elements that are identified as discrete units of accounting. Because the Company has no vendor specific objective evidence or third party evidence for its systems due to the Company's variability in its pricing across the regions into which it sells its products, the allocation of product revenue is based on

best estimated selling price for the products sold. The objective of best estimated selling price is to determine the price at which the Company would transact a sale, had the product been sold on a stand-alone basis. The Company determines best estimated selling price for its systems by considering multiple factors. The Company regularly reviews best estimated selling price. At December 31, 2017 and 2016, the Company had $0.4 million and $0.1 million, respectively, of short-term deferred revenue on its consolidated balance sheets related to future performance obligations. At each of December 31, 2017 and 2016, the Company had less than $0.1 million of long-term deferred revenue included in “Other non-current liabilities” on it consolidated balance sheets related to future performance obligations. Freight costs charged to customers are recorded as a component of product revenue. Taxes that the Company invoices to its customers and remits to governments are recorded on a net basis, which excludes such tax from product revenue.

The Company receives reimbursement under its U.S. government contract with the Biomedical Advanced Research and Development Authority (“BARDA”) that supports research and development of defined projects. See “Note 14. Development and License Agreements—Agreement with BARDA” below. The contract generally provides for reimbursement of approved costs incurred under the terms of the contract. Revenue related to the cost reimbursement provisions under the Company’s U.S. government contract are recognized as the qualified direct and indirect costs on the projects are incurred. The Company invoices under its U.S. government contract using the provisional rates in the government contract and thus is subject to future audits at the discretion of government. These audits could result in an adjustment to government contract revenue previously reported, which adjustments potentially could be significant. The Company believes that revenue for periods not yet audited has been recorded in amounts that are expected to be realized upon final audit and settlement. Costs incurred related to services performed under the contract are included as a component of research and development or selling, general and administrative expenses in the Company’s consolidated statements of operations. The Company’s use of estimates in recording accrued liabilities for government contract activities (see “Use of Estimates” above) affects the revenue recorded from development funding and under the government contract.

Research and Development Expenses

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

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

Cash Equivalents

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

Investments

Investments with original maturities of greater than three months primarily include corporate debt and U.S. government agency securities are designated as available-for-sale and classified as short-term investments or

investment in marketable equity securities. Available-for-sale securities are carried at estimated fair value. The Company views its available-for-sale portfolio as available for use in its current operations. Unrealized gains and losses derived by changes in the estimated fair value of available-for-sale securities were recorded in “Net unrealized (losses) gains on available-for-sale investments, net of taxes” on the Company’s consolidated statements of comprehensive loss. Realized gains (losses) from the sale of available-for-sale investments were recorded in “Other income, net” on the Company’s consolidated statements of operations. The costs of securities sold are based on the specific identification method, if applicable. The Company reported the amortization of any premium and accretion of any discount resulting from the purchase of debt securities as a component of interest income.

The Company also reviews its available-for-sale securities on a regular basis to evaluate whether any security has experienced an other-than-temporary decline in fair value. Other-than-temporary declines in market value, if any, are recorded in “Other income, net” on the Company’s consolidated statements of operations.

Restricted Cash

As of December 31, 2017 and 2016, the Company also had certain non-U.S. dollar denominated deposits recorded as "Restricted cash" in compliance with certain foreign contractual requirements.

Concentration of Credit Risk

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

Pursuant to the Company's investment policy, substantially all of the Company's cash, cash equivalents and available-for-sale securities are maintained at major financial institutions of high credit standing. The Company monitors the financial credit worthiness of the issuers of its investments and limits the concentration in individual securities and types of investments that exist within its investment portfolio. Generally, all of the Company's investments carry high credit quality ratings, which is in accordance with its investment policy. At December 31, 2017, the Company does not believe there is significant financial risk from non-performance by the issuers of the Company's cash equivalents and short-term investments.

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

The Company had three customers that accounted for more than 10% of the Company's outstanding trade receivables at both December 31, 2017 and 2016. These customers cumulatively represented approximately 53% and 46% of the Company's outstanding trade receivables at December 31, 2017 and 2016, respectively. To date, the Company has not experienced collection difficulties from these customers.

Inventories

At December 31, 2017 and 2016, inventory consisted of work-in-process and finished goods only. Finished goods include INTERCEPT disposable kits, illuminators, and certain replacement parts for the illuminators. Platelet and plasma systems' disposable kits generally have 18 to 24 months shelf lives from the date of manufacture. Illuminators and replacement parts do not have regulated expiration dates. Work-in-process includes certain components that are manufactured over a protracted length of time before being sold to, and ultimately incorporated and assembled by Fresenius Kabi Deutschland GmbH or Fresenius, Inc. (with their affiliates, "Fresenius") into the finished INTERCEPT disposable kits. The Company maintains an inventory balance based on its current sales projections, and at each reporting period, the Company evaluates whether its work-in-process inventory would be sold to Fresenius for production of finished units in order to sell to existing and prospective customers within the next twelve-month period. It is not customary for the Company's production cycle for inventory to exceed twelve months. Instead, the Company uses its best judgment to factor in lead times for the production of its work-in-process and finished units to meet the Company's forecasted demands. If actual results differ from those estimates, work-in-process inventory could potentially accumulate for periods exceeding one year. At December 31, 2017 and 2016, the Company classified its work-in-process inventory as a current asset on its consolidated balance sheets based on its evaluation that the work-in-process inventory would be sold to Fresenius for finished disposable kit production within each respective subsequent twelve-month period.

Inventory is recorded at the lower of cost, determined on a first-in, first-out basis, or net realizable value. The Company uses significant judgment to analyze and determine if the composition of its inventory is obsolete, slow-moving or unsalable and frequently reviews such determinations. The Company writes down specifically identified unusable, obsolete, slow-moving, or known unsalable inventory that has no alternative use in the period that it is first recognized by using a number of factors including product expiration dates, open and unfulfilled orders, and sales forecasts. Any write-down of its inventory to net realizable value establishes a new cost basis and will be maintained even if certain circumstances suggest that the inventory is recoverable in subsequent periods. Costs associated with the write-down of inventory are recorded in “Cost of product revenue” on the Company’s consolidated statements of operations. At both December 31, 2017 and 2016, the Company had $0.1 million recorded for potential obsolete, expiring or unsalable product.

Property and Equipment, net

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

Goodwill and Intangible Assets, net

Intangible assets, net, which include a license for the right to commercialize the INTERCEPT Blood System in Asia, are subject to ratable amortization over the original estimated useful life of ten years. The amortization of the Company's intangible assets, net, is recorded in "Amortization of intangible assets" on the Company's consolidated statements of operations. Goodwill is not amortized but instead is subject to an impairment test performed on an annual basis, or more frequently if events or changes in circumstances indicate that goodwill may be impaired. Such impairment analysis is performed on August 31 of each fiscal year, or more frequently if indicators of impairment exist. The test for goodwill impairment may be assessed using qualitative factors to determine whether it is more likely than not that the fair value of a reporting unit is less than the carrying amount. If the Company determines that it is more likely than not that the fair value of a reporting unit is less than the carrying amount, the Company must then proceed with performing the quantitative goodwill impairment test. The Company may choose not to perform the qualitative assessment to test goodwill for impairment and proceed directly to the quantitative impairment test; however, the Company may revert to the qualitative assessment to test goodwill for impairment in any subsequent period. The quantitative goodwill impairment test compares the fair value of each reporting unit with its respective carrying amount, including goodwill. The Company has determined that it operates in one reporting unit and estimates the fair value of its one reporting unit using the enterprise approach under which it considers the quoted market capitalization of the Company as reported on the Nasdaq Global Market. The Company considers quoted market prices that are available in active markets to be the best evidence of fair value. The Company also considers other factors, which include future forecasted results, the economic environment and overall market conditions. If the fair value of the reporting unit exceeds its carrying amount, goodwill of the reporting unit is considered not impaired. If the carrying amount of the reporting unit's goodwill exceeds the implied fair value of that goodwill, an impairment loss is recognized in an amount equal to that excess, limited to the carrying amount of goodwill in the Company's one reporting unit.

