CERUS CORP

FORM 8-K
(Current report filing)

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Address	2550 STANWELL DRIVE CONCORD, CA 94520
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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): February 28, 2013

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

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 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))

Item 2.02 Results of Operations and Financial Condition

On February 28, 2013, Cerus Corporation (the "Company") announced its financial results for its fourth quarter and year ended December 31, 2012. A copy of the Company's press release, entitled "Cerus Corporation Reports Fourth Quarter and Year-End 2012 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 February 28, 2013, entitled "Cerus Corporation Reports Fourth Quarter and Year-End 2012 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: February 28, 2013

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

EXHIBIT INDEX

Exhibit Number	Description
99.1	Press release, dated February 28, 2013, entitled “Cerus Corporation Reports Fourth Quarter and Year-End 2012 Results.”

Exhibit 99.1

Contact:

Kevin D. Green
Vice President, Finance & CFO
Cerus Corporation
(925) 288-6138

Cerus Corporation Reports Fourth Quarter and Year-End 2012 Results

- Year-over-year product revenue growth of 20%; 2013 revenue guidance of $41-43 million.
- INTERCEPT Blood System disposable kit demand up 28% from 2011.
- Reached agreement with U.S. FDA to proceed with INTERCEPT platelet PMA based on existing portfolio of clinical data.
- Filed first of four modules for INTERCEPT plasma PMA.

CONCORD, CA, February 28, 2013- Cerus Corporation (NASDAQ: CERS) today announced financial results for the fourth quarter and year ended December 31, 2012.

“We believe 2013 will be a pivotal year for Cerus in which we plan to both complete our INTERCEPT plasma PMA submission and begin planning for the PMA filing for INTERCEPT platelets,“ said William “Obi” Greenman, president and chief executive officer of Cerus Corporation. “In addition, we anticipate revenue in the range of $41 million to $43 million, representing 12% to 17% growth or 16% to 21% when compared in constant currency, building on our 2012 revenue growth.“

Revenue

Product revenue for the fourth quarter of 2012 was $10.5 million, a 6% increase over the fourth quarter of 2011. The increase in product revenue was driven by 14% growth in demand for INTERCEPT disposable kits during the fourth quarter of 2012 compared to the fourth quarter of 2011.

The Company did not recognize any government grant revenue during the fourth quarter of 2012, as government grants in support of the Company's red blood cell system had been fully utilized by January, 2012. During the fourth quarter of 2011, the Company recognized $0.5 million of government grant revenue.

Product revenue for the year ended December 31, 2012 was $36.7 million and represented a 20% increase over product revenue recognized during the year ended December 31, 2011. The year over year increase in product revenue was driven primarily by 28% growth in demand for INTERCEPT disposable kits.

Government grant revenue for the year ended December 31, 2012 was $0.1 million, down from $2.4 million recognized during the year ended December 31, 2011. The last government grant awarded to Cerus in support of the Company's red blood cell system occurred in August, 2011. The Company does not currently expect any government grant revenue for the foreseeable future.

Gross Margins

Gross margins on product sales for the fourth quarter of 2012 of 51%, compared to 37% for the fourth quarter of 2011. Gross margins on product sales for the year ended December 31, 2012 were 44%, compared to 39% for same period in 2011. The improvement in gross margins on product sales was driven primarily by lower costs for products sold as a result of improved overhead absorption due to higher manufacturing levels.

Operating Expenses

Total operating expenses for the fourth quarter of 2012 were $9.0 million, compared to $7.6 million for the fourth quarter of 2011. Total operating expenses for the year ended December 31, 2012 were $33.5 million, compared to $30.4 million for the year ended December 31, 2011. The increase in these operating expenses for both the fourth quarter and year ended December 31, 2012 was related to increases in selling, general and administrative expenses in support of growing the commercial business in Europe, the Middle East, and The Commonwealth of Independent States; as well as the expansion into new markets and geographies.

Operating expenses are expected to increase in 2013, largely driven by higher cost of product revenue as a function of the anticipated revenue growth and by increased research and development expenses. The Company expects to incur increased regulatory costs in 2013 in support of the ongoing modular PMA submission to the FDA for the licensure of the INTERCEPT plasma system . The Company also expects to incur development costs in Europe and the United States for planned clinical trials and *in vitro* studies to support potential regulatory approval of the INTERCEPT red blood cell system.

Operating and Net Loss

Operating losses during the fourth quarter of 2012 were $3.6 million, compared to $3.3 million for the fourth quarter of 2011. Operating losses during the year ended December 31, 2012 were $17.3 million, compared to $15.9 million for the year ended December 31, 2011.

Net loss for the fourth quarter of 2012 was $1.7 million, or $0.07 per diluted share, compared to a net loss of $7.7 million, or $0.16 per diluted share, for the fourth quarter of 2011. Net loss for the year ended December 31, 2012 was $15.9 million, or $0.33 per diluted share, compared to a net loss of $17.0 million, or $0.35 per diluted share, for the year ended December 31, 2011. Net losses were impacted by the mark-to-market adjustments of Cerus' outstanding warrants to fair value, which resulted in non-cash gains of $2.0 million during the fourth quarter of 2012, non-cash losses of $3.3 million during the comparable period in 2011, and $2.1 million and $0.5 million in non-cash gains during the years ended December 31, 2012 and 2011, respectively.

Cash and Investments

At December 31, 2012, the Company had cash, cash equivalents and short-term investments of $26.7 million. The Company continued to tightly manage its working capital, including accounts receivable and payables, which resulted in lower cash used for operations during the year ended December 31, 2012 compared to the comparable period in 2011.

