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): August 1, 2019

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

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

2550 Stanwell Dr.
Concord, California 94520
(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 Instructions A.2. below):

☐ 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 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 (§ 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 August 1, 2019, Cerus Corporation (the "Company") announced its financial results for its second quarter ended June 30, 2019. A copy of the Company's press release, entitled "Cerus Corporation Announces Record Second 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 August 1, 2019, entitled "Cerus Corporation Announces Record Second Quarter 2019 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: August 1, 2019

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

Cerus Corporation Announces Record Second Quarter 2019 Results

CONCORD, CA, Aug 1, 2019 – Cerus Corporation (Nasdaq: CERS) today announced financial results for the second quarter ended June 30, 2019.

Recent developments and highlights include:

- Total second quarter revenue of $22.5 million
  - Record quarterly product revenue of $18.2 million, an 18% increase compared to the prior year quarter
  - Government contract revenue of $4.3 million
- Worldwide disposable kit demand increased 23% in the quarter compared to the prior year quarter
- Raising 2019 full year product revenue guidance to a range of $72 million to $75 million from $71 million to $74 million given the strong demand for INTERCEPT
- Cash, cash equivalents, and short-term investments of $96.2 million at June 30, 2019
- Received European CE Mark approval for INTERCEPT plasma with DEHP-free plastic disposable kits

“We are pleased to report another strong quarter of commercial execution and record product revenues. Increasing customer adoption of INTERCEPT Blood Systems continues to be driven by the clinical, operational, and economic benefits conferred by our pathogen inactivation technology,” said William ‘Obi’ Greenman, Cerus’ president and chief executive officer. “Robust demand for INTERCEPT kits was reported across multiple geographies with the greatest volume increase in the U.S. as blood centers and hospitals implement pathogen reduction in advance of the expected FDA final guidance document on bacterial risk control strategies for platelet collection and transfusion. In the face of increasing demand for our products from blood centers, we are continuing to invest in working capital, particularly in inventory.”

“Pathogen-reduced cryoprecipitate continues to be an exciting pipeline opportunity and a product which could have a meaningful impact on improving patient outcomes. We now believe that we will be able to optimize the availability of plasma in order to realize manufacturing efficiencies for cryoprecipitate production with our blood center partners, potentially affording us with improved economics,” continued Greenman.

Revenue

Product revenue during the second quarter of 2019 was $18.2 million, compared to $15.4 million during the same period in 2018. Revenue growth in the quarter benefited from the higher INTERCEPT kit demand in the U.S. and select international markets, partially offset by product mix in France and the strengthening of the U.S. dollar relative to the Euro compared to prior year exchange rates. Year-to-date product revenue totaled $35.7 million, an increase of 23% compared to the same period in 2018.

Government contract revenue from the Company's Biomedical Advanced Research and Development Authority (BARDA) agreement was $4.3 million during the second quarter of 2019, compared to $4.0 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 $8.7 million compared to $7.5 million in the first half of 2018. The total potential value of the current BARDA agreement is $201 million with $34 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 second quarter of 2019 were 55%, compared to 50% for the second quarter of 2018. The increase in gross margin was tied to economies of scale realized for our cost of goods sold and additional manufacturing efficiencies. Gross margins during the first half of 2019 were 54% compared to 48% reported in the first half of 2018.

Operating Expenses

Total operating expenses for the second quarter of 2019 were $31.2 million compared to $24.3 million for the same period the prior year. Year-to-date, operating expenses totaled $60.8 million compared to $47.4 million for the first half of 2018.

Selling, general, and administrative (SG&A) expenses for the second quarter of 2019 totaled $16.7 million, compared to $14.4 million for the second quarter of 2018. The year-over-year increase in SG&A expenses was tied to higher investments in our manufacturing and supply chain capabilities. Year-to-date SG&A expenses totaled $32.9 million compared to $28.0 million for the first half of 2018.

Research and development (R&D) expenses for the second quarter of 2019 were $14.4 million, compared to $9.9 million for the second quarter of 2018. The increase in year-over-year R&D expenses was largely due to additional activities tied to the development of our INTERCEPT red blood cell system, including BARDA activities and initiatives aimed at ensuring supply and compatibility for our platelet and plasma products. Year-to-date R&D expenses totaled $27.9 million compared to $19.3 million for the first half of 2018.