The Company performs an impairment test on its intangible assets, if certain events or changes in circumstances occur which indicate that the carrying amounts of its intangible assets may not be recoverable. If the intangible assets are not recoverable, an impairment loss would be recognized by the Company based on the excess amount of the carrying value of the intangible assets over its fair value. For further details regarding the impairment analysis, reference is made to the section below under "Long-lived Assets." See Note 6 for further information regarding the Company's impairment analysis and the valuation of goodwill and intangible assets, net.

Long-lived Assets

The Company evaluates its long-lived assets for impairment by continually monitoring events and changes in circumstances that could indicate carrying amounts of its long-lived assets may not be recoverable. When such events or changes in circumstances occur, the Company assesses recoverability by determining whether the carrying value of such assets will be recovered through the undiscounted expected future cash flows. If the expected undiscounted future cash flows are less than the carrying amount of these assets, the Company then measures the amount of the

impairment loss based on the excess of the carrying amount over the fair value of the assets.

Foreign Currency Remeasurement

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

Stock-Based Compensation

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

For stock-based awards issued to non-employees, the measurement date at which the fair value of the stock-based award is measured to be the earlier of (i) the date at which a commitment for performance by the grantee to earn the equity instrument is reached or (ii) the date at which the grantee's performance is complete. The Company recognizes stock-based compensation expense for the fair value of the vested portion of the non-employee stock-based awards in its consolidated statements of operations.

See Note 12 for further information regarding the Company's stock-based compensation assumptions and expenses.

Income Taxes

The provision for income taxes is accounted for using an asset and liability approach, under which deferred tax assets and liabilities are determined based on differences between the financial reporting and tax bases of assets and liabilities and are measured using the enacted tax rates and laws that will be in effect when the differences are expected to reverse. The Company does not recognize tax positions that do not have a greater than 50% likelihood of being recognized upon review by a taxing authority having full knowledge of all relevant information. Use of a valuation allowance is not an appropriate substitute for derecognition of a tax position. The Company recognizes accrued interest and penalties related to unrecognized tax benefits in its income tax expense. To date, the Company has not recognized any interest and penalties in its consolidated statements of operations, nor has it accrued for or made payments for interest and penalties. Although the Company believes it more likely than not that a taxing authority would agree with its current tax positions, there can be no assurance that the tax positions the Company has taken will be substantiated by a taxing authority if reviewed. The Company's U.S. federal tax returns for years 1998 through 2016 and California tax returns for years through 2016 remain subject to examination by the taxing jurisdictions due to unutilized net operating losses and research credits. The Company continues to carry a full valuation allowance on substantially all of its net deferred tax assets.

Net Loss Per Share

Basic net loss per share is computed by dividing net loss by the weighted average number of common shares outstanding for the period. Diluted net loss per share gives effect to all potentially dilutive common shares outstanding for the period. The potentially dilutive securities include stock options, employee stock purchase plan rights, warrants, and restricted stock units, which are calculated using the treasury stock method.

For the years ended December 31, 2017, 2016 and 2015, certain potential dilutive securities outstanding have been excluded from the computation of dilutive weighted average shares outstanding because such securities have an antidilutive impact due to losses reported.

The following table sets forth the reconciliation of the numerator and denominator used in the computation of basic and diluted net loss per share for the years ended December 31, 2017, 2016 and 2015 (in thousands, except per share amounts):

	Year Ended December 31,		
	2017	2016	2015
Numerator for Basic and Diluted:			
Net loss used for basic calculation	$(60,585)	$(62,906)	$(55,868)
Effect of revaluation of warrant liability	—	—	(3,566)
Adjusted net loss used for dilution calculation	$(60,585)	$(62,906)	$(59,434)
Denominator:			

Basic weighted average number of shares outstanding	108,221	101,826	96,068
Effect of dilutive potential shares	—	—	837
Diluted weighted average number of shares outstanding	108,221	101,826	96,905
Net loss per share:			
Basic	$(0.56)	$(0.62)	$(0.58)
Diluted	(0.56)	(0.62)	(0.61)

The table below presents shares underlying stock options, restricted stock units, and employee stock purchase plan rights that were excluded from the calculation of the weighted average number of shares outstanding used for the calculation of diluted net loss per share. These are excluded from the calculation due to their anti-dilutive effect for the years ended December 31, 2017, 2016 and 2015 (shares in thousands):

	Year Ended December 31,		
	2017	2016	2015
Weighted average number of anti-dilutive potential shares:			
Stock options	17,373	15,592	13,681
Restricted stock units	1,225	576	—
Employee stock purchase plan rights	21	43	5
Total	18,619	16,211	13,686

Guarantee and Indemnification Arrangements

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

The Company generally provides for a one-year warranty on certain of its INTERCEPT blood-safety products covering defects in materials and workmanship. The Company accrues costs associated with warranty obligations when claims become known and are estimable. The Company has not experienced significant or systemic warranty claims nor is it aware of any existing current warranty claims. Accordingly, the Company had not accrued for any future warranty costs for its products at December 31, 2017 and 2016.

Fair Value of Financial Instruments

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

assesses any transfers among fair value measurement levels at the end of each reporting period.

See Note 3 for further information regarding the Company’s valuation of financial instruments.

New Accounting Pronouncements

In May 2014, the Financial Accounting Standards Board (“FASB”) issued ASU No. 2014-09, Revenue from Contracts with Customers (Topic 606), which provides a single comprehensive model for entities to use in accounting for revenue arising from contracts with customers and will supersede most current revenue recognition guidance. This ASU is based on the principle that revenue is recognized to depict the transfer of goods or services to customers in an amount that reflects the consideration to which the entity expects to be entitled in exchange for those goods or services. The ASU also requires additional disclosure about the nature, amount, timing and uncertainty of revenue and cash flows arising from customer contracts, including significant judgments and changes in judgments and assets recognized from costs incurred to obtain or fulfill a contract. Subsequently, the FASB has issued the following standards related to ASU 2014-09: ASU No. 2016-08, Revenue from Contracts with Customers (Topic 606): Principal versus Agent Considerations (Reporting Revenue Gross versus Net); ASU No. 2016-10, Revenue from Contracts with Customers (Topic 606): Identifying Performance Obligations and Licensing; ASU No. 2016-12, Revenue from Contracts with Customers (Topic 606):

Narrow-Scope Improvements and Practical Expedients; and ASU No. 2016-20, Technical Corrections and Improvements to Topic 606, Revenue from Contracts with Customers. The Company will adopt these ASUs on January 1, 2018, using the modified retrospective approach. To date the Company has primarily derived its revenues from product sales of its INTERCEPT Blood System and reimbursement under its U.S. government contract. The Company has categorized its current revenue streams into homogenous populations based on the terms and conditions included in the contracts of its customers to date. The Company has completed the evaluation of the impact of the adoption to the Company's financial statements, and the evaluation of the accounting policies as well as the disclosure requirements under the new standard. The Company has concluded that the adoption of ASU 2014-09 will not have a material impact on its consolidated financial statements.

In January 2016, the FASB issued ASU No. 2016-01, Financial Instruments-Overall (Subtopic 825-10), which requires all equity investments to be measured at fair value with changes in the fair value recognized through net income (other than those accounted for under equity method of accounting or those that result in consolidation of the investee). The amendments also require an entity to present separately in other comprehensive income the portion of the total change in the fair value of a liability resulting from a change in the instrument-specific credit risk when the entity has elected to measure the liability at fair value in accordance with the fair value option for financial instruments. In addition, this ASU eliminates the requirement to disclose the fair value of financial instruments measured at amortized cost for entities that are not public business entities and the requirement to disclose the method(s) and significant assumptions used to estimate the fair value that is required to be disclosed for financial instruments measured at amortized cost on the balance sheet for public business entities. The Company will adopt this ASU on January 1, 2018. The adoption of this ASU is not expected to have a material impact on the Company's consolidated financial statements.

