
**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): October 16, 2018

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 October 16, 2018, Cerus Corporation (the “Company”) announced its preliminary product revenue results for the third quarter ended September 30, 2018. A copy of the Company’s press release, entitled “Cerus to Provide Update to Development Programs and Outline Growth Strategy at 2018 Institutional Investor Meeting,” 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 October 16, 2018, entitled “Cerus to Provide Update to Development Programs and Outline Growth Strategy at 2018 Institutional Investor Meeting.”](#)

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: October 16, 2018

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



Cerus to Provide Update to Development Programs and Outline Growth Strategy at 2018 Institutional Investor Meeting

Announces preliminary Q3 product revenue of \$15.4 million; raises full year revenue outlook

CONCORD, CA, October 16, 2018—Cerus Corporation (Nasdaq: CERS) is presenting its strategic roadmap and outlining its multi-year growth strategy at the 2018 Cerus Institutional Investor Meeting today in Boston.

“Our efforts to establish the INTERCEPT Blood System as the standard of care for transfused blood components globally continue to gain traction,” commented William ‘Obi’ Greenman, Cerus’ president and chief executive officer. “With the increasing visibility into our commercial opportunities and the advances in our research and development pipeline, we believe that we are poised to sustain meaningful product revenue growth for the next several years.”

“Our preliminary Q3 product revenue of \$15.4 million underscores the strong market demand for the INTERCEPT Blood System during the quarter, especially in the U.S. Given our preliminary Q3 results, we are raising our full year product revenue guidance from a range of \$56 million to \$58 million to our new range of \$58 million to \$60 million, representing an increase of 33% to 38% compared to 2017 product revenue,” continued Greenman.

“Growth in 2018 has been largely driven by the conversion of the French platelet market to INTERCEPT-treated platelets and from strong growth in the U.S.,” noted Kevin D. Green, Cerus’ vice president and chief financial officer. “As we look ahead to 2019, we anticipate revenue growth from continued U.S. market adoption, with or without a final FDA guidance document on bacterial safety of platelets, and contribution from the German market toward the latter part of 2019. In 2020 and beyond, we anticipate revenue growth to accelerate due to the anticipated regulatory approval and commercialization of our pipeline product candidates, including INTERCEPT red blood cells in Europe and extended storage pathogen-reduced cryoprecipitate.”

The agenda for today’s meeting will cover the following:

INTERCEPT Red Blood Cells : Dr. Richard Benjamin, Cerus’ chief medical officer will provide a framework on our U.S. and European clinical development efforts and the timelines for regulatory submission. The Company is on track to submit its CE Mark filing by the end of this year.

Pathogen-Reduced Cryoprecipitate : Dr. Laurence Corash, Cerus’ co-founder and chief scientific officer will outline the clinical rationale for pathogen-reduced cryoprecipitate with a targeted post-thaw shelf life of five days compared to four to six hours for conventional cryoprecipitate. The Company anticipates submitting the PMA-supplement for pathogen-reduced cryoprecipitate in the second half of 2019.

Commercial Update : Vivek K. Jayaraman, Cerus' chief commercial officer, will provide an update on the Company's domestic and international growth opportunities.

Financial Update : Kevin D. Green, Cerus vice president of finance and chief financial officer will provide a framework on the Company's anticipated near to mid-term product revenue growth prospects, the potential impact of increasing kit volumes on gross margin, and the anticipated operating leverage from the Company's commercial infrastructure as the business scales.

Guest speakers at today's meeting include:

Dr. Edward Snyder, Professor Laboratory Medicine, Yale University Medical School, Director, Blood and Tissue Bank Services. Dr. Snyder will discuss Yale's experience with INTERCEPT platelets and the clinical need for pathogen-reduced red blood cells.

Dr. Melissa Cushing, Associate Professor of Clinical Pathology and Laboratory Medicine at Weill Cornell Medical College, Associate Director of Clinical Laboratories and the Director of Transfusion Medicine and Cellular Therapy at New York-Presbyterian Hospital, Weill Cornell Campus. Dr. Cushing will discuss the critical role of rapid cryoprecipitate transfusion in treating coagulopathy in bleeding patients.

Dr. Susan Stramer, Vice President, Scientific Affairs, Biomedical Services, American Red Cross. Dr. Stramer will discuss the American Red Cross' strategy and plans to more broadly roll-out pathogen-reduced platelets.

Webcast Information

A live webcast of Cerus' Institutional Investor Meeting will be available today, October 16, starting at 9:30 a.m. E.T. and can be accessed from the Investor Relations page of the Cerus web site at <http://www.cerus.com/ir>. A replay will be available for approximately two weeks following the completion of the event.

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 concerning Cerus' adjusted 2018 annual product revenue guidance; the potential contract value of Cerus' amended agreement with BARDA; the potential to avoid septic platelet transfusions with the INTERCEPT Blood System; the potential to expand the usage claims for the INTERCEPT Blood System; Cerus' planned INTERCEPT red blood cell system CE Mark submission and the anticipated timing thereof; Cerus' mission to establish INTERCEPT Blood Systems as the standard of care for transfused blood components globally; Cerus' belief that it is poised to sustain meaningful product revenue growth for the next several years; Cerus' expectation for revenue growth in 2019 and in 2020 and beyond, and the anticipated reasons therefor; anticipated regulatory approval and commercialization of Cerus' pipeline product candidates, including INTERCEPT red blood cells in Europe and extended storage pathogen-reduced cryoprecipitate, and the anticipated timing thereof; Cerus' planned INTERCEPT red blood cell system CE Mark submission and planned PMA supplement for extended storage pathogen-reduced cryoprecipitate, and the anticipated timing thereof; Cerus' expectations for increasing kit volumes and future operating leverage; 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 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; 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 file for CE Mark approval of the red blood cell system in Europe on the anticipated timeframe or at all, and 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, (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, and (f) 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; 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 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.

This press release includes Cerus' preliminary product revenue results for the quarter ended September 30, 2018. Cerus is currently in the process of finalizing its full financial results for the quarter ended September 30, 2018, and the preliminary product revenue results presented in this press release is based only upon preliminary information available to Cerus as of October 16, 2018. Cerus' preliminary product revenue results should not be viewed as a substitute for full interim 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 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

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 from the product revenue results that will be reflected in Cerus' complete condensed consolidated financial statements for the three months ended September 30, 2018.

Contact:

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