Recent Highlights

- 2012 product revenues of $36.7 million, exceeding 2012 guidance of $34-$36 million;
- 28% year-over-year demand growth for INTERCEPT disposables;
- First of four modules filed with FDA for INTERCEPT plasma PMA. Submission of final module expected before year end.
- FDA agreement to accept INTERCEPT platelet PMA based on existing portfolio of clinical and hemovigilance data.
- Kevin D. Green appointed as the Company's Chief Financial Officer.
- Carol Moore promoted to Senior Vice President, Regulatory, Quality and Clinical.

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 web site, or by dialing 855-859-2056 (U.S.) or 404-537-3406 (international) and entering conference ID number 96997633. The replay will be available approximately three hours after the call through March 13, 2013.

ABOUT CERUS

Cerus Corporation is a biomedical products company focused on commercializing the INTERCEPT Blood System to enhance blood safety. The INTERCEPT system is designed to reduce the risk of transfusion-transmitted diseases 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 enables INTERCEPT treatment to inactivate established transfusion threats, such as hepatitis B and C, HIV, West Nile virus and bacteria, and is designed to inactivate emerging pathogens such as influenza, malaria and dengue. Cerus currently markets and sells the INTERCEPT Blood System for both platelets and plasma in Europe, The Commonwealth of Independent States, the Middle East and selected countries in other regions around the world. In the United States, Cerus is seeking regulatory approval of the INTERCEPT Blood System for plasma, and is in discussion with FDA to define the additional clinical data required for a regulatory submission for the INTERCEPT Blood System for platelets. The INTERCEPT Blood System for red blood cells is in clinical development. See http://www.cerus.com for more information.

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 results, including statements concerning Cerus' expectations regarding its 2013 revenues, the timing for completion of a modular PMA to the FDA for the INTERCEPT Blood System for plasma, the timing of beginning a modular PMA filing for the INTERCEPT Blood System for platelets, future governmental grant revenue, future operating expenses, research and development activity and expenses in support of Cerus' regulatory submissions, and the future development of the INTERCEPT Blood System for red blood cells. 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, the uncertain and time-consuming clinical development and regulatory process, that Cerus may encounter unanticipated difficulties complying with the prescribed submission timing or other modular PMA requirements related to the INTERCEPT Blood System for plasma, that Cerus may be unable to reach agreement with the FDA on the planned modular submission protocol for the INTERCEPT Blood System for platelets or may be required to conduct additional clinical development of the platelet system, and that if additional clinical development of the platelet system is required it will require funding that Cerus does not currently have, adverse market and economic conditions, adverse fluctuations in foreign exchange rates, Cerus' reliance on third parties to market, sell, distribute and maintain its products, Cerus' ability to maintain an effective manufacturing supply chain, intellectual property protection, 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, 2012 filed with the SEC on November 8, 2012. Cerus disclaims any obligation or undertaking to update or revise any forward-looking statements contained in this press release.

Financial Tables Attached

CERUS CORPORATION
CONDENSED CONSOLIDATED UNAUDITED STATEMENTS OF OPERATIONS
(in thousands except per share information)

	Three Months Ended December 31,		Twelve Months Ended December 31,	
	2012	2011	2012	2011
Product Related:				
Product revenue	$10,528	$ 9,896	$ 36,695	$ 30,602
Cost of product revenue	5,117	6,206	20,616	18,535
Gross profit on product revenue	5,411	3,690	16,079	12,067
Government grant and cooperative agreements revenue	—	527	91	2,442
Operating expenses:				
Research and development	2,164	1,562	7,603	7,178
Selling, general and administrative	6,794	5,938	25,665	23,053
Amortization of intangible assets	51	50	202	202
Total operating expenses	9,009	7,550	33,470	30,433
Loss from operations	(3,598)	(3,333)	(17,300)	(15,924)
Non-operating income (expense), net	1,993	(4,353)	1,625	(915)
Loss from operations before income taxes	(1,605)	(7,686)	(15,675)	(16,839)
Provision for income taxes	111	49	242	143
Net loss	$ (1,716)	$ (7,735)	$(15,917)	$(16,982)
Net loss per common share:				
Basic	$ (0.03)	$ (0.16)	$ (0.29)	$ (0.35)
Diluted	$ (0.07)	$ (0.16)	$ (0.33)	$ (0.35)
Weighted average common shares outstanding used for computing net loss per common share:				
Basic	55,663	49,390	54,515	48,050
Diluted	55,912	49,390	55,061	48,050

CERUS CORPORATION
CONDENSED CONSOLIDATED UNAUDITED BALANCE SHEETS
(in thousands)

	December 31, 2012	December 31, 2011
Cash, cash equivalents, and short-term investments	$ 26,696	$ 25,784
Accounts receivable and other current assets	7,120	7,511
Inventories	10,180	6,444
Property and equipment, net	1,698	2,032
Goodwill and intangible assets	2,862	3,064
Other assets	363	532
Total assets	$ 48,919	$ 45,367
Accounts payable and accrued liabilities	$ 14,805	$ 10,505
Deferred revenue	77	111
Debt - current	4,828	2,519
Warrant liability	5,903	7,979
Debt - non-current	2,896	4,697
Other non-current liabilities	1,303	1,243
Total liabilities	29,812	27,054
Stockholders' equity	19,107	18,313
Total liabilities and stockholders' equity	$ 48,919	$ 45,367