In February 2016, the FASB issued ASU No. 2016-02, Leases, which, for operating leases, requires a lessee to recognize a right-of-use asset and a lease liability, initially measured at the present value of the lease payments, in its balance sheet. The standard also requires a lessee to recognize a single lease cost, calculated so that the cost of the lease is allocated over the lease term, on a generally straight-line basis. The standard is effective for annual periods beginning after December 15, 2018, and interim periods thereafter, with early application permitted. The Company does not anticipate early adoption of the new standard and is currently assessing the future impact of this ASU on its consolidated financial statements. The Company anticipates that the Company's operating lease commitments will be subject to the new standard and be recognized as operating lease liabilities and right-of-use assets upon the adoption of this ASU, which will increase the total assets and total liabilities on the Company's Consolidated Balance Sheets. The adoption of this ASU is not expected to have a material impact on the Company's Consolidated Statements of Operations.

In March 2016, the FASB issued ASU No. 2016-09, Compensation-Stock Compensation (Topic 718):Improvements to Employee Share-Based Payment Accounting, which requires entities to record all excess tax benefits and tax deficiencies as income tax expense or benefit in the income statement when awards vest or are settled, and eliminates additional paid-in capital pools. The ASU also changes the accounting for an employee's use of shares to satisfy the employer's statutory income tax withholding obligation, and the accounting for forfeitures, and provides two practical expedients for nonpublic entities. The Company adopted this ASU in the first quarter of fiscal year 2017 and it did not have a significant impact on the Company's consolidated financial statements.

In June 2016, the FASB issued ASU No. 2016-13, Financial Instruments—Credit Losses (Topic 326): Measurement of Credit Losses on Financial Instruments, which requires measurement and recognition of expected credit losses for financial assets held. The standard is effective for annual periods beginning after December 15, 2019, and interim periods thereafter, with early application permitted. The Company does not anticipate early adoption of the new standard and is currently assessing the future impact of this ASU on the Company's consolidated financial statements.

In January 2017, the FASB issued ASU No. 2017-04, Intangibles—Goodwill and Other (Topic 350): Simplifying the Test for Goodwill Impairment, which removes Step 2 from the goodwill impairment test and modifies the goodwill impairment to be the amount by which a reporting unit's carrying value exceeds its fair value, not to exceed the carrying amount of goodwill allocated to that report unit. The standard is effective for annual periods beginning after December 15, 2019, and interim periods thereafter, with early application permitted for impairment tests performed after January 1, 2017. The Company adopted this ASU in the first quarter of fiscal year 2017 and it had no impact on the Company's consolidated financial statements.

In May 2017, the FASB issued ASU No. 2017-09, Compensation-Stock Compensation (Topic 718): Scope of Modification Accounting, which provides guidance about which changes to the terms or conditions of a share-based payment award require an entity to apply modification accounting in Topic 718. The Company will adopt this ASU on January 1, 2018. The adoption of this ASU is not expected to have a material impact on the Company's consolidated financial statements.

Note 3. Available-for-sale Securities and Fair Value on Financial Instruments

Available-for-sale Securities

The following is a summary of available-for-sale securities at December 31, 2017 (in thousands):

	December 31, 2017			
	Amortized Cost	Gross Unrealized Gain	Gross Unrealized Loss	Fair Value
Money market funds	$3,758	$ —	$ —	$3,758
United States government agency securities	11,252	—	(24)	11,228
Corporate debt securities	35,858	—	(73)	35,785
Total available-for-sale securities	$50,868	$ —	$ (97)	$50,771

The following is a summary of available-for-sale securities at December 31, 2016 (in thousands):

	December 31, 2016			
	Amortized Cost	Gross Unrealized Gain	Gross Unrealized Loss	Fair Value
Money market funds	$8,991	$ —	$ —	$8,991
United States government agency securities	8,030	—	(1)	8,029
Corporate debt securities	37,110	—	(23)	37,087
Marketable equity securities	—	3,952	—	3,952
Total available-for-sale securities	$54,131	$ 3,952	$ (24)	$58,059

Available-for-sale securities at December 31, 2017 and 2016, consisted of the following by contractual maturity (in thousands):

	December 31, 2017		December 31, 2016	
	Amortized Cost	Fair Value	Amortized Cost	Fair Value
One year or less	$38,836	$38,781	$54,131	$54,107
Marketable equity securities	—	—	—	3,952
Greater than one year and less than five years	12,032	11,990	—	—
Total available-for-sale securities	$50,868	$50,771	$54,131	$58,059

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

	December 31, 2017					
	Less than 12 Months		12 Months or Greater		Total	
	Fair Value	Unrealized Loss	Fair Value	Unrealized Loss	Fair Value	Unrealized Loss
Money market funds	$—	$ —	$ —	$ —	$—	$ —
United States government agency securities	8,729	(24)	—	—	8,729	(24)
Corporate debt securities	35,785	(73)	—	—	35,785	(73)
Total available-for-sale securities	$44,514	$ (97)	$ —	$ —	$44,514	$ (97)

	December 31, 2016					
	Less than 12 Months		12 Months or Greater		Total	
	Fair Value	Unrealized Loss	Fair Value	Unrealized Loss	Fair Value	Unrealized Loss
Money market funds	$—	$ —	$ —	$ —	$—	$ —
United States government agency securities	6,035	(1)	—	—	6,035	(1)
Corporate debt securities	34,086	(23)	—	—	34,086	(23)
Total available-for-sale securities	$40,121	$ (24)	$ —	$ —	$40,121	$ (24)

As of December 31, 2017, the Company considered the declines in market value of its marketable securities investment portfolio to be temporary in nature and did not consider any of its investments other-than-temporarily impaired. The Company typically invests in highly-rated securities, and its investment policy limits the amount of credit exposure to any one issuer. The policy generally requires

investments to be investment grade, with the primary objective of minimizing the potential risk of principal loss. Fair values were determined for each individual security in the investment portfolio. When evaluating an investment for other-than-temporary impairment, the Company reviews factors such as the length of time and extent to which fair value has been below its cost basis, the financial condition of the issuer and any changes thereto, changes in market interest rates, and the Company's intent to sell, or whether it is more likely than not it will be required to sell, the investment before recovery of the investment's cost basis. During the years ended December 31, 2017, 2016 and 2015, the Company did not recognize any other-than-temporary impairment loss. The Company has no current requirement or intent to sell the securities in an unrealized loss position. The Company expects to recover up to (or beyond) the initial cost of investment for securities held.

The Company recognized $3.5 million, $0.8 million and minimal gross realized gains during the years ended December 31, 2017, 2016 and 2015, respectively. The Company did not record any gross realized losses during the years ended December 31, 2017, 2016 and 2015.

Fair Value Disclosures

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

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

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

To estimate the fair value of Level 2 debt securities as of December 31, 2017, the Company's primary pricing service relies on inputs from multiple industry-recognized pricing sources to determine the price for each investment. Corporate debt and U.S. government agency securities are systematically priced by this service as of the close of business each business day. If the primary pricing service does not price a specific asset a secondary pricing service is utilized.

The fair values of the Company's financial assets and liabilities were determined using the following inputs at December 31, 2017 (in thousands):

Balance sheet classification	Total	Quoted Prices in Active Markets for Identical Assets (Level 1)	Significant Other Observable Inputs (Level 2)	Significant Unobservable Inputs (Level 3)

Money market funds	Cash and cash equivalents	$3,758	$ 3,758	$ —	$ —
United States government agency securities	Short-term investments	11,228	—	11,228	—
Corporate debt securities	Short-term investments	35,785	—	35,785	—
Total financial assets		$50,771	$ 3,758	$ 47,013	$ —

The fair values of the Company's financial assets and liabilities were determined using the following inputs at December 31, 2016 (in thousands):

	Balance sheet classification	Total	Quoted Prices in Active Markets for Identical Assets (Level 1)	Significant Other Observable Inputs (Level 2)	Significant Unobservable Inputs (Level 3)
Money market funds	Cash and cash equivalents	$8,991	$ 8,991	$ —	$ —
United States government agency securities	Short-term investments	8,029	—	8,029	—
Corporate debt securities	Short-term investments	37,087	—	37,087	—
Marketable equity securities	Marketable equity securities	3,952	3,952	—	—
Total financial assets		$58,059	$ 12,943	$ 45,116	$ —

The Company did not have any transfers among fair value measurement levels during the years ended December 31, 2017 and 2016.

