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**UNITED STATES  
SECURITIES AND EXCHANGE COMMISSION  
WASHINGTON, DC 20549**

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**FORM 8-K**

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

**Date of report (Date of earliest event reported): November 1, 2018**

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**CERUS CORPORATION**

(Exact Name of Registrant as Specified in Charter)

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**Delaware**  
(State or Other Jurisdiction  
of Incorporation)

**000-21937**  
(Commission  
File Number)

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

**2550 Stanwell Drive**  
**Concord, California**  
(Address of Principal Executive Offices)

**94520**  
(Zip Code)

**Registrant's Telephone Number, Including Area Code (925) 288-6000**

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**(Former Name or Former Address, if Changed Since Last Report)**

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

- Written communication pursuant to Rule 425 under the Securities Act (17 CFR 230.425)
- Soliciting material pursuant to Rule 14a-12 under the Exchange Act (17 CFR 240.14a-12)
- Pre-commencement communication pursuant to Rule 14d-2(b) under the Exchange Act (17 CFR 240.14d-2(b))
- Pre-commencement communication pursuant to Rule 13e-4(c) under the Exchange Act (17 CFR 240.13e-4(c))

Indicate by check mark whether the registrant is an emerging growth company as defined in Rule 405 of the Securities Act of 1933 (17 CFR §230.405) or Rule 12b-2 of the Securities Exchange Act of 1934 (17 CFR §240.12b-2).

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.

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**Item 2.02 Results of Operations and Financial Condition**

On November 1, 2018, Cerus Corporation (the “Company”) announced its financial results for its third quarter ended September 30, 2018. A copy of the Company’s press release, entitled “Cerus Corporation Reports Third Quarter 2018 Results,” is furnished pursuant to Item 2.02 as Exhibit 99.1 hereto.

The information in this report, including the exhibit hereto, shall not be deemed to be “filed” for purposes of Section 18 of the Securities Exchange Act of 1934, as amended, or otherwise subject to the liabilities of Section 11 and 12(a)(2) of the Securities Act of 1933, as amended. The information contained herein and in the accompanying exhibit shall not be incorporated by reference into any filing with the U.S. Securities and Exchange Commission made by the Company, whether made before or after the date hereof, except as shall be expressly set forth by specific reference in such filing.

**Item 9.01 Financial Statements and Exhibits**

(d) Exhibits.

The following exhibit is furnished with this report:

99.1 [Press release, dated November 1, 2018, entitled “Cerus Corporation Reports Third Quarter 2018 Results.”](#)

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**SIGNATURE**

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

CERUS CORPORATION

Dated: November 1, 2018

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



## Cerus Corporation Reports Third Quarter 2018 Results

*Product revenue increases 43% compared to 2017*

CONCORD, CA, November 1, 2018—Cerus Corporation (Nasdaq: CERS) announced today financial results for the third quarter ended September 30, 2018.

### Third Quarter Highlights and Recent Events

- Third quarter product revenue of \$15.4 million, a 43% increase compared to the third quarter of 2017
- Year-over-year worldwide disposable kit volumes increased 85% in the third quarter of 2018
- 2018 product revenue guidance revised upwards to a range of \$58 million to \$60 million, representing an increase of 33% to 38% compared to 2017 product revenue
- Notified TÜV SÜD in October of the Company's request to file its planned CE Mark submission in 60 days for INTERCEPT red blood cells
- Received FDA Breakthrough Device Designation for pathogen-reduced cryoprecipitate

“The market adoption of the INTERCEPT Blood System continues to be strong with third quarter product revenue totaling \$15.4 million,” said William ‘Obi’ Greenman, Cerus’ president and chief executive officer. “Year-over-year product revenue growth was driven by sales of INTERCEPT platelet kits and was broad based with all major geographic regions delivering gains. Given our strong year-to-date results and increasing visibility into our commercial pipeline, we recently revised our 2018 product revenue guidance to a range of \$58 million to \$60 million.”

“In addition to our strong third quarter results, we recently notified TÜV SÜD, our Notified Body, of our request to file our CE Mark submission in 60 days for INTERCEPT red blood cells. Our red cell team is working diligently in preparation for the planned submission and is on track to deliver on this important milestone,” continued Greenman.

