UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
WASHINGTON, DC 20549

FORM 8-K

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

Date of report (Date of earliest event reported): February 26, 2019

CERUS CORPORATION
(Exact Name of Registrant as Specified in Charter)

Delaware	**000-21937**	**68-0262011**
(State or Other Jurisdiction of Incorporation)	**(Commission File Number)**	**(I.R.S. Employer Identification No.)**

2550 Stanwell Drive **Concord, California**	**94520**
(Address of Principal Executive Offices)	**(Zip Code)**

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

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

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. ☐

Item 2.02 Results of Operations and Financial Condition

On February 26, 2019, Cerus Corporation (the "Company") announced its financial results for its fourth quarter and year ended December 31, 2018. A copy of the Company's press release, entitled "Cerus Corporation Announces Record Fourth Quarter and Full Year 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 February 26, 2019, entitled "Cerus Corporation Announces Record Fourth Quarter and Full Year 2018 Results."

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: February 26, 2019

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

Cerus Corporation Announces Record Fourth Quarter and Full Year 2018 Results

CONCORD, CA, February 26, 2019 – Cerus Corporation (Nasdaq: CERS) today announced complete financial results for the fourth quarter and year ended December 31, 2018.

Recent developments and highlights include:

- Record fourth quarter product revenue of $16.5 million.
- Provided 2019 annual product revenue guidance of $70 million to $73 million, representing a 15% to 20% increase over 2018 reported product revenue.
- Filed CE Mark registration for the Company's INTERCEPT Blood System for red blood cells (RBCs).
- Initiated enrollment in ReCePI, Cerus' U.S. Phase 3 study evaluating the safety and efficacy of the INTERCEPT Blood System for RBCs in patients undergoing complex cardiac surgery.
- Expanded the executive management team with the appointment of William Moore as senior vice president of manufacturing operations and supply chain.
- The recently issued annual planned FDA guidance agenda from CBER (Center for Biologics Evaluation and Research) indicates that a final platelet bacterial safety guidance document is planned for 2019.

"We believe we are entering a transformational period in the U.S., with a final platelet bacterial guidance document now anticipated by the end of this year," said William 'Obi' Greenman, Cerus' president and chief executive officer. "Our recent momentum is expected to continue into 2019 as we push forward on our mission to establish INTERCEPT as the standard of care for transfused blood components globally by executing on our commercial strategy and advancing our pipeline opportunities."

Revenue

Product revenue during the fourth quarter of 2018 was $16.5 million, compared to $16.2 million during the same period in 2017. Strong gains in fourth quarter platelet kit sales were partially offset by a year-over-year decline in illuminator sales. During the fourth quarter of 2017, total product revenue benefited from illuminator shipments pursuant to the Company's expanded supply agreement with EFS, the French National Blood Service, and large plasma kit orders to distributors. Full-year 2018 product revenue totaled $60.9 million, an increase of 40% compared to 2017 product revenue.

Government contract revenue from the Company's Biomedical Advanced Research and Development Authority (BARDA) agreement was $3.7 million during the fourth quarter of 2018, compared to $2.4 million during the same period in 2017, as a result of increasing

INTERCEPT red blood cell clinical and development activities. Government contract revenue from the Company's BARDA agreement for the year ended December 31, 2018, was $15.1 million compared to $7.8 million for the year ended December 31, 2017. The total potential value of the current BARDA agreement is $201 million with $25 million recognized as revenue to date.

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 fourth quarter of 2018 were 49%, compared to 44% for the fourth quarter of 2017. Gross margins in the quarter benefited from a favorable product mix and higher average selling prices for platelet kits. Gross margins on product revenue for the full-year 2018 and 2017 totaled 48%.

Operating Expenses

Total operating expenses for the fourth quarter 2018 were $27.3 million compared to $20.3 million for the same period the prior year. Full-year 2018 operating expenses totaled $99.4 million compared to $86.3 million for the full-year 2017.

Selling, general, and administrative (SG&A) expenses for the fourth quarter of 2018 totaled $14.8 million, compared to $12.6 million for the fourth quarter of 2017. The year-over-year increase was primarily tied to higher commercial activity in the U.S. Full-year 2018 SG&A expenses totaled $56.8 million, compared to $52.6 million for the full-year 2017 with the increase primarily tied to higher headcount and compensation related costs.

