# UNITED STATES
# SECURITIES AND EXCHANGE COMMISSION
**Washington, D.C. 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 13, 2020**

---

# Cerus Corporation
**(Exact name of registrant as specified in its charter)**

---

| **Delaware** | **000-21937** | **68-0262011** |
|---|---|---|
| **(State or other jurisdiction of incorporation)** | **(Commission File Number)** | **(IRS Employer Identification No.)** |

| | |
|---|---|
| **1220 Concord Avenue, Suite 600**<br>**Concord, California**<br>**(Address of principal executive offices)** | **94520**<br>**(Zip Code)** |

**(925) 288-6000**
**Registrant's telephone number, including area code**

**N/A**
**(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 obligations of the registrant under any of the following provisions:

☐ Written communications 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 communications pursuant to Rule 14d-2(b) under the Exchange Act (17 CFR 240.14d-2(b))

☐ Pre-commencement communications pursuant to Rule 13e-4(c) under the Exchange Act (17 CFR 240.13e-4(c))

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

| Title of each class | Trading Symbol(s) | Name of each exchange on which registered |
|---|---|---|
| **Common Stock, par value $0.001** | **CERS** | **The Nasdaq Stock Market LLC** |

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

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 13, 2020, Cerus Corporation (the "Company" or "Cerus") announced its preliminary product revenue results for the fourth quarter and fiscal year ended December 31, 2019. A copy of the Company's press release, entitled "Cerus Corporation Announces Preliminary Product Revenue Results for Fourth Quarter and Full Year 2019 Product Revenue," is furnished pursuant to Item 2.02 as Exhibit 99.1 hereto.

Additionally, on January 28, 2020, the Company filed with the U.S. Securities and Exchange Commission (the "SEC") a preliminary prospectus supplement (the "Preliminary Prospectus") pursuant to Rule 424(b) under the Securities Act of 1933, as amended, relating to its Registration Statement on Form S-3 (File No. 333-219727) filed with the SEC on August 4, 2017, amended on November 6, 2017 and December 29, 2017, and declared effective on January 8, 2018, in connection with a proposed public offering. In the Preliminary Prospectus, the Company disclosed that it expects to report that it had cash, cash equivalents and short-term investments of approximately $85.7 million as of December 31, 2019.

Such financial results as reported are preliminary, unaudited and subject to completion. The Company's independent registered public accounting firm has not audited or performed any procedures with respect to these preliminary results and does not express an opinion or any other form of assurance with respect thereto. The Company's financial closing procedures for the three months and year ended December 31, 2019 are not yet complete and, as a result, the final results upon completion of the closing procedures may vary from the preliminary estimates, and any such differences may be material. The Company's total product revenue and cash, cash equivalents and short-term investments information presented herein should not be viewed as a substitute for full financial statements prepared in accordance with U.S. generally accepted accounting principles, and undue reliance should not be placed on these preliminary financial results.

*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***

| Exhibit Number | Description |
|---|---|
| 99.1 | Press release, dated January 13, 2020, entitled "Cerus Corporation Announces Preliminary Product Revenue Results for Fourth Quarter and Full Year 2019 Product Revenue." |
| 104 | Cover page interactive data file (formatted as Inline XBRL) |

**SIGNATURES**

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 28, 2020

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

**CERUS CORPORATION ANNOUNCES PRELIMINARY FOURTH QUARTER AND FULL YEAR 2019 PRODUCT REVENUE**

January, 13 2020

*Company provides 2020 product revenue guidance range of $89 million to $93 million representing growth of approximately 20% to 25% over preliminary 2019 full year results*

CONCORD, Calif.—(BUSINESS WIRE)— Cerus Corporation (Nasdaq:CERS) announced today preliminary product revenue for the fourth quarter and full year 2019 and provided 2020 product revenue guidance.

Cerus' unaudited preliminary product revenue for the fourth quarter of 2019 totaled $20.9 million, an increase of 27%, compared to the $16.5 million recognized during the same period in the prior year. Based on its fourth quarter unaudited preliminary product revenue, the Company expects full year 2019 product revenue of $74.6 million, at the top end of the Company's most recent 2019 product guidance range of $72 million to $75 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 Cerus.