Note 4. Inventories

Inventories at December 31, 2017 and 2016, consisted of the following (in thousands):

	December 31,	
	2017	2016
Work-in-process	$4,299	$5,044
Finished goods	10,158	7,487
Total inventories	$14,457	$12,531

Note 5. Property and Equipment, net

Property and equipment, net at December 31, 2017 and 2016, consisted of the following (in thousands):

	December 31,	
	2017	2016
Leasehold improvements	$5,698	$5,678
Machinery and equipment	2,028	1,925
Demonstration equipment	177	167
Furniture and fixtures	904	871
Computer equipment	514	603
Computer software	2,932	2,908
Consigned equipment	1,190	1,058
Construction-in-progress	70	62
Total property and equipment, gross	13,513	13,272
Accumulated depreciation and amortization	(11,394)	(10,287)
Total property and equipment, net	$2,119	$2,985

Depreciation and amortization expense related to property and equipment, net was $1.2 million, $1.1 million and $1.1 million for the years ended December 31, 2017, 2016 and 2015, respectively. The impairment of long-lived assets

were zero, $0.2 million, and zero for the years ended December 31, 2017, 2016 and 2015, respectively. As part of the Company's 2016 review of property and equipment, an impairment of long-lived assets on the consolidated statement of operations was recorded for construction-in-progress related to a deposit associated with a terminated agreement.

Note 6. Goodwill and Intangible Assets, net

Goodwill

During the year ended December 31, 2017, the Company did not dispose of or recognize additional goodwill. On August 31, 2017, the Company performed its impairment test of goodwill. As described in Note 2 above, the Company applied the enterprise approach by reviewing the quoted market capitalization of the Company as reported on the Nasdaq Global Market to calculate the fair value. In addition, the Company considered its future forecasted results, the economic environment and overall market conditions. As a result of the Company's assessment that its fair value of the reporting unit exceeded its carrying amount, the Company determined that goodwill was not impaired.

Intangible Assets, net

The following is a summary of intangible assets, net at December 31, 2017 (in thousands):

	December 31, 2017		
	Gross Carrying Amount	Accumulated Amortization	Net Carrying Amount
Acquisition-related intangible assets:			
Reacquired license - INTERCEPT Asia	$2,017	$ (1,481)	$ 536
Total intangible assets	$2,017	$ (1,481)	$ 536

The following is a summary of intangible assets, net at December 31, 2016 (in thousands):

	December 31, 2016		
	Gross Carrying Amount	Accumulated Amortization	Net Carrying Amount
Acquisition-related intangible assets:			
Reacquired license - INTERCEPT Asia	$2,017	$ (1,279)	$ 738
Total intangible assets	$2,017	$ (1,279)	$ 738

During the years ended December 31, 2017, 2016 and 2015, there were no impairment charges recognized related to the Company's intangible assets.

At December 31, 2017, the expected annual amortization expense of the intangible assets, net is $0.2 million beginning with the year ending December 31, 2018, through the year ending December 31, 2019, and $0.1 million for the year ending December 31, 2020.

Note 7. Marketable Equity Investments

In connection with the agreements to license the immunotherapy technologies to Aduro Biotech, Inc., ("Aduro") in 2009, the Company received preferred shares of Aduro, a privately held company at the time the Company received such shares. Pursuant to these license agreements, the Company was eligible to receive a 1% royalty fee on any future sales resulting from the licensed technology. For the years ended December 31, 2017, 2016 and 2015, the Company had not received any royalty payments from Aduro pursuant to this agreement. The Company historically accounted for the investment under the cost method of accounting with a net carrying value of zero. In April 2015, Aduro's common stock began trading on the Nasdaq Global Select Market, under the symbol "ADRO". At the time of Aduro's initial public offering ("IPO"), the Company's preferred shares in Aduro converted to 396,700 shares of common stock,

and the fair value of the Company's investment became readily determinable and, as a result became a marketable equity security. Therefore, the Company no longer accounted for the investment in Aduro under the cost basis of accounting. The Company reflected the investment in Aduro as an available-for-sale security included in investment in marketable equity securities on the Company's consolidated balance sheets (Note 3) and adjusted the carrying value of this investment to fair value each quarterly reporting period, with changes in fair value recorded within other comprehensive income (loss), net of tax. During the years ended December 31, 2017 and 2016, respectively, the Company sold 346,700 and 50,000 shares of Aduro common stock and recognized a gain of $3.5 million and $0.8 million in "Other income, net" on the Company's consolidated statements of operations. As of December 31, 2017, the Company had no remaining investment in Aduro's common stock.

Note 8. Accrued Liabilities

Accrued liabilities at December 31, 2017 and 2016, consisted of the following (in thousands):

	December 31,	
	2017	2016
Accrued compensation and related costs	$7,372	$7,098
Accrued professional services	2,605	2,511
Accrued insurance premiums	507	476
Accrued customer obligations	481	534
Other accrued expenses	747	599
Total accrued liabilities	$11,712	$11,218

Note 9. Debt

Debt at December 31, 2017, consisted of the following (in thousands):

	December 31, 2017		
	Principal	Unamortized Discount	Net Carrying Value
Loan and Security Agreement	$30,000	$ (202)	$ 29,798
Less: debt - current	—	—	—
Debt - non-current	$30,000	$ (202)	$ 29,798

Debt at December 31, 2016, consisted of the following (in thousands):

	December 31, 2016		
	Principal	Unamortized Discount	Total
Loan and Security Agreement	$19,499	$ (124)	$19,375
Less: debt - current	(7,013)	79	(6,934)
Debt - non-current	$12,486	$ (45)	$12,441

Expected future principal and interest payments based on debt balances at December 31, 2017, are expected to be as follows:

Year ended December 31,	Principal	Interest	Total
2018	$—	$2,554	2,554
2019	7,857	2,280	10,137
2020	8,571	1,558	10,129
2021	8,572	822	9,394
2022	5,000	2,542	7,542
Total	$30,000	$9,756	$39,756

Loan and Security Agreement

Prior to December 31, 2016, the Company maintained a five year loan and security agreement (the “Term Loan Agreement”) with Oxford Finance LLC (“Oxford”), under which the Company borrowed $20.0 million. The Company received $10.0 million from the first tranche (“Term Loan A”) in June 2014. The second tranche of $10.0 million (“Term Loan B”) was drawn in June 2015. Term Loan A bore an interest rate of 6.95%. Term Loan B bore an interest rate of 7.01%. Term Loans A and B were set to mature on June 1, 2019, with various interest only periods.

On April 27, 2017, the Term Loan Agreement was amended to include an additional interest-only period for all advances under the Term Loan Agreement. As amended, the Company was required to make interest only payments from May 2017 through December 2017, followed by eighteen months of equal principal and interest payments thereafter. The Company determined that each of these amendments to the Term Loan Agreement resulted in a debt modification. As a result, the accounting treatment for the Term Loan continued under the interest method, with a new effective interest rate based on revised cash flows calculated on a prospective basis upon the execution of each of these amendments to the Term Loan Agreement. The Company was also required to make a final payment equal to 7% of the principal amounts of the Term Loans drawn payable on the earlier to occur of maturity or prepayment.

