
**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): May 8, 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 May 8, 2018, Cerus Corporation (the “Company”) announced its financial results for its first quarter ended March 31, 2018. A copy of the Company’s press release, entitled “Cerus Corporation Reports First Quarter 2018 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 8, 2018, entitled “Cerus Corporation Reports First Quarter 2018 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 8, 2018

By: /s/ Kevin D. Green

Kevin D. Green

Vice President, Finance and Chief Financial Officer



Cerus Corporation Reports First Quarter 2018 Results

CONCORD, CA, May 8, 2018—Cerus Corporation (Nasdaq: CERS) announced today financial results for the first quarter ended March 31, 2018, and raised its full year guidance for product revenue.

First Quarter Highlights and Recent Events

- First quarter product revenue of \$13.6 million
- Year-over-year Q1 worldwide disposable kit volume up over 100%
- Raising full year product revenue guidance range to \$53 million to \$55 million from \$51 million to \$53 million
- Cash and cash equivalents balance of \$105.9 million at March 31, 2018
- Received Canadian regulatory approval for INTERCEPT Blood Systems for platelets
- Expanded enrollment sites for the phase 3 RedeS clinical trial of INTERCEPT-treated red blood cells into Texas and Florida

“The commercial momentum we experienced exiting 2017 continued into 2018 with first quarter product revenue of \$13.6 million, exceeding our expectations. Global demand for platelet kits continued to be robust with first quarter platelet kit sales volumes more than doubling compared to the prior year, led by increased shipments in France and in the U.S.,” said William ‘Obi’ Greenman, Cerus’ president and chief executive officer. “Given the strong first quarter results and the current visibility into our commercial pipeline, we are raising our full year product revenue guidance range to \$53 million to \$55 million compared to our previous range of \$51 million to \$53 million.”

“We continue to push forward with our mission to establish INTERCEPT as the global standard of care for transfused blood components,” continued Greenman. “In the U.S., blood centers are continuing to increase production of INTERCEPT platelets to meet the ever growing hospital demand for pathogen-reduced platelets. In France, we gained additional regulatory approvals on our dual storage processing set for INTERCEPT platelets and shelf-life extension from five to seven days which should allow for increased blood center operational efficiencies and lower product wastage.”

During the quarter, the Company’s development programs continued to progress with the Ultra-Performance Liquid Chromatography (UPLC) lot release assay achieving validation to support its anticipated CE Mark submission for INTERCEPT red cells, and the INTERCEPT cryoprecipitate program advancing the required stability studies for its planned premarket approval (PMA) supplement submission to the U.S. Food and Drug Administration (FDA).

Revenue

Product revenue for the first quarter of 2018 was \$13.6 million, compared to \$7.0 million during the same period in 2017. The increase in product revenue was driven by quarter-over-quarter increases in platelet kit demand, partially offset by declines in plasma kits and illuminator sales. Reported product revenue in the quarter also benefitted from favorable foreign currency exchange rates.

Government contract revenue from the Company's Biomedical Advanced Research and Development Authority (BARDA) agreement was \$3.5 million in the first quarter of 2018 compared to \$1.4 million during the same period in 2017 as a result of increasing INTERCEPT red cell clinical and development activities. BARDA is part of the Office of the Assistant Secretary for Preparedness and Response within the U.S. Department of Health and Human Services.

Gross Margins

Gross margins on product revenue for the first quarter of 2018 were 46%, compared to 47% for the first quarter of 2017. Gross margins on product sales remained relatively stable due to a variety of factors including economies of scale and lower costs due to increased platelet production, pricing for high volume customers, and foreign exchange rates.

Operating Expenses

Total operating expenses were \$23.0 million for the quarter ended March 31, 2018, compared to \$22.8 million for the quarter ended March 31, 2017.

Selling, general, and administrative expenses for the first quarter of 2018 remained relatively flat at \$13.6 million, compared to \$13.7 million for the first quarter of 2017 as the Company continued to leverage its existing commercial and back-office infrastructure.

Research and development (R&D) expenses for the first quarter of 2018 were \$9.4 million compared to \$9.2 million for the first quarter of 2017. Expenses associated with the clinical development of the Company's INTERCEPT red blood cell program increased while non-BARDA related R&D expenses declined as the Company re-allocated R&D personnel to the BARDA activities.

