# 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 30, 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.)** |

| | |
|---|---|
| **1220 Concord Ave, Suite 600**<br>**Concord, California**<br>**(Address of Principal Executive Offices)** | **94520**<br>**(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))

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 per share** | **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 (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 30, 2019, Cerus Corporation (the "Company") announced its financial results for its third quarter ended September 30, 2019. A copy of the Company's press release, entitled "Cerus Corporation Announces Third Quarter 2019 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 October 30, 2019, entitled "Cerus Corporation Announces Third Quarter 2019 Results." |
| 104 | Cover Page Interactive Data File (embedded within the Inline XBRL document). |

**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 30, 2019

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

**Cerus Corporation Announces Third Quarter 2019 Results**

CONCORD, CA, October 30, 2019 - Cerus Corporation (Nasdaq: CERS) today announced financial results for the third quarter ended September 30, 2019.

Recent developments and highlights include:

- FDA issued its final guidance document on strategies to mitigate the risk of bacterial contamination in transfused platelet components
- Total third quarter revenue of $22.8 million
  - Quarterly product revenue of $18.0 million, a 17% increase compared to the prior year quarter
  - Government contract revenue of $4.8 million
- Worldwide demand for INTERCEPT continued to increase; calculated number of treatable platelet doses increased nearly 20% worldwide compared to the prior year quarter
- 2019 product revenue guidance reaffirmed at $72 million to $75 million, up 18-23% over 2018, driven by strong global demand for INTERCEPT platelets
- Over 20 posters and abstracts presented at the 2019 AABB Conference, highlighting the clinical and operational benefits of INTERCEPT

“The recent finalization of the FDA guidance document is great for patients, transfusion medicine and Cerus,” said William ‘Obi’ Greenman, Cerus’ president and chief executive officer. “INTERCEPT is uniquely positioned to provide a solution for blood centers to comply with the final guidance that confers optimal operational simplicity, clinical efficacy, and economic value to blood centers and hospitals. In this regard, the American Red Cross and many other large U.S. blood centers have stated that pathogen reduction is their preferred solution to safeguarding the platelet supply.”

“We have built a strong foundation of awareness for INTERCEPT as evidenced by another quarter of strong commercial execution with the calculated number of treatable platelet doses in the U.S. up nearly 70% compared to the prior year. With this solid base of existing blood center customers scaling their production of INTERCEPT platelets, we are ramping our efforts to support U.S. blood centers and hospitals to be compliant with the FDA’s final guidance document by the end of Q1 2021,” continued Greenman.

**Revenue**

Product revenue during the third quarter of 2019 was $18.0 million, compared to $15.4 million during the same period in 2018. Revenue growth in the quarter benefited from continued demand for INTERCEPT platelet kits in the U.S. and the timing of large plasma kit orders in EMEA, which were partially offset by the conversion to our double dose platelet kits in France and a 4% negative impact of foreign currency exchange rates. Year-to-date product revenue totaled $53.7 million, an increase of 21% compared to the same period in 2018.

Government contract revenue from the Company's Biomedical Advanced Research and Development Authority (BARDA) agreement was $4.8 million during the third quarter of 2019, compared to $3.9 million during the same period in 2018, as a result of increasing INTERCEPT red blood cell clinical and development activities. Year-to-date government contract revenue totaled $13.6 million compared to $11.4 million in the first nine months of 2018. The total potential value of the current BARDA agreement is $201 million with $39 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 third quarter of 2019 were 58%, compared to 47% for the third quarter of 2018. The increase in gross margin was tied to economies of scale realized for our cost of goods sold, favorable platelet product mix, namely the French conversion to double dose platelet kits and additional manufacturing efficiencies. Gross margins during the first nine months of 2019 were 55% compared to 48% reported in the same period the year prior.

**Operating Expenses**

Total operating expenses for the third quarter of 2019 were $32.2 million compared to $24.8 million for the same period the prior year. Year-to-date, operating expenses totaled $93.0 million compared to $72.2 million for the first three quarters of 2018.

Selling, general, and administrative (SG&A) expenses for the third quarter of 2019 totaled $16.1 million, compared to $14.0 million for the third quarter of 2018. The year-over-year increase in SG&A expenses was tied to increased non-cash stock compensation, higher investments in our supply chain capabilities and focused investments on preparatory activities for our anticipated cryoprecipitate launch. Year-to-date SG&A expenses totaled $49.0 million compared to $42.0 million for the first nine months of 2018.

Research and development (R&D) expenses for the third quarter of 2019 were $16.1 million, compared to $10.8 million for the third quarter of 2018. The increase in year-over-year R&D expenses was largely due to product enhancements and initiatives for expanded label claims, development activities to support our anticipated cryoprecipitate PMA supplement, as well as additional activities tied to the development of our INTERCEPT red blood cell system. Year-to-date R&D expenses totaled $43.9 million compared to $30.1 million for the first nine months of 2018.

**Net Loss**

Net loss for the third quarter of 2019 was $18.0 million, or $0.13 per diluted share, compared to a net loss of $14.2 million, or $0.11 per diluted share, for the third quarter of 2018. Year-to-date net loss was $54.3 million or $0.39 per diluted share compared to $41.4 million, or $0.32 per diluted share in the first nine months of 2018.