On July 31, 2017 (the “Closing Date”), the Company entered into an amended and restated loan and security agreement (the “Amended Credit Agreement”) with Oxford, which amends and restates the Term Loan Agreement in its entirety. The Amended Credit Agreement provides for secured growth capital term loans of up to $40.0 million (the “2017 Term Loans”). All of the Company’s current and future assets, excluding its intellectual property and 35% of the Company’s investment in Cerus Europe B.V., are secured for its borrowings under the Amended Credit Agreement. The 2017 Term Loans are available in two tranches. The first tranche of $30.0 million (“2017 Term Loan A”) was drawn by the Company on July 31, 2017, with the proceeds used in part to repay in full all of the outstanding term loans under the Term Loan Agreement of $17.6 million and the final payment of the Term Loan Agreement of $1.4 million. The second tranche of $10.0 million (“2017 Term Loan B”) will be made available to the Company upon the Company’s achieving consolidated trailing six-month revenues as defined in the agreement (the “Revenue Milestone”). If the Revenue Milestone is achieved, the Company may draw the 2017 Term Loan B through the earlier of (i) January 31, 2019, and (ii) the date which is 60 days after the achievement of the Revenue Milestone. The 2017 Term Loans require interest-only payments through February 1, 2019, followed by 42 months payments of equal principal plus declining interest payments. However, if the Company draws the 2017 Term Loan B, then the interest-only period will be extended through August 1, 2019, and the amortization period will be reduced to 36 months. Interest on 2017 Term Loan A and 2017 Term Loan B will bear interest at a rate equal to the greater of (i)

8.01% and (ii) the three-month U.S. LIBOR rate plus 6.72%. The interest rate of Term Loan A at December 31, 2017, was approximately 8.4%. The Company will also be required to make a final payment fee of 8.00% of the principal amounts of the 2017 Term Loans. The Amended Credit Agreement contains certain nonfinancial covenants, with which the Company was in compliance at December 31, 2017.

Note 10. Commitments and Contingencies

Operating Leases

The Company leases its office facilities, located in Concord, California and Amersfoort, the Netherlands, and certain equipment and automobiles under non-cancelable operating leases with initial terms in excess of one year that require the Company to pay operating costs, property taxes, insurance and maintenance. The operating leases expire at various dates through 2023, with certain of the leases providing for renewal options, provisions for adjusting future lease payments based on the consumer price index, and the right to terminate the lease early. The Company's leased facilities qualify as operating leases and as such, are not included on its consolidated balance sheets.

Future minimum non-cancelable lease payments under operating leases as of December 31, 2017, are as follows (in thousands):

Year ended December 31,	Lease Payments
2018	$ 1,387
2019	1,169
2020	239
2021	200
2022	177
Thereafter	17
Total	$ 3,189

Rent expense for office facilities was $1.0 million, $0.8 million and $0.8 million for the years ended December 31, 2017, 2016 and 2015, respectively.

Financed Leasehold Improvements

In 2010, the Company financed $1.1 million of leasehold improvements. The Company pays for the financed leasehold improvements as a component of rent and is required to reimburse its landlord over the remaining life of the respective leases. At December 31, 2017, the Company had an outstanding liability of $0.3 million related to these leasehold improvements, of which $0.2 million was reflected in "Accrued liabilities" and $0.1 million was reflected in "Other non-current liabilities" on the Company's consolidated balance sheets.

Purchase Commitments

The Company is party to agreements with certain providers for certain components of INTERCEPT Blood System which the Company purchases from third party manufacturers. Certain of these agreements require minimum purchase commitments from the Company. The Company has paid $6.7 million, $6.9 million and $7.7 million for goods under agreements which are subject to minimum purchase commitments during the years ended December 31, 2017, 2016 and 2015, respectively. As of December 31, 2017, the Company has future minimum purchase commitments under these agreements of approximately $9.6 million, $2.4 million, $2.6 million and $4.9 million for the years ending December 31, 2018, 2019, 2020, and 2021 respectively.

In June 2014, the Company terminated its distribution agreement with one of its distributors in certain countries and entered into an agreement to provide for specific post-termination obligations (the “Transition Agreement”). The Transition Agreement expired September 30, 2014. The Company is required to pay this former distributor certain fees for platelet systems sold by the Company to any customer in certain countries commencing with the termination of the agreement through April 1, 2018, subject to a maximum payment of €3 million. As this former distributor remains as a customer in other countries, any fees paid to the former distributor related to INTERCEPT disposable kits are offset against the revenue associated with the sale of INTERCEPT disposable kits in those territories.

Note 11. Stockholders’ Equity

Sales Agreement

On May 5, 2016, the Company entered into Amendment No. 2 to the Controlled Equity Offering^{SM} Sales Agreement, dated August 31, 2012, as previously amended on March 21, 2014, (together, the “Prior Cantor Agreement”) with Cantor Fitzgerald & Co.

("Cantor") that provides for the issuance and sale of shares of the Company's common stock having an aggregate offering price of up to $132.2 million through Cantor over the term of the Amended Cantor Agreement. As a result of Amendment No. 2, at May 5, 2016, the Company had $70 million of common stock available to be sold under the Amended Cantor Agreement. During the years ended December 31, 2017 and 2016, 11.0 million and 3.5 million shares, respectively, of the Company's common stock were sold under the Prior Cantor Agreement for net proceeds of $30.3 million and $22.0 million, respectively.

On August 4, 2017, the Company entered into Amendment No. 3 to the Prior Cantor Agreement (together, the "Amended Cantor Agreement"). The Amended Cantor Agreement became effective on January 8, 2018, and provides for the issuance and sale of shares of the Company's common stock having an aggregate offering price of up to $70.0 million through Cantor, which amount includes the $31.4 million of unsold shares of common stock available for sale under the Prior Cantor Agreement immediately prior to the effectiveness of the Amended Cantor Agreement. Under the Amended Cantor Agreement, Cantor also acts as the Company's sales agent and receives compensation based on an aggregate of 2% of the gross proceeds on the sale price per share of its common stock. The issuance and sale of these shares by the Company pursuant to the Amended Cantor Agreement are deemed an "at-the-market" offering and are registered under the Securities Act of 1933, as amended.

Stockholder Rights Plan

In October 2009, the Company's Board of Directors adopted an amendment to its 1999 stockholder rights plan, commonly referred to as a "poison pill," to reduce the exercise price, extend the expiration date and revise certain definitions under the plan. The stockholder rights plan is intended to deter hostile or coercive attempts to acquire the Company. The stockholder rights plan enables stockholders to acquire shares of the Company's common stock, or the common stock of an acquirer, at a substantial discount to the public market price should any person or group acquire more than 15% of the Company's common stock without the approval of the Board of Directors under certain circumstances. The Company has designated 250,000 shares of Series C Junior Participating preferred stock for issuance in connection with the stockholder rights plan. As of December 31, 2017, no Series C Junior Participating preferred stock has been issued. The expiration date of the rights issued under the stockholder rights plan is October 27, 2019.

Note 12. Stock-Based Compensation

Employee Stock Plans

Employee Stock Purchase Plan

The Company maintains an Employee Stock Purchase Plan (the "Purchase Plan"), which is intended to qualify as an employee stock purchase plan within the meaning of Section 423(b) of the Internal Revenue Code. Under the Purchase Plan, the Company's Board of Directors may authorize participation by eligible employees, including officers, in periodic offerings. Under the Purchase Plan eligible employee participants may purchase shares of common stock of the Company at a purchase price equal to 85% of the lower of the fair market value per share on the start date of the offering period or the fair market value per share on the purchase date. The Purchase Plan consists of a fixed offering period of 12 months with two purchase periods within each offering period. At December 31, 2017, the Company had 1.2 million shares available for future issuance.