Research and development (R&D) expenses for the fourth quarter of 2018 were $12.4 million, compared to $7.8 million for the fourth 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 cell system, including preparation for the CE Mark submission, trials and activities in pursuit of a potential FDA approval of INTERCEPT red blood cells and activities aimed at obtaining expanded label claims for INTERCEPT platelets and plasma. Full-year 2018 R&D expenses totaled $42.6 million, compared to $33.7 million for the full-year 2017. The increase in full-year 2018 R&D expenses compared to full-year 2017 R&D expenses was primarily due to costs associated with clinical development of INTERCEPT red blood cell system, the pursuit of supplemental approvals for the platelet and plasma systems, and activities related to the BARDA agreement.

Net Loss

Net loss for the fourth quarter of 2018 was $16.2 million, or $0.12 per diluted share, compared to a net loss of $11.5 million, or $0.10 per diluted share, for the fourth quarter of 2017. Net loss for the year ended December 31, 2018, was $57.6 million, or $0.44 per diluted share, compared to a net loss of $60.6 million, or $0.56 per diluted share, for the same period in 2017.

Cash, Cash Equivalents and Investments

At December 31, 2018, the Company had cash, cash equivalents and short-term investments of $117.6 million, compared to $60.7 million at December 31, 2017.

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

2019 Product Revenue Guidance

The Company expects 2019 product revenue to be in the range of $70 million to $73 million, representing 15% to 20% growth compared to 2018 reported product revenue.

QUARTERLY CONFERENCE CALL

The Company will host a conference call and webcast at 4:30 P.M. ET 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 2392137. The replay will be available approximately three hours after the call through March 12, 2019.

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' 2019 annual product revenue guidance; Cerus' mission to establish INTERCEPT as the standard of care for transfused blood components globally by executing on its commercial strategy and advancing its pipeline opportunities; the potential FDA approval of INTERCEPT red blood cells; the potential for expanded label claims for INTERCEPT platelets and plasma; 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 revenue guidance for 2019, (b) grow sales in its U.S. and European markets, including in France, and/or realize expected revenue contribution 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 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 Cerus' 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 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 September 30, 2018, filed with the SEC on November 1, 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 December 31,		Twelve Months Ended December 31,	
	2018	2017	2018	2017
Product revenue	$ 16,525	$ 16,240	$ 60,908	$ 43,568
Cost of product revenue	8,442	9,129	31,634	22,531
Gross profit on product revenue	8,083	7,111	29,274	21,037
Government contract revenue	3,713	2,378	15,143	7,758
Operating expenses:				
Research and development	12,421	7,783	42,564	33,710
Selling, general and administrative	14,833	12,557	56,841	52,615
Total operating expenses	27,254	20,340	99,405	86,325
Loss from operations	(15,458)	(10,851)	(54,988)	(57,530)
Non-operating (expense) income, net	(687)	(709)	(2,347)	832
Loss before income taxes	(16,145)	(11,560)	(57,335)	(56,698)
Provision (benefit) for income taxes	60	(74)	229	3,887
Net loss	$ (16,205)	$ (11,486)	$ (57,564)	$ (60,585)
Net loss per share:				
Basic	$ (0.12)	$ (0.10)	$ (0.44)	$ (0.56)
Diluted	$ (0.12)	$ (0.10)	$ (0.44)	$ (0.56)
Weighted average shares outstanding used for calculating net loss per share:				
Basic	136,006	114,342	131,663	108,221
Diluted	136,006	114,342	131,663	108,221

CERUS CORPORATION
CONDENSED CONSOLIDATED UNAUDITED BALANCE SHEETS
(in thousands)

	December 31, 2018	December 31, 2017
ASSETS		
Current assets:		
Cash and cash equivalents	$ 28,859	$ 13,683
Short-term investments	88,718	47,013
Accounts receivable	8,752	12,415
Inventories	13,539	14,457
Other current assets	7,034	2,330
Total current assets	146,902	89,898
Non-current assets:		
Property and equipment, net	8,130	2,119
Goodwill and intangible assets, net	1,650	1,852
Restricted cash and other assets	6,778	4,375
Total assets	$ 163,460	$ 98,244
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities:		
Accounts payable and accrued liabilities	$ 38,395	$ 22,686
Debt – current	7,857	—
Manufacturing and development obligations – current	5,928	—
Deferred product revenue – current	498	445
Total current liabilities	52,678	23,131
Non-current liabilities:		
Debt – non-current	22,013	29,798
Manufacturing and development obligations – non-current	—	5,766
Other non-current liabilities	4,250	609
Total liabilities	78,941	59,304
Stockholders' equity	84,519	38,940
Total liabilities and stockholders' equity	$ 163,460	$ 98,244