A Notified Body is an organization accredited by a member country of the European Union to determine if a product conforms to predetermined standards.

### Revenue

Product revenue during the third quarter of 2018 was \$15.4 million, compared to \$10.8 million during the same period in 2017. The increase in third quarter product revenue was led by gains in platelet kit sales, which were partially offset by a year-over-year decline in illuminator sales. Third quarter 2017 illuminator sales benefited from the initial instrument shipments pursuant to the Company's expanded supply agreement with EFS, the French National Blood Service. Year-to-date product revenue totaled \$44.4 million, an increase of 62% compared to the same period of the prior year.

Government contract revenue from the Company's Biomedical Advanced Research and Development Authority (BARDA) agreement was \$3.9 million during the third quarter of

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2018, compared to \$2.3 million during the same period in 2017, as a result of increasing INTERCEPT red cell clinical and development activities. Year-to-date government contract revenue totaled \$11.4 million compared to \$5.4 million in the first nine months of 2017.

BARDA is part of the Office of the Assistant Secretary for Preparedness and Response within the U.S. Department of Health and Human Services. The development of the INTERCEPT red blood cell program has been funded in whole or in part with Federal funds from the Department of Health and Human Services; Office of the Assistant Secretary for Preparedness and Response; Biomedical Advanced Research and Development Authority, under Contract No. HHSO100201600009C.

### **Gross Margins**

Gross margins on product revenue during the third quarter of 2018 were 47%, compared to 50% for the third quarter of 2017. The change in gross margin was primarily attributable to lower selling prices associated with high volume customers, and to a lesser extent, the unfavorable impact of foreign exchange rates. Gross margins through the first nine months of 2018 were 48% compared to 51% in the same period of the prior year.

### **Operating Expenses**

Total operating expenses were \$24.8 million for the quarter ended September 30, 2018, compared to \$20.1 million for the quarter ended September 30, 2017. Year-to-date, operating expenses totaled \$72.2 million compared to \$66.0 million in the same period of the prior year.

Selling, general, and administrative (SG&A) expenses for the third quarter of 2018 totaled \$14.0 million, compared to \$12.2 million for the third quarter of 2017. The year-over-year increase was primarily tied to higher commercial activity in the U.S. Year-to-date SG&A expenses totaled \$42.0 million, compared to \$40.1 million during the first nine months of 2017.

Research and development (R&D) expenses for the third quarter of 2018 were \$10.8 million, compared to \$7.9 million for the third quarter of 2017. The increase in year-over-year R&D expenses was primarily due to additional activities and costs tied to the development of INTERCEPT red blood cells, including preparation for the planned CE Mark submission, trials and activities in pursuit of FDA approval of INTERCEPT red blood cells and activities aimed at expanded label claims for INTERCEPT platelets and plasma. Year-to-date R&D expenses through the third quarter of 2018 totaled \$30.1 million, compared to \$25.9 million during the first nine months of 2017.

### **Net Loss**

Net loss for the third quarter of 2018 was \$14.2 million, or \$0.11 per diluted share, compared to a net loss of \$13.4 million, or \$0.12 per diluted share, for the third quarter of 2017. Year-to-date net loss was \$41.4 million, or \$0.32 per diluted share, compared to a net loss of \$49.1 million, or \$0.46 per diluted share, in the first nine months of 2017.

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## **Cash, Cash Equivalents and Investments**

At September 30, 2018, the Company had cash, cash equivalents and short-term investments of \$119.0 million, compared to \$60.7 million at December 31, 2017.

At September 30, 2018, the Company had approximately \$29.9 million in outstanding debt under its loan agreement with Oxford Finance compared to \$29.8 million at December 31, 2017.

## **QUARTERLY CONFERENCE CALL**

The Company will host a conference call and webcast at 4:15 P.M. EDT this afternoon, during which management will discuss the Company's financial results and provide a general business overview and outlook. To access the live webcast, please visit the Investor Relations page of the Cerus website at <http://www.cerus.com/ir>. Alternatively, you may access the live conference call by dialing (866) 235-9006 (U.S.) or (631) 291-4549 (international).

A replay will be available on the Company's website, or by dialing (855) 859-2056 (U.S.) or (404) 537-3406 (international) and entering conference ID number 7095077. The replay will be available approximately three hours after the call through November 15, 2018.