2008 Equity Incentive Plan and Inducement Plan

The Company also maintains an equity compensation plan to provide long-term incentives for employees, contractors, and members of its Board of Directors. The Company currently grants equity awards from one plan, the 2008 Equity Incentive Plan (the "2008 Plan"). The 2008 Plan allows for the issuance of non-statutory and incentive stock options, restricted stock, restricted stock units ("RSUs"), stock appreciation rights, other stock-related awards, and performance awards which may be settled in cash, stock, or other property. On June 6, 2012 and June 12, 2013, the stockholders approved amendments to the 2008 Plan (collectively the "Amended 2008 Plan") such that the Amended 2008 Plan had reserved for issuance an amount not to exceed 19.5 million shares. On June 10, 2015, the Company's stockholders approved an amendment and restatement of the 2008 Plan that increased the aggregate number of shares of common stock authorized for issuance under the 2008 Plan by 5,000,000 shares. On June 7, 2017, the Company's stockholders approved an amendment and restatement of the 2008 Plan that increased the aggregate number of shares of common stock authorized for issuance under the 2008 Plan by 6,000,000 shares. Awards under the Amended 2008 Plan generally have a maximum term of 10 years from the date of the award. The Amended 2008 Plan generally requires options to be granted at 100% of the fair market value of the Company's common stock subject to the option on the date of grant. Options granted by the Company to employees generally vest over four years. RSUs are measured based on the fair market value of the underlying stock on the date of grant and will generally vest over three years. Performance-based stock or cash awards granted under the Amended 2008 Plan are limited to either 500,000 shares of common stock or $1.0 million per recipient per calendar year. The attainment of any performance-based awards granted shall be conclusively determined by a committee designated by the Company's Board of Directors. At December 31, 2017, no performance-based stock options were outstanding. On August 31, 2016, the Company's Board of Directors

adopted the Cerus Corporation Inducement Plan (the "Inducement Plan"), and reserved 1,250,000 shares of its common stock under the Inducement Plan to be used exclusively for the issuance of non-statutory stock options and restricted stock units to individuals who were not previously employees or directors of the Company, or who had experienced a bona fide period of non-employment, as an inducement material to the individual's entry into employment with the Company within the meaning of Rule 5635(c)(4) of the Nasdaq Listing Rules. The Inducement Plan was approved by the Company's Board of Directors without stockholder approval pursuant to Rule 5635(c)(4), and the terms and conditions of the Inducement Plan are substantially similar to the Amended 2008 Plan. Effective June 7, 2017, the Company no longer issues shares from the Inducement Plan.

At December 31, 2017, the Company had an aggregate of approximately 26.4 million shares of its common stock subject to outstanding options or RSUs, or remaining available for future issuance under the Amended 2008 Plan, of which approximately 17.1 million shares and 1.3 million shares were subject to outstanding options and outstanding RSUs, respectively, and approximately 8.0 million shares were available for future issuance under the Amended 2008 Plan. The Company's policy is to issue new shares of common stock upon the exercise of options or vesting of RSUs.

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

	Number of Options Outstanding	Weighted Average Exercise Price per Share
Balances at December 31, 2016	15,787	$ 4.39
Granted	3,304	4.14
Forfeited	(1,087)	5.18
Expired	(322)	7.80
Exercised	(544)	3.11
Balances at December 31, 2017	17,138	4.27

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

	Number of Shares Outstanding	Weighted Average Grant Date Fair Value per Share
Balances at December 31, 2016	739	$ 5.26
Granted	918	4.18

Forfeited	(132	)	4.53
Vested	(269	)	5.35
Balances at December 31, 2017	1,256		4.53

The total fair value of RSUs as of their respective vesting dates, for the years ended December 31, 2017, 2016 and 2015, were $1.0 million, zero and zero, respectively.

Information regarding the Company's stock options outstanding, stock options vested and expected to vest, and stock options exercisable at December 31, 2017, was as follows (in thousands except weighted average exercise price and contractual term):

	Number of Shares	Weighted Average Exercise Price	Weighted Average Remaining Contractual Term (Years)	Aggregate Intrinsic Value
Balances at December 31, 2017				
Stock options outstanding	17,138	$ 4.27	6.3	$ 3,691
Stock options vested and expected to vest	16,911	4.27	6.2	3,681
Stock options exercisable	12,109	4.12	5.4	3,487

The aggregate intrinsic value in the table above is calculated as the difference between the exercise price of the stock option and the Company's closing stock price on the last trading day of each respective fiscal period.

The total intrinsic value of options exercised for the years ended December 31, 2017, 2016 and 2015, was $0.6 million, $1.9 million and $1.2 million, respectively.

Stock-based Compensation Expense

Stock-based compensation expense recognized on the Company's consolidated statements of operations for the years ended December 31, 2017, 2016 and 2015, was as follows (in thousands):

	Year Ended December 31,		
	2017	2016	2015
Stock-based compensation expense by caption:			
Research and development	$1,323	$1,091	$1,260
Selling, general and administrative	8,032	6,974	5,470
Total stock-based compensation expense	$9,355	$8,065	$6,730

Stock-based compensation expense in the above table does not reflect any income taxes as the Company has experienced a history of net losses since its inception and has a full valuation allowance on its deferred tax assets. In addition, there was neither income tax benefits realized related to stock-based compensation expense nor any stock-based compensation costs capitalized as part of an asset during the years ended December 31, 2017, 2016 and 2015. The Company has also not recorded any stock-based compensation associated with performance-based stock options during the years ended December 31, 2017, 2016 and 2015.

As of December 31, 2017, the Company expects to recognize the remaining unamortized stock-based compensation expense of $9.7 million and $3.6 million, respectively, related to non-vested stock options and RSUs, net of estimated forfeitures, over an estimated remaining weighted average period of 2.4 years and 1.8 years, respectively.

Valuation Assumptions for Stock-based Compensation

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

The expected life of the stock options is based on observed historical exercise patterns. Groups of employees having similar historical exercise behavior are considered separately for valuation purposes. The Company estimates stock option forfeitures based on historical data for employee groups. The total number of stock options expected to vest is adjusted by actual and estimated forfeitures.

The expected volatility is estimated by using historical volatility of the Company's common stock. The risk-free interest rate is based on the implied yield on a U.S. Treasury zero-coupon issue with a remaining term commensurate with the expected term of the option. The Company does not anticipate paying any cash dividends in the foreseeable future and therefore uses an expected dividend yield of zero.

The weighted average assumptions used to value the Company's stock-based awards for the years ended December 31, 2017, 2016 and 2015, was as follows:

	Year Ended December 31,		
	2017	2016	2015
Stock Options:			
Expected term (in years)	6.12	5.85	5.66
Estimated volatility	47%	49%	56%
Risk-free interest rate	2.14%	1.41%	1.55%
Expected dividend yield	0%	0%	0%
Employee Stock Purchase Plan Rights:			
Expected term (in years)	0.92	0.76	0.75
Estimated volatility	57%	47%	53%
Risk-free interest rate	1.08%	0.55%	0.28%
Expected dividend yield	0%	0%	0%

The weighted average grant-date fair value of stock options granted during the years ended December 31, 2017, 2016 and 2015, was $1.98 per share, $2.55 per share and $2.35 per share, respectively. The weighted average grant-date fair value of employee stock

purchase rights during the years ended December 31, 2017, 2016 and 2015, was $1.18 per share, $1.87 per share and $1.54 per share, respectively.

Note 13. Retirement Plan

The Company maintains a defined contribution savings plan (the "401(k) Plan") that qualifies under the provisions of Section 401(k) of the Internal Revenue Code and covers eligible U.S. employees of the Company. Under the terms of the 401(k) Plan, eligible U.S. employees may make pre-tax dollar contributions of up to 60% of their eligible pay up to a maximum cap established by the IRS. The Company may contribute a discretionary percentage of qualified individual employee's salaries, as defined, to the 401(k) Plan. The Company has not contributed to the 401(k) Plan during the years ended December 31, 2017, 2016 and 2015.

Note 14. Development and License Agreements

Agreements with Fresenius

Fresenius manufactures and supplies the platelet and plasma systems to the Company under a supply agreement (the "Supply Agreement"). Fresenius is obligated to sell, and the Company is obligated to purchase, finished disposable kits for the Company's platelet and plasma systems and the Company's red blood cell system product candidate (the "RBC Sets"). The Supply Agreement permits the Company to purchase platelet and plasma systems and RBC Sets from third parties to the extent necessary to maintain supply qualifications with such third parties or where local or regional manufacturing is needed to obtain product registrations or sales. Pricing terms per unit are initially fixed and decline at specified annual production levels, and are subject to certain adjustments after the initial pricing term. Under the Supply Agreement, the Company maintains the amounts due from the components sold to Fresenius as a current asset on its accompanying consolidated balance sheets until such time as the Company purchases finished disposable kits using those components.