Operating and Net Loss

Operating losses during the first quarter of 2018 were \$13.4 million, compared to \$18.1 million during the first quarter of 2017.

Net loss for the first quarter of 2018 was \$13.9 million, or \$0.11 per diluted share, compared to a net loss of \$18.6 million, or \$0.18 per diluted share, for the first quarter of 2017.

Cash, Cash Equivalents and Investments

At March 31, 2018, the Company had cash, cash equivalents and short-term investments of \$105.9 million compared to \$60.7 million at December 31, 2017.

At March 31, 2018, the Company had approximately \$29.8 million in outstanding debt under its loan agreement with Oxford Finance. The loan agreement provides for an additional \$10 million term loan (and, if drawn, an extension of the interest only period) upon the Company achieving pre-determined revenue levels. The Company achieved the pre-determined revenue levels as of March 31, 2018, but has not currently exercised its option on the additional \$10 million term loan and interest only extension. The option expires on May 14, 2018.

QUARTERLY CONFERENCE CALL

The Company will host a conference call and webcast at 4:15 p.m. Eastern time today to discuss its 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 2366225. The replay will be available approximately three hours after the call through May 22, 2018.

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' 2018 annual product revenue guidance; Cerus' mission to establish INTERCEPT as the global standard of care for transfused blood components; Cerus' planned INTERCEPT red blood cell system CE Mark submission; Cerus' planned PMA supplement submission for INTERCEPT-treated extended storage cryoprecipitate from plasma; Cerus' expectation that additional French regulatory approvals on its dual storage processing set for INTERCEPT platelets and shelf-life extension should allow for increased blood center operational efficiencies and lower product wastage; 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 European markets, including in France, and/or realize expected revenue contribution resulting from its 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; 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; 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 sells 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' Annual Report on Form 10-K for the year ended December 31, 2017, filed with the SEC on March 8, 2018. 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,	
	2018	2017
Product revenue	\$ 13,564	\$ 7,006
Cost of product revenue	7,330	3,694
Gross profit on product revenue	6,234	3,312
Government contract revenue	3,455	1,428
Operating expenses:		
Research and development	9,437	9,150
Selling, general and administrative	13,607	13,683
Total operating expenses	23,044	22,833
Loss from operations	(13,355)	(18,093)
Non-operating expense, net	(476)	(470)
Loss before income taxes	(13,831)	(18,563)
Provision for income taxes	54	35
Net loss	<u>\$ (13,885)</u>	<u>\$ (18,598)</u>
Net loss per share:		
Basic	\$ (0.11)	\$ (0.18)
Diluted	\$ (0.11)	\$ (0.18)
Weighted average shares outstanding used for calculating net loss per share:		
Basic	124,814	103,564
Diluted	124,814	103,564

CERUS CORPORATION
CONDENSED CONSOLIDATED UNAUDITED BALANCE SHEETS
(in thousands)

	<u>March 31,</u> <u>2018</u>	<u>December 31,</u> <u>2017</u>
ASSETS		
Current assets:		
Cash and cash equivalents	\$ 14,877	\$ 13,683
Short-term investments	90,988	47,013
Accounts receivable	10,489	12,415
Inventories	13,165	14,457
Other current assets	4,257	2,330
Total current assets	<u>133,776</u>	<u>89,898</u>
Non-current assets:		
Property and equipment, net	1,969	2,119
Goodwill and intangible assets, net	1,802	1,852
Restricted cash and other assets	6,874	4,375
Total assets	<u>\$ 144,421</u>	<u>\$ 98,244</u>
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities:		
Accounts payable and accrued liabilities	\$ 21,588	\$ 22,686
Debt — current	1,429	—
Deferred product revenue — current	639	445
Total current liabilities	<u>23,656</u>	<u>23,131</u>
Non-current liabilities:		
Debt — non-current	28,387	29,798
Manufacturing and development obligations — non-current	5,996	5,766
Other non-current liabilities	784	609
Total liabilities	<u>58,823</u>	<u>59,304</u>
Stockholders' equity	<u>85,598</u>	<u>38,940</u>
Total liabilities and stockholders' equity	<u>\$ 144,421</u>	<u>\$ 98,244</u>