## **ABOUT CERUS**

Cerus Corporation is a biomedical products company focused in the field of blood transfusion safety. The INTERCEPT Blood System is designed to reduce the risk of transfusion-transmitted infections by inactivating a broad range of pathogens such as viruses, bacteria and parasites that may be present in donated blood. The nucleic acid targeting mechanism of action of the INTERCEPT treatment is designed to inactivate established transfusion threats, such as hepatitis B and C, HIV, West Nile virus and bacteria, as well as emerging pathogens such as chikungunya, malaria and dengue. Cerus currently markets and sells the INTERCEPT Blood System for both platelets and plasma in the United States, Europe, the Commonwealth of Independent States, the Middle East and selected countries in other regions around the world. The INTERCEPT red blood cell system is in clinical development. See <http://www.cerus.com> for information about Cerus.

INTERCEPT and the INTERCEPT Blood System are trademarks of Cerus Corporation.

## **Forward Looking Statements**

Except for the historical statements contained herein, this press release contains forward-looking statements concerning Cerus' products, prospects and expected results, including statements concerning Cerus' adjusted 2018 annual product revenue guidance; Cerus' planned INTERCEPT red blood cell system CE Mark submission and the anticipated timing thereof; and other statements that are not historical facts. Actual results could differ materially from these forward-looking statements as a result of certain factors, including, without limitation: risks associated with the commercialization and market acceptance of, and customer demand for, the INTERCEPT Blood System, including the risks that Cerus may not (a) meet its adjusted revenue guidance for 2018, (b) grow sales in its U.S. and European markets, including in France, and/or realize expected revenue contribution

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resulting from its U.S. and European market agreements, and/or (c) realize meaningful revenue contributions from U.S. customers in the near term or at all, particularly since Cerus cannot guarantee the volume or timing of commercial purchases, if any, that its U.S. customers may make under Cerus' commercial agreements with these customers; risks associated with Cerus' lack of commercialization experience in the United States and its ability to develop and maintain an effective and qualified U.S.-based commercial organization, as well as the resulting uncertainty of its ability to achieve market acceptance of and otherwise successfully commercialize the INTERCEPT Blood System for platelets and plasma in the United States, including as a result of licensure requirements that must be satisfied by U.S. customers prior to their engaging in interstate transport of blood components processed using the INTERCEPT Blood System; risks related to Fresenius Kabi's efforts to assure an uninterrupted supply of platelet additive solution (PAS); risks related to how any future PAS supply disruption could affect INTERCEPT's acceptance in the marketplace; risks related to how any future PAS supply disruption might affect current commercial contracts; risks related to Cerus' ability to demonstrate to the transfusion medicine community and other health care constituencies that pathogen reduction and the INTERCEPT Blood System is safe, effective and economical; the uncertain and time-consuming development and regulatory process, including the risks (a) that Cerus may be unable to comply with the FDA's post-approval requirements for the INTERCEPT platelet and plasma systems, including by successfully completing required post-approval studies, which could result in a loss of U.S. marketing approval for the INTERCEPT platelet and/or plasma systems, (b) that Cerus may be unable to file for CE Mark approval of the red blood cell system in Europe on the anticipated timeframe or at all, including as a result of Cerus' failure to complete the development and other prerequisites necessary to file for CE Mark approval, and that even if filed, Cerus may be unable to obtain CE Mark approval, or any other regulatory approvals, of the red blood cell system in a timely manner or at all, (c) related to Cerus' ability to expand the label claims and product configurations for the INTERCEPT platelet and plasma systems in the United States, including for INTERCEPT-treated extended storage cryoprecipitate from plasma, which will require additional regulatory approvals, and (d) that applicable regulatory authorities may disagree with Cerus' interpretations of the data from its clinical studies and/or may otherwise determine not to approve Cerus' regulatory submissions, including the planned CE Mark submission, in a timely manner or at all; risks associated with the uncertain nature of BARDA's funding over which Cerus has no control as well as actions of Congress and governmental agencies which may adversely affect the availability of funding under Cerus' BARDA agreement and/or BARDA's exercise of any potential subsequent option periods, such that the anticipated activities that Cerus expects to conduct with the funds available from BARDA may be delayed or halted and that Cerus may not otherwise realize the total potential value under its agreement with BARDA; risk related to product safety, including the risk that the septic platelet transfusions may not be avoidable with the INTERCEPT Blood System; risks related to adverse market and economic conditions, including continued or more severe adverse fluctuations in foreign exchange rates and/or weakening economic conditions in the markets where Cerus currently sells and is anticipated to sell its products; Cerus' reliance on third parties to market, sell, distribute and maintain its products; Cerus' ability to maintain an effective manufacturing supply chain, including the ability of its manufacturers to comply with extensive FDA and foreign regulatory agency requirements, and Cerus' ability to maintain its primary kit manufacturing agreement and its other supply agreements with its third party suppliers; the impact of legislative or regulatory healthcare reforms that may make it more difficult and costly for Cerus to produce, market and distribute its products; risks related to future opportunities and plans, including the