The Supply Agreement also requires the Company to make certain payments totaling €8.6 million ("Manufacturing and Development Payments") to Fresenius. In 2016, the Company paid €3.1 million to Fresenius. The remaining €5.5 million will be paid on December 31 of the earlier of (a) the year of achievement of certain production volumes or (b) 2022. Because these payments represent unconditional payment obligations, the Company recognized its liability for these payments at their net present value at discount rate of 9.72% based on the Company's effective borrowing rate at that time. The Manufacturing and Development Payments liability is accreted through interest expense based on the estimated timing of its ultimate settlement. As of December 31, 2017 and 2016, the Company accrued $5.8 million (€4.8 million) and $4.8 million (€4.5 million), respectively, related to the remaining Manufacturing and Development Payments, which were included in "Manufacturing and development obligations - non-current" on the Company's consolidated balance sheets.

The Manufacturing and Development Payments are made to support certain projects Fresenius has and will perform on behalf of the Company related to certain R&D activities and manufacturing efficiency activities. The Company allocated $4.8 million to R&D activities and $2.4 million to manufacturing efficiency activities based on their market

value in October 2015. The prepaid asset related to amounts paid up front for the R&D activities to be conducted by Fresenius on behalf of the Company is expensed over the period which such activities occur. The manufacturing efficiency asset is expensed on a straight line basis over the life of the 2015 Agreement. The following table summarizes the amount of prepaid R&D asset and manufacturing efficiency asset at December 31, 2017 and December 31, 2016.

	December 31,	
(in thousands)	2017	2016
Prepaid R&D asset - current [1]	$114	$923
Prepaid R&D asset - non-current [2]	2,162	1,984
Manufacturing efficiency asset [2]	1,839	2,085

(1) Included in “Other current assets” in the Company's consolidated balance sheets.
(2) Included in “Other assets” in the Company's consolidated balance sheets.

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

The Company made payments to Fresenius of $18.1 million, $16.1 million and $14.9 million relating to the manufacturing of the Company’s products during the years ended December 31, 2017, 2016 and 2015, respectively. At December 31, 2017 and

December 31, 2016, the Company owed Fresenius $4.7 million and $3.0 million, respectively, for INTERCEPT disposable kits manufactured, and the amounts were included in “Accounts Payable” and “Accrued liabilities” on the Company’s consolidated balance sheets. At December 31, 2017 and December 31, 2016, amounts due from Fresenius were $0.2 million and $0.3 million, respectively, and the amounts were included in “Other current assets” on the Company’s consolidated balance sheets.

Agreement with BARDA

In June 2016, the Company entered into an agreement with BARDA to support the Company’s development and implementation of pathogen reduction technology for platelet, plasma, and red blood cells.

The five-year agreement with BARDA includes a base period (the “Base Period”) and options (each an “Option Period”) with committed funding as of December 31, 2017, of up to $88.2 million for clinical development of the INTERCEPT Blood System for red blood cells (the “red blood cell system”), and the potential for the exercise by BARDA of subsequent Option Periods that, if exercised by BARDA and completed, would bring the total funding opportunity to $186.2 million over the five-year contract period. If exercised by BARDA, subsequent Option Periods would fund activities related to broader implementation of the platelet and plasma system or the red blood cell system in areas of Zika virus risk, clinical and regulatory development programs in support of the potential licensure of the red blood cell system in the U.S., and development, manufacturing and scale-up activities for the red blood cell system. The Company is responsible for co-investment of $5.0 million and would be responsible for an additional $9.6 million, if certain Option Periods are exercised. BARDA will make periodic assessments of the Company’s progress and the continuation of the agreement is based on the Company’s success in completing the required tasks under the Base Period and each exercised Option Period. BARDA has rights under certain contract clauses to terminate the agreement, including the ability to terminate the agreement for convenience at any time.

Under the contract, the Company is reimbursed and recognizes revenue as allowable direct contract costs are incurred plus allowable indirect costs, based on approved provisional indirect billing rates, which permit recovery of fringe benefits, overhead and general and administrative expenses. As of December 31, 2017 and 2016, $1.4 million and $1.0 million, respectively, of billed and unbilled amounts were included in accounts receivable on the Company’s condensed consolidated balance sheets related to the BARDA agreement.

Note 15. Income Taxes

On December 22, 2017, new tax legislation, Tax Cuts and Jobs Act (the “Tax Act”), was signed into law which significantly changes the Internal Revenue Code of 1986, as amended. The Tax Act, among other things, contains significant changes to corporate taxation including a change in the statutory tax rate on income to 21% and a mandatory deemed repatriation of previously unremitted foreign earnings. The Tax Act changes have been applied to reasonably estimate adjustments which are included in the below. These provisional amounts are based on the available regulatory guidance and the Company’s internal estimates as available at issuance of financial statements. The Company is continuing its analysis of both regulatory guidance and its internal information and any changes to the provisional estimates will be recorded as needed.

U.S and foreign components of consolidated loss before income taxes for the years ended December 31, 2017, 2016 and 2015, was as follows (in thousands):

	2017	2016	2015
Loss before income taxes:			
U.S.	$(57,925)	$(63,246)	$(59,897)
Foreign	1,227	515	358
Loss before income taxes	$(56,698)	$(62,731)	$(59,539)

The provision for income taxes for the years ended December 31, 2017, 2016 and 2015, was as follows (in thousands):

	2017	2016	2015
Provision for income taxes:			
Current:			
Foreign	$181	$147	$147
Federal	—	—	—
State	—	—	—
Total current	181	147	147
Deferred:			
Foreign	—	—	—
Federal	3,659	28	(3,750)
State	47	—	(68)
Total deferred	3,706	28	(3,818)
Provision (benefit) for income taxes	$3,887	$175	$(3,671)

The difference between the provision for income taxes and the amount computed by applying the federal statutory income tax rate to loss before taxes for the years ended December 31, 2017, 2016 and 2015, was as follows (in thousands):

	2017	2016	2015
Federal statutory tax	$(19,277)	$(21,329)	$(20,243)
Tax Act revaluation of deferred taxes	81,923	—	—
Tax Act deemed income inclusion	1,083	—	—
Federal research credits	(1,000)	(809)	(838)
Warrants	—	—	(3,565)
Expiration of federal loss carryovers	—	—	3,337
Expiration of California loss carryovers	1,475	—	—
Change in valuation allowance	(59,462)	3,940	11,754
Non-deductible stock based compensation	1,382	484	449
Change in state apportionment	—	—	4,085
Revision to prior year items	—	17,200	—
Other	(2,237)	689	1,350
Provision (benefit) for income taxes	$3,887	$175	$(3,671)

On December 31, 2015, the California Supreme Court issued a decision disallowing the use of an income apportionment method pursuant to the Multistate Tax Compact. On October 10, 2016, the U.S Supreme Court decided not to hear an appeal of this decision. Previously the Company had relied on lower court decisions allowing the use of this apportionment method to file its 2013 and 2014 tax returns and to determine its deferred tax balances. Based on the California Supreme Court decision, the Company adjusted the apportionment for its deferred tax balances and the respective valuation allowance as of December 31, 2015.

During 2017 the Company reviewed its cumulative research tax credits and tax losses. As part of this review, revisions were made to the amounts as originally estimated which are reflected in the deferred tax balances and the respective valuation allowance as of December 31, 2017.

The Tax Act resulted in a significant revaluation in the Company’s deferred tax balances as of the date of December 22, 2017, enactment due to the change in the statutory rate. In addition, all of the previously unremitted earnings of Cerus Europe B.V. were deemed to be distributed as of December 31, 2017, which resulted in a one-time deemed income inclusion.