"We finished 2019 with momentum with preliminary fourth quarter product revenue up 27% driven by strong INTERCEPT platelet kit demand in North America and platelet and plasma kit demand in EMEA. We expect the robust sales growth experienced during the past year to continue into 2020 driven in part by the need for U.S. blood centers and hospitals to comply with the final FDA guidance document on bacterial safety," said William 'Obi' Greenman, Cerus' president and chief executive officer.

"We are looking forward to an exciting year as we continue to help our blood center partners safeguard their blood component production against known and unknown infectious disease. With the planned increase in product revenue and margins, and continued leverage we expect from our SG&A investments, we anticipate lower cash use from operations during 2020 compared to 2019. In addition, we are looking forward to the anticipated expansion of our product portfolio with our first biologic therapeutic product, pathogen-reduced cryoprecipitate, which has been granted FDA breakthrough device designation for the treatment of critically bleeding patients. An anticipated U.S. regulatory submission is planned for the first half of 2020, with a potential approval decision in the second half of the year," continued Greenman.

Given the 2019 strength and anticipated increase in platelet kit demand as U.S. blood centers become compliant with the FDA guidance document, the Company expects full year 2020 product revenue will be in the range of $89 million to $93 million, representing growth of approximately 20% to 25% compared to preliminary unaudited 2019 full year results.

Cerus will provide complete fourth quarter and full year 2019 financial results and host a call to discuss both 2019 results and 2020 expectations in late February.

**ABOUT CERUS**

Cerus Corporation is dedicated solely to safeguarding the world's blood supply and aims to become the preeminent global blood products company. Based in Concord, California, our employees are dedicated to deploying and supplying vital technologies and pathogen-protected blood components for blood centers, hospitals and ultimately patients who rely on safe blood. With the INTERCEPT Blood System, we are focused on protecting patients by delivering the full complement of reliable products and expertise for transfusion medicine. Cerus develops and markets the INTERCEPT Blood System, and remains the only company in the blood transfusion space to earn both CE Mark and FDA approval for pathogen reduction of both platelet and plasma components. Cerus currently markets and sells the INTERCEPT Blood System 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. For more information about Cerus, visit www.cerus.com.

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' 2020 annual product revenue guidance; Cerus' expectation that sales growth will continue into 2020 that Cerus believes will be underpinned by the need for U.S. blood centers and hospitals to comply with the final FDA guidance document on bacterial safety; Cerus continuing to help its blood center partners safeguard their blood component production against known and unknown infectious disease; Cerus' expectation that cash use from operations during 2020 will lessen compared to 2019 and the reasons therefor; the potential for pathogen-reduced cryoprecipitate to be Cerus' first biologic product; the planned U.S. regulatory submission for pathogen-reduced cryoprecipitate, the timing therefor and the timing of an anticipated approval decision; 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 2020 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, (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 pathogen-reduced cryoprecipitate, which will require additional regulatory approvals, (c) that Cerus may be unable to submit its planned regulatory submission to the FDA for pathogen-reduced cryoprecipitate 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 pathogen-reduced cryoprecipitate in a timely manner or at all, (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' anticipated submission for pathogen-reduced cryoprecipitate, in a timely manner or at all, and (e) even if Cerus' regulatory submissions are approved, Cerus may not receive label claims for all requested indications or for indications with the highest unmet need or market acceptance; risks associated with Cerus' lack of experience in marketing products directly to hospitals and expertise complying with regulations governing finished biologics; 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, secure 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; Cerus' ability to identify and obtain additional partners to manufacture pathogen-reduced cryoprecipitate; risks associated with Cerus' ability to meet its debt service obligations and its need for additional funding; 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, 2019, filed with the SEC on October 30, 2019. 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, 2019. Cerus is currently in the process of finalizing its full financial results for the quarter and year ended December 31, 2019, and the preliminary product revenue results presented in this press release are based only upon preliminary information available to Cerus as of January 13, 2020. 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, 2019.

CONTACTS

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