**Cash, Cash Equivalents and Investments**

At September 30, 2019, the Company had cash, cash equivalents and short-term investments of $85.1 million, compared to $117.6 million at December 31, 2018.

At September 30, 2019, the Company had approximately $39.4 million in outstanding term loan debt and $5.0 million of borrowings under its revolving loan credit agreement, compared to $29.9 million in outstanding term loan debt at December 31, 2018.

**2019 Product Revenue Guidance**

The Company reaffirms its 2019 product revenue guidance to the range of $72 million to $75 million. The guidance range represents 18% to 23% growth compared to 2018 reported product revenue and is based on the strong global demand for INTERCEPT platelet kits.

**QUARTERLY CONFERENCE CALL AND WEBCAST**

The Company will host a conference call and webcast at 4:30 P.M. EDT this afternoon, during which management will discuss the Company's financial results and provide a general business overview and outlook. To listen to the live webcast and view the presentation slides, 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 November 13, 2019.

**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**

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 and anticipated increasing customer demand; INTERCEPT's ability to provide a solution for blood centers to comply with the final guidance that confers optimal operational simplicity, clinical efficacy, and economic value to blood centers and hospitals; the potential value of Cerus' agreement with BARDA; 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 globally, including in its U.S. and European markets, 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) 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 require additional regulatory approvals, (c) that Cerus may be unable to submit anticipated regulatory submissions, such as the anticipated premarket approval application supplement for INTERCEPT-treated extended storage cryoprecipitate from plasma in a timely manner or at all and even if submitted, such submissions may not be accepted or approved in a timely manner or 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 INTERCEPT-treated extended storage cryoprecipitate from plasma, 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 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, 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; 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 June 30, 2019, filed with the SEC on August 1, 2019. 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, | |
|---|---|---|---|---|
| | 2019 | 2018 | 2019 | 2018 |
| Product revenue | $ 18,019 | $ 15,399 | $ 53,732 | $ 44,383 |
| Cost of product revenue | 7,583 | 8,142 | 24,126 | 23,192 |
| Gross profit on product revenue | 10,436 | 7,257 | 29,606 | 21,191 |
| Government contract revenue | 4,827 | 3,928 | 13,554 | 11,430 |
| Operating expenses: | | | | |
| Research and development | 16,081 | 10,825 | 43,938 | 30,143 |
| Selling, general and administrative | 16,140 | 13,964 | 49,041 | 42,008 |
| Total operating expenses | 32,221 | 24,789 | 92,979 | 72,151 |
| Loss from operations | (16,958) | (13,604) | (49,819) | (39,530) |
| Non-operating expense, net | (949) | (532) | (4,321) | (1,660) |
| Loss before income taxes | (17,907) | (14,136) | (54,140) | (41,190) |
| Provision for income taxes | 60 | 56 | 181 | 169 |
| Net loss | $ (17,967) | $ (14,192) | $ (54,321) | $ (41,359) |
| Net loss per share: | | | | |
| Basic and diluted | $ (0.13) | $ (0.11) | $ (0.39) | $ (0.32) |
| Weighted average shares outstanding used for calculating net loss per share: | | | | |
| Basic and diluted | 140,908 | 134,326 | 138,779 | 130,199 |

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

| | September 30, 2019 | December 31, 2018 |
|---|---|---|
| **ASSETS** | | |
| Current assets: | | |
| Cash and cash equivalents | $ 24,425 | $ 28,859 |
| Short-term investments | 60,686 | 88,718 |
| Accounts receivable | 14,502 | 8,752 |
| Inventories | 20,906 | 13,539 |
| Prepaid and other current assets | 5,798 | 7,034 |
| Total current assets | 126,317 | 146,902 |
| Non-current assets: | | |
| Property and equipment, net | 15,218 | 8,130 |
| Goodwill and intangible assets, net | 1,499 | 1,650 |
| Operating lease right-of-use assets | 14,110 | — |
| Restricted cash and other assets | 7,294 | 6,778 |
| Total assets | $ 164,438 | $ 163,460 |
| **LIABILITIES AND STOCKHOLDERS' EQUITY** | | |
| Current liabilities: | | |
| Accounts payable and accrued liabilities | $ 38,413 | $ 38,395 |
| Manufacturing and development obligations | — | 5,928 |
| Debt – revolving loan | 4,993 | — |
| Debt – term loan | — | 7,857 |
| Operating lease liabilities – current | 1,592 | — |
| Deferred product revenue – current | 561 | 498 |
| Total current liabilities | 45,559 | 52,678 |
| Non-current liabilities: | | |
| Debt – non-current | 39,371 | 22,013 |
| Operating lease liabilities – non-current | 18,458 | — |
| Other non-current liabilities | 242 | 4,250 |
| Total liabilities | 103,630 | 78,941 |
| Stockholders' equity | 60,808 | 84,519 |
| Total liabilities and stockholders' equity | $ 164,438 | $ 163,460 |