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): May 7, 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.)

2550 Stanwell Drive Concord, California	94520
(Address of Principal Executive Offices)	(Zip Code)

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

Not Applicable
(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))

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. ☐

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**

Item 2.02 Results of Operations and Financial Condition

On May 7, 2019, Cerus Corporation (the "Company") announced its financial results for its first quarter ended March 31, 2019. A copy of the Company's press release, entitled "Cerus Corporation Announces Record First 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 May 7, 2019, entitled "Cerus Corporation Announces Record First 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: May 7, 2019

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

Exhibit 99.1

Cerus Corporation Announces Record First Quarter 2019 Results

CONCORD, CA, May 7, 2019—Cerus Corporation (Nasdaq: CERS) today announced financial results for the first quarter ended March 31, 2019.

Recent developments and highlights include:

- Total first quarter revenue of $22.0 million
  - Record quarterly product revenue of $17.5 million, a 29% increase compared to the prior year quarter
  - Government contract revenue of $4.5 million
- Worldwide disposable kit demand increased 35% from the prior year quarter
- 2019 full year product revenue guidance being raised to range of $71 million to $74 million from $70 million to $73 million
- Regulatory feedback on INTERCEPT red cell CE Mark submission will add to the overall review period
- Strengthened balance sheet with a $90 million new debt facility consisting of a staged $70 million term loan and a $5 million revolving line of credit, expandable up to $20 million

“Our first quarter results reflect the continued strong underlying demand by blood centers and hospitals for INTERCEPT treated components which provides lower risk of transfusion transmitted infections from both known and emerging pathogens,” said William ‘Obi’ Greenman, Cerus’ president and chief executive officer. “The robust sales momentum we experienced in 2018 has extended into 2019 driven by further U.S. adoption in advance of an expected FDA final guidance document on bacterial risk control strategies for platelet collection and transfusion this year.”

“We are continuing to progress our development programs and to enhance our capabilities surrounding quality, manufacturing and supply chain continuity. In Europe, recent discussions with our Notified Body for the INTERCEPT red blood cell CE Mark submission have provided us with additional information which we expect, however, will extend the review process. We are using this opportunity to take measures to enhance our supply chain security prior to the anticipated commercial launch,” continued Greenman.

Revenue

Product revenue during the first quarter of 2019 was $17.5 million, compared to $13.6 million during the same period in 2018. Revenue growth in the quarter benefited from the volume growth in disposable kit sales in the U.S., and increased disposable kit sales in the Middle East, partially offset by product mix in France and the strengthening of the U.S. dollar relative to the Euro.

Government contract revenue from the Company's Biomedical Advanced Research and Development Authority (BARDA) agreement was $4.5 million during the first quarter of 2019, compared to $3.5 million during the same period in 2018, as a result of increasing INTERCEPT red blood cell clinical and development activities. The total potential value of the current BARDA agreement is $201 million with $29 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 first quarter of 2019 were 52%, compared to 46% for the first quarter of 2018. Gross margins in the quarter benefited from economies of scale and lower pricing from our contract manufacturer, favorable product mix in France and overall increased demand for platelet kits.

Operating Expenses

Total operating expenses for the first quarter 2019 were $29.6 million compared to $23.0 million for the same period the prior year.

Selling, general, and administrative (SG&A) expenses for the first quarter of 2019 totaled $16.2 million, compared to $13.6 million for the first quarter of 2018. The year-over-year increase was primarily tied to investments in our manufacturing and supply chain capabilities. This focus and investment is consistent with our plan that is designed to ensure stability of supply, improved management of our supply chain and preparation for planned global growth of demand for our products.

Research and development (R&D) expenses for the first quarter of 2019 were $13.4 million, compared to $9.4 million for the first quarter of 2018. The increase in year-over-year R&D expenses was primarily due to additional activities and costs tied to the development of INTERCEPT red blood cell system and activities related to the BARDA agreement.

Net Loss

Net loss for the first quarter of 2019 was $18.8 million, or $0.14 per diluted share, compared to a net loss of $13.9 million, or $0.11 per diluted share, for the first quarter of 2018.

Cash, Cash Equivalents and Investments

At March 31, 2019, the Company had cash, cash equivalents and short-term investments of $100.4 million, compared to $117.6 million at December 31, 2018.

At March 31, 2019, the Company had approximately $39.4 million in outstanding term loan debt compared to $29.9 million at December 31, 2018.

Revised 2019 Product Revenue Guidance

The Company currently expects 2019 product revenue to be in the range of $71 million to $74 million compared to our previous guidance range of $70 million to $73 million. The new guidance range represents 17% to 21% 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 3932269. The replay will be available approximately three hours after the call through May 21, 2019.

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

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 planned global growth of demand for Cerus' products; Cerus' expectations with respect to its red blood cell CE Mark submission; the anticipated commercial launch of the red blood cell system; the financial capacity available under Cerus' new debt facility; the potential value of Cerus' agreement with BARDA; Cerus' plan designed to ensure stability of supply and improved management of its supply chain; 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) 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, (c) 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, and (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' CE Mark submission, in a timely manner or at all; 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 risk that the anticipated financial capacity under Cerus' new debt facility may not be available when expected, or at all, including as a result of Cerus' inability to satisfy the conditions to the funding of the remaining available advances under the facility; 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' Annual Report on Form 10-K for the year ended December 31, 2018, filed with the SEC on February 27, 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 March 31,	
	2019	**2018**
Product revenue	$ 17,504	$ 13,564
Cost of product revenue	8,432	7,330
Gross profit on product revenue	9,072	6,234
Government contract revenue	4,461	3,455
Operating expenses:		
Research and development	13,440	9,437
Selling, general and administrative	16,161	13,607
Total operating expenses	29,601	23,044
Loss from operations	(16,068)	(13,355)
Non-operating expense, net:	(2,664)	(476)
Loss before income taxes	(18,732)	(13,831)
Provision for income taxes	60	54
Net loss	$ (18,792)	$ (13,885)
Net loss per share:		
Basic	$ (0.14)	$ (0.11)
Diluted	$ (0.14)	$ (0.11)
Weighted average shares outstanding used for calculating net loss per share:		
Basic	137,108	124,814
Diluted	137,108	124,814

CERUS CORPORATION
CONDENSED CONSOLIDATED UNAUDITED BALANCE SHEETS
(in thousands)

	March 31, 2019	December 31, 2018
ASSETS		
Current assets:		
Cash and cash equivalents	$ 29,002	$ 28,859
Short-term investments	71,426	88,718
Accounts receivable	13,756	8,752
Inventories	15,778	13,539
Other current assets	4,958	7,034
Total current assets	134,920	146,902
Non-current assets:		
Property and equipment, net	16,089	8,130
Goodwill and intangible assets, net	1,600	1,650
Operating lease right-of-use assets	15,631	—
Restricted cash and other assets	7,686	6,778
Total assets	$ 175,926	$ 163,460
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities:		
Accounts payable and accrued liabilities	$ 39,309	$ 38,395
Debt—current	—	7,857
Manufacturing and development obligations—current	5,962	5,928
Operating lease liabilities – current	1,560	—
Deferred product revenue – current	763	498
Total current liabilities	47,594	52,678
Non-current liabilities:		
Debt—non-current	39,433	22,013
Operating lease liabilities – non-current	19,311	—
Other non-current liabilities	88	4,250
Total liabilities	106,426	78,941
Stockholders' equity	69,500	84,519
Total liabilities and stockholders' equity	$ 175,926	$ 163,460