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uncertainty of Cerus' future capital requirements and its future revenues and other financial performance and results, as well as other risks detailed in Cerus' filings with the Securities and Exchange Commission, including Cerus' Quarterly Report on Form 10-Q for the quarter ended June 30, 2018, filed with the SEC on August 2, 2018. Cerus disclaims any obligation or undertaking to update or revise any forward-looking statements contained in this press release.

Contact:

Tim Lee – Investor Relations Director  
Cerus Corporation  
925-288-6137

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

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2018	2017	2018	2017
Product revenue	\$ 15,399	\$ 10,797	\$ 44,383	\$ 27,328
Cost of product revenue	8,142	5,348	23,192	13,402
Gross profit on product revenue	7,257	5,449	21,191	13,926
Government contracts revenue	3,928	2,285	11,430	5,380
Operating expenses:				
Research and development	10,825	7,886	30,143	25,927
Selling, general and administrative	13,964	12,230	42,008	40,058
Total operating expenses	24,789	20,116	72,151	65,985
Loss from operations	(13,604)	(12,382)	(39,530)	(46,679)
Non-operating (expense) income, net	(532)	(986)	(1,660)	1,541
Loss before income taxes	(14,136)	(13,368)	(41,190)	(45,138)
Provision for income taxes	56	50	169	3,961
Net loss	<u>\$ (14,192)</u>	<u>\$ (13,418)</u>	<u>\$ (41,359)</u>	<u>\$ (49,099)</u>
Net loss per share:				
Basic	\$ (0.11)	\$ (0.12)	\$ (0.32)	\$ (0.46)
Diluted	\$ (0.11)	\$ (0.12)	\$ (0.32)	\$ (0.46)
Weighted average shares outstanding used for calculating net loss per share:				
Basic	134,326	109,846	130,199	106,159
Diluted	134,326	109,846	130,199	106,159

**CERUS CORPORATION**  
**CONDENSED CONSOLIDATED UNAUDITED BALANCE SHEETS**  
(in thousands)

	<u>September 30,</u> <u>2018</u>	<u>December 31,</u> <u>2017</u>
<b>ASSETS</b>		
Current assets:		
Cash and cash equivalents	\$ 22,327	\$ 13,683
Short-term investments	96,669	47,013
Accounts receivable	10,476	12,415
Inventories	13,322	14,457
Other current assets	7,360	2,330
Total current assets	150,154	89,898
Non-current assets:		
Property and equipment, net	3,124	2,119
Goodwill and intangible assets, net	1,701	1,852
Restricted cash and other assets	6,678	4,375
Total assets	\$ 161,657	\$ 98,244
<b>LIABILITIES AND STOCKHOLDERS' EQUITY</b>		
Current liabilities:		
Accounts payable and accrued liabilities	\$ 31,097	\$ 22,686
Debt – current	5,714	—
Manufacturing and development obligations – current	5,858	—
Deferred product revenue – current	533	445
Total current liabilities	43,202	23,131
Non-current liabilities:		
Debt – non-current	24,138	29,798
Manufacturing and development obligations – non-current	—	5,766
Other non-current liabilities	2,516	609
Total liabilities	69,856	59,304
Stockholders' equity		
Total liabilities and stockholders' equity	\$ 161,657	\$ 98,244