Net Loss

Net loss for the second quarter of 2019 was $17.6 million, or $0.13 per diluted share, compared to a net loss of $13.3 million, or $0.10 per diluted share, for the second quarter of 2018. Year-to-date net loss was $36.4 million or $0.26 per diluted share compared to $27.2 million, or $0.21 per diluted share in the first half of 2018.

Cash, Cash Equivalents and Investments

At June 30, 2019, the Company had cash, cash equivalents and short-term investments of $96.2 million, compared to $117.6 million at December 31, 2018.

At June 30, 2019, the Company had approximately $39.3 million in outstanding term loan debt and $4.5 million of borrowings under its revolving loan credit agreement, compared to $29.9 million in outstanding term loan debt at December 31, 2018.

Revised 2019 Product Revenue Guidance

The Company now expects 2019 product revenue to be in the range of $72 million to $75 million compared to our previous guidance range of $71 million to $74 million. The new guidance range represents 18% to 23% growth compared to 2018 reported product revenue.

QUARTERLY CONFERENCE CALL

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 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 2898719. The replay will be available approximately three hours after the call through August 15, 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; Cerus' expectation for the FDA final guidance document on bacterial risk control strategies for platelet collection and transfusion; Cerus' efforts to enhance supply chain security and ensure availability of INTERCEPT kits; the prospects

for pathogen-reduced cryoprecipitate as a pipeline opportunity and the potential for pathogen-reduced cryoprecipitate to have a meaningful impact on improving patient outcomes; 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, (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, and (f) that anticipated regulatory guidance documents may not be issued in a timely manner or at all; 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 March 31, 2019, filed with the SEC on May 7, 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 June 30,		Six Months Ended June 30,	
	2019	2018	2019	2018
Product revenue	$ 18,209	$ 15,420	$ 35,713	$ 28,984
Cost of product revenue	8,111	7,720	16,543	15,050
Gross profit on product revenue	10,098	7,700	19,170	13,934
Government contract revenue	4,266	4,047	8,727	7,502
Operating expenses:				
Research and development	14,417	9,881	27,857	19,318
Selling, general and administrative	16,740	14,437	32,901	28,044
Total operating expenses	31,157	24,318	60,758	47,362
Loss from operations	(16,793)	(12,571)	(32,861)	(25,926)
Non-operating expense, net	(708)	(652)	(3,372)	(1,128)
Loss before income taxes	(17,501)	(13,223)	(36,233)	(27,054)
Provision for income taxes	61	59	121	113
Net loss	$ (17,562)	$ (13,282)	$ (36,354)	$ (27,167)
Net loss per share:				
Basic and diluted	$ (0.13)	$ (0.10)	$ (0.26)	$ (0.21)
Weighted average shares outstanding used for calculating net loss per share:				
Basic and diluted	138,281	131,352	137,698	128,101

CERUS CORPORATION
CONDENSED CONSOLIDATED UNAUDITED BALANCE SHEETS
(in thousands)

	June 30, 2019	December 31, 2018
ASSETS		
Current assets:		
Cash and cash equivalents	$ 23,543	$ 28,859
Short-term investments	72,659	88,718
Accounts receivable	13,432	8,752
Inventories	17,447	13,539
Other current assets	8,756	7,034
Total current assets	135,837	146,902
Non-current assets:		
Property and equipment, net	15,345	8,130
Goodwill and intangible assets, net	1,549	1,650
Operating lease right-of-use assets	14,417	—
Restricted cash and other assets	7,479	6,778
Total assets	$ 174,627	$ 163,460
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities:		
Accounts payable and accrued liabilities	$ 37,712	$ 38,395
Manufacturing and development obligations	6,198	5,928
Debt – revolving loan	4,496	—
Debt – term loan	—	7,857
Operating lease liabilities – current	1,711	—
Deferred product revenue – current	665	498
Total current liabilities	50,782	52,678
Non-current liabilities:		
Debt – non-current	39,327	22,013
Operating lease liabilities – non-current	18,722	—
Other non-current liabilities	164	4,250
Total liabilities	108,995	78,941
Stockholders' equity	65,632	84,519
Total liabilities and stockholders' equity	$ 174,627	$ 163,460