Deferred income taxes reflect the net tax effects of temporary differences between the carrying amounts of assets and liabilities for financial reporting purposes and the amounts used for income tax purposes at the enacted rates. The significant components of the Company's deferred tax assets and liabilities at December 31, 2017 and 2016, were as follows (in thousands):

	December 31,	
	2017	2016
Deferred tax assets:		
Net operating loss carryforwards	$117,028	$176,490
Research and development credit carryforwards	25,061	22,128
Capitalized research and development	17,195	22,575
Deferred compensation	7,011	8,242
Other	3,116	3,184
Total deferred tax assets	169,411	232,619
Valuation allowance	(169,332)	(228,794)
Net deferred tax assets	$79	$3,825
Deferred tax liabilities:		
Unrealized gain on investments	$—	$3,825
Amortization of goodwill	111	150
Total deferred tax liabilities	$111	$3,975

The valuation allowance decreased by $59.5 million for the year ended December 31, 2017, compared to the increase of $3.9 million and $11.8 million for the years ended December 31, 2016 and 2015, respectively. The Company believes that, based on a number of factors, the available objective evidence creates sufficient uncertainty regarding the realizability of the deferred tax assets such that a valuation allowance has been recorded. These factors include the Company's history of net losses since its inception, the need for regulatory approval of the Company's products prior to commercialization and expected near-term future losses. The Company expects to maintain a valuation allowance until circumstances change.

For the year ended December 31, 2017, the Company reported pretax net losses on its consolidated statement of operations and calculated taxable losses for both federal and state taxes. The difference between reported net loss and taxable loss are due to differences between book accounting and the respective tax laws.

The Company's tax losses and credits are subject to varying carryforward periods. The gross amounts and dates of expiration of the significant carryforwards are as follows:

	Total	Expires 2018-2020	Expires 2021-2027	Expires 2028-2037	No Expiration
Federal losses carryovers	$531,303	$ 74,073	$ 145,248	$ 311,982	$ —
California loss carryovers	73,860	19,243	—	54,617	—
Federal research credits	17,642	3,262	9,866	4,514	—
California research credits	9,391	—	—	—	9,391
Federal foreign tax credits	610	—	610	—	—

The Company's ability to utilize net operating loss and research and development credit carryforwards is limited by (a)

its ability to generate future taxable income, (b) varying apportionment and allocation rules including new provisions as part of the Tax Act, and (c) limitations pursuant to the ownership change rules in accordance with Section 382 of the Internal Revenue Code of 1986 and with Section 383 of the Internal Revenue Code of 1986, as well as similar state provisions.

The Company’s unrecognized tax benefits relate to federal and California research tax credits. These tax credits have not been utilized on any tax return and currently have no impact on the Company’s tax expense due to the Company’s operating losses and the related valuation allowances.

The following is a tabular reconciliation of the total amounts of unrecognized tax benefits (in thousands):

	December 31, 2017	December 31, 2016
Unrecognized tax benefits at beginning of period	$ 10,836	$ —
Increases related to prior year tax positions	19	10,691
Increases related to current year tax positions	207	145
Unrecognized tax benefits at end of period	$ 11,062	$ 10,836

The Company will recognize accrued interest and penalties related to unrecognized tax benefits in its income tax expense. To date, the Company has not recognized any interest and penalties in its consolidated statements of operations, nor has it accrued for or made payments for interest and penalties.

The Company’s federal tax returns for years 1998 through 2016 and California tax returns for years through 2016 remain subject to examination by the taxing jurisdictions due to unutilized net operating losses and research credits. The Netherlands tax returns of the Company’s Europe B.V. subsidiary for the years 2014 through 2016 are still subject to examination. There was no income tax audit activity in 2016 nor has the Company been notified by any tax agency of any planned audits.

Note 16. Segment, Customer and Geographic Information

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

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

The Company had the following significant customers that accounted for more than 10% of the Company’s total product revenue, all of which operate in a country outside of the U.S., during the years ended December 31, 2017, 2016 and 2015 (in percentages):

	Year Ended December 31,

	2017	2016	2015
Etablissement Francais du Sang	22%	*	23%
Advanced Technology Company K.S.C.	*	12%	*

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

Revenues by geographical location were based on the location of the customer during the years ended December 31, 2017, 2016 and 2015, and was as follows (in thousands):

	Year Ended December 31,		
	2017	2016	2015
Product revenue:			
France	$9,692	$3,485	$7,732
United States	6,316	4,480	563
Belgium	6,263	6,392	5,728
Spain and Portugal	3,432	3,360	4,070
Kuwait	2,788	4,415	1,959
Other countries	15,077	15,051	14,171
Total product revenue	43,568	37,183	34,223
Government contract revenue:			
United States	7,758	2,092	—
Total government contract revenue	7,758	2,092	—
Total revenue	$51,326	$39,275	$34,223

Long-lived assets by geographical location, which consist of property and equipment, net and intangible assets, net, at December 31, 2017 and 2016, were as follows (in thousands):

	December 31,	
	2017	2016
U.S. and territories	$2,443	$3,529
Europe & other	212	194
Total long-lived assets	$2,655	$3,723

Note 17. Quarterly Financial Information (Unaudited)

The following tables summarize the Company’s quarterly financial information for the years ended December 31, 2017 and 2016 (in thousands except per share amounts):

	Three Months Ended			
	March 31,	June 30,	September 30,	December 31,
	2017	2017	2017	2017
Product revenue	$7,006	$9,525	$ 10,797	$ 16,240
Gross profit on product revenue	3,312	5,165	5,449	7,111

Government contract revenue	1,428	1,667	2,285	2,378
Net loss	(18,598)	(17,083)	(13,418)	(11,486)
Net loss per share:				
Basic	(0.18)	(0.16)	(0.12)	(0.10)
Diluted	(0.18)	(0.16)	(0.12)	(0.10)

	Three Months Ended			
	March 31,	June 30,	September 30,	December 31,
	2016	2016	2016	2016
Product revenue	$7,632	$9,251	$10,175	$10,125
Gross profit on product revenue	3,369	4,275	4,724	4,520
Government contract revenue	—	—	261	1,831
Net loss	(16,863)	(18,166)	(14,376)	(13,501)
Net loss per share:				
Basic	(0.17)	(0.18)	(0.14)	(0.13)
Diluted	(0.17)	(0.18)	(0.14)	(0.13)

Note 18. Subsequent Event

In January 2018, the Company issued and sold 14,030,000 shares of the Company’s common stock, par value $0.001 per share, at $4.10 per share in an underwritten public offering. The total proceeds to the Company from this offering were $57.5 million, before deducting estimated offering expenses payable by the Company.

SIGNATURES

Pursuant to the requirement of Section 13 or 15(d) of the Securities Exchange Act of 1934, the Registrant has duly caused this report to be signed on its behalf by the undersigned, thereunto duly authorized, in the City of Concord, State of California, on the 8th day of March, 2018.

CERUS CORPORATION

By: /s/ William M. Greenman
William M. Greenman
President and Chief Executive Officer

Each person whose signature appears below constitutes and appoints William M. Greenman and Kevin D. Green, his true and lawful attorney-in-fact and agent, each acting alone, with full power of substitution and resubstitution, for him and in his name, place and stead, in any and all capacities, to sign any or all amendments to the Annual Report on Form 10-K and to file the same, with all exhibits thereto, and all documents in connection therewith, with the Securities and Exchange Commission, granting unto said attorney-in-fact and agent, full power and authority to do and perform each and every act and thing requisite and necessary to be done in and about the premises, as fully to all intents and purposes as he might or could do in person, hereby ratifying and confirming all that said attorney-in-fact and agent, or his substitute or substitutes, may lawfully do or cause to be done by virtue hereof.

Pursuant to the requirements of the Securities Exchange Act of 1934, this report has been signed below by the following persons in the capacities and on the dates indicated.

Signature	Title	Date
/s WILLIAM M. GREENMAN	President, Chief Executive	
	Officer and Director	March 8, 2018
William M. Greenman	(Principal Executive Officer)	
/s/ Kevin D. Green	Vice President, Finance and	
	Chief Financial Officer	March 8, 2018
Kevin D. Green	(Principal Financial Officer)	
/s/ Daniel. N. Swisher, jr.	Chairman of the Board of Directors	March 8, 2018

Daniel N. Swisher, Jr.

/s/ Timothy B. Anderson

Director March 8, 2018

Timothy B. Anderson

/s/ Laurence M. Corash, M.D.

Director March 8, 2018

Laurence M. Corash, M.D.

/s/ Gail Schulze

Director March 8, 2018

Gail Schulze

/s/ Frank Witney

Director March 8, 2018

Frank Witney, PHD.