
**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): January 7, 2019

CERUS CORPORATION

(Exact Name of Registrant as Specified in Charter)

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

(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 January 7, 2019, Cerus Corporation (the “Company”) announced its preliminary product revenue results for the fourth quarter and fiscal year ended December 31, 2018. A copy of the Company’s press release, entitled “Cerus Corporation Announces Preliminary Fourth Quarter and Full Year 2018 Product Revenue,” 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 January 7, 2019, entitled “Cerus Corporation Announces Preliminary Fourth Quarter and Full Year 2018 Product Revenue.”](#)

SIGNATURE

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

CERUS CORPORATION

Dated: January 7, 2019

By: /s/ Kevin D. Green

Kevin D. Green

Vice President, Finance and Chief Financial Officer



Cerus Announces Preliminary Fourth Quarter and Full Year 2018 Product Revenue

2019 product revenue guidance of \$70 million to \$73 million, representing growth of 15% to 20% over preliminary 2018 results

CONCORD, CA, January 7, 2019 - Cerus Corporation (Nasdaq:CERS) today announced unaudited preliminary product revenue for the fourth quarter and full year 2018 and provided 2019 product revenue guidance.

Cerus' unaudited preliminary product revenue for the fourth quarter of 2018 totaled \$16.5 million compared to \$16.2 million during the same period the prior year. Based on the fourth quarter unaudited preliminary product revenue, the Company expects full year 2018 product revenue to be \$60.9 million, ahead of the top end of the range of the Company's most recent guidance of \$58 million to \$60 million. The preliminary product revenue results have not been audited and are subject to change.

Preliminary fourth quarter product revenue would represent the highest quarterly product revenue ever reported by the Company. Cerus expects 2019 product revenue to be in the range of \$70 million to \$73 million, representing 15% to 20% growth compared to the preliminary 2018 results.

"The revenue growth we generated in 2018 underscores the increasing demand for safer blood components. We finished 2018 strong with quarter-over-quarter and year-to-date growth in disposable kits led by French national conversion and U.S. demand," said William 'Obi' Greenman, Cerus' president and chief executive officer.

"Over the past few months, U.S. customer orders for INTERCEPT platelets have been increasing. With the recent FDA publication of the draft guidance document on bacterial risk control strategies for platelet collection and transfusion, we could potentially experience further acceleration in customer demand in the U.S.," continued Greenman.

Heading into 2019, the Company will continue to advance its mission to make INTERCEPT the standard of care for transfused blood components globally and to enable its customers to deliver safe and effective blood products to patients. In addition to delivering on the stated revenue growth goals, other anticipated 2019 milestones include the planned U.S. regulatory submission on pathogen-reduced cryoprecipitate, additional cryoprecipitate manufacturing partnerships, and progress on the U.S. INTERCEPT red blood cell clinical studies.

Cerus will provide complete fourth quarter and full year 2018 financial results and host a call to discuss both 2018 results and 2019 expectations in late February.

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 and Preliminary Product Revenue Results

Except for the historical statements contained herein, this press release contains forward-looking statements concerning Cerus' products, prospects and expected results, including statements relating to Cerus' 2019 annual product revenue guidance; the potential for further acceleration in customer demand in the U.S.; Cerus' mission to make INTERCEPT the standard of care for transfused blood components globally and to enable its customers to deliver safe and effective blood products to patients; Cerus' anticipated 2019 milestones, including the planned U.S. regulatory submission on pathogen-reduced cryoprecipitate, additional cryoprecipitate manufacturing partnerships, and ongoing advancement of its U.S. red blood cell clinical program; and other statements that are not historical fact. 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 2019 annual product revenue guidance, (b) grow sales in its U.S. and European markets and/or realize expected revenue contribution resulting from its U.S. and European market agreements, and/or (c) realize meaningful and/or increasing 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; and/or (d) realize any revenue contribution from its pipeline product candidates, whether due to Cerus' inability to obtain regulatory approval of its pipeline product candidates, or otherwise; 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) 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, (c) 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, (d) that Cerus may be unable to submit its planned PMA supplement to the FDA for INTERCEPT-treated extended storage cryoprecipitate from plasma on the anticipated timeframe or at all, and even if submitted, Cerus may be unable to obtain FDA approval, or any other regulatory approvals, of INTERCEPT-treated extended storage cryoprecipitate from plasma in a timely manner or at all, (e) 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 in a timely manner or at all, (f) that Cerus may be unable to obtain FDA clearance to initiate a potential additional Phase 3 clinical trial of the red blood cell system and may otherwise be unable to advance the development of the red blood cell system in the U.S. in a timely manner or at all, and (g) that anticipated clinical trials of the INTERCEPT Blood System may not be initiated on the anticipated timing or at all, or if initiated, may be extended, delayed, suspended or terminated, including as result of safety concerns; 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; risks 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, Cerus' ability to maintain its primary kit manufacturing agreement and its other supply agreements with its third party suppliers, and Cerus' ability to identify and obtain additional partners to manufacture extended-storage cryoprecipitate; 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.

This press release includes Cerus' preliminary product revenue results for the quarter and year ended December 31, 2018. Cerus is currently in the process of finalizing its full financial results for the quarter and year ended December 31, 2018, and the preliminary product revenue results presented in this press release are based only upon preliminary information available to Cerus as of January 7, 2019. Cerus' preliminary product revenue results should not be viewed as a substitute for full audited financial statements prepared in accordance with U.S. GAAP, and undue reliance should not be placed on Cerus' preliminary product revenue results. In addition, Cerus' independent registered public accounting firm has not audited or reviewed the preliminary product revenue results included in this press release or expressed any opinion or other form of assurance on such preliminary product revenue results. In addition, items or events may be identified or occur after the date hereof due to the completion of operational and financial closing procedures, final audit adjustments and other developments may arise that would require Cerus to make material adjustments to the preliminary product revenue results included in this press release. Therefore, the preliminary product revenue results included in this press release may differ, perhaps materially, from the product revenue results that will be reflected in Cerus' audited consolidated financial statements for the year ended December 31, 2018.

Contact:

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