CERUS CORP

FORM 8-K
(Current report filing)

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Address	2550 STANWELL DRIVE CONCORD, CA 94520
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Industry	Biotechnology & Drugs
Sector	Healthcare
Fiscal Year	12/31

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): April 30, 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 April 30, 2013, Cerus Corporation (the "Company") announced its financial results for its first quarter ended March 31, 2013. A copy of the Company's press release, entitled "Cerus Corporation Reports First Quarter 2013 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 April 30, 2013, entitled "Cerus Corporation Reports First Quarter 2013 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: April 30, 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 April 30, 2013, entitled “Cerus Corporation Reports First Quarter 2013 Results.”

Exhibit 99.1

Contact:

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

Cerus Corporation Reports First Quarter 2013 Results

- Year-over-year INTERCEPT revenue growth of 12%;
- U.S. FDA acceptance of proposed modular Premarket Approval (PMA) application shell for reveiw of INTERCEPT platelets; last module expected to be submitted by March 2014;
- $40.25 million in gross proceeds raised from public offering of common stock

CONCORD, CA, April 30, 2013- Cerus Corporation (NASDAQ: CERS) today announced financial results for the first quarter ended March 31, 2013.

“We ended the first quarter of 2013 with a stronger balance sheet and a clear focus on successfully submmitting the INTERCEPT platelet and plasma modular PMA applications in the U.S.,” said William ‘Obi’ Greenman, president and chief executive officer of Cerus Corporation. “With regard to our ongoing sales growth in our current commercial markets, we are on plan to reach our guidance of $41-$43 million in product revenue for the year.”

Revenue

Product revenue for the first quarter of 2013 was $9.7 million, a 12% increase over the first quarter of 2012. Continued growth in certain markets and continued placement of INTERCEPT illumination devices drove the revenue growth.

The Company did not recognize any government grant revenue during the first quarter of 2013, as government grants in support of the Company’s red blood cell system had been fully utilized by January 2012. During the first quarter of 2012, the Company recognized $0.1 million of government grant revenue.

Gross Margins

Gross margins on product sales for the first quarter of 2013 were 48%, compared to 37% for the first quarter of 2012. 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 during the second half of 2012.

Operating Expenses

Total operating expenses for the first quarter of 2013 were $9.6 million, compared to $7.8 million for the first quarter of 2012. The increase in these operating expenses was due to regulatory activities for the preparation and submission of the first module for the Company’s PMA application for INTERCEPT plasma and the preparation and submission of a proposal for a modular PMA application for INTERCEPT platelets, costs for the preparation of planned Phase III clinical trials related to the Company’s red blood cell

program in Europe and 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.

Operating expenses are expected to continue to increase in 2013, largely driven by increased research and development expenses. The Company expects to incur increased development and regulatory costs in 2013 in support of the modular PMA submissions to the FDA for the licensure of the INTERCEPT platelet and plasma systems. In addition, the Company expects to incur costs related to preparatory marketing activities in anticipation of the potential future U.S. launch of both products. The planned clinical trials and *in vitro* studies to support potential regulatory approval of the INTERCEPT red blood cell system will also contribute to the expected increase in operating expenses.

Operating and Net Loss

Operating losses during the first quarter of 2013 were $5.0 million, compared to $4.6 million during the first quarter of 2012. The increase in operating losses was driven by higher operating expenses incurred during the first quarter of 2013 compared to the first quarter of 2012, partially offset by increased product revenue and improved gross margins on product sales during the first quarter of 2013.

Net loss for the first quarter of 2013 was $10.3 million, or $0.17 per share, compared to a net loss of $8.8 million, or $0.17 per share, for the first quarter of 2012. Net losses were impacted by the mark-to-market adjustments of the Company's outstanding warrants to fair value, which resulted in non-cash charges of $5.1 million during the first quarter of 2013 compared to $4.5 million during the first quarter of 2012.

Cash and Cash Equivalents

At March 31, 2013, the Company had cash and cash equivalents of $69.2 million. In April 2013, the Company repaid its outstanding $4.2 million of term debt. The Company's $7.0 million revolving line of credit remains outstanding with approximately $4.0 million available for future borrowing.

Recent Highlights

- FDA accepts the INTERCEPT platelet PMA application shell structure and timing
- Swissmedic and Swiss Red Cross present national haemovigilance data showing favourable safety profile for INTERCEPT-treated platelet components
- Cerus signs INTERCEPT platelet agreements with two key blood component suppliers in Germany and Austria
- Cerus closes public offering of common stock, raising $40.25 million in gross proceeds.

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 May 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 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 future sales growth and its 2013 revenues, the timing and success of modular PMA submissions to the FDA for the INTERCEPT Blood System for plasma and platelets, the potential U.S. commercial launch of the INTERCEPT Blood System for plasma and platelets, future operating expenses, research and development activity, including additional clinical development, in support of Cerus' regulatory submissions and the expenses related thereto, marketing activity and expenses in support of Cerus' planned commercialization activities, and the future development and potential regulatory approval of the INTERCEPT Blood System for red blood cells and the expenses related thereto. 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, Cerus' ability to successfully initiate and conduct planned clinical triials in the anticipated timeframes, or at all, the fact 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 and/or platelets, the fact that Cerus may be required to conduct additional clinical development in support of its modulat PMA submissions, and that if additional clinical development is required it will require funding that Cerus does not currently have and will significantly delay and could preclude regulatory approval of the INTERCEPT Blood System for plasma and platelets in the United States, 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' Annual

Report on Form 10-K for the year ended December 31, 2012 filed with the SEC on March 12, 2013. 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 March 31,	
	2013	2012
Product Related:		
Product revenue	$ 9,733	$ 8,691
Cost of product revenue	5,090	5,514
Gross profit on product revenue	4,643	3,177
Government grant and cooperative agreements revenue	—	91
Operating expenses:		
Research and development	2,700	1,824
Selling, general and administrative	6,853	5,966
Amortization of intangible assets	50	50
Total operating expenses	9,603	7,840
Loss from operations	(4,960)	(4,572)
Non-operating income (expense), net	(5,241)	(4,227)
Loss from operations before income taxes	(10,201)	(8,799)
Provision for income taxes	51	35
Net loss	$(10,252)	$ (8,834)
Net loss per common share:		
Basic and Diluted	$ (0.17)	$ (0.17)
Weighted average common shares outstanding used for computing net loss per common share:		
Basic and Diluted	59,730	53,088

CERUS CORPORATION
CONDENSED CONSOLIDATED UNAUDITED BALANCE SHEETS
(in thousands)

	March 31, 2013	December 31, 2012
Cash and cash equivalents	$69,163	$ 26,696
Accounts receivable and other current assets	6,521	7,120
Inventories	11,756	10,180
Property and equipment, net	1,595	1,698
Goodwill and intangible assets	2,812	2,862
Other assets	360	363
Total assets	$92,207	$ 48,919
Accounts payable and accrued liabilities	$12,036	$ 14,805
Deferred revenue	174	77
Debt - current	4,470	4,828
Warrant liability	10,976	5,903
Debt - non-current	2,485	2,896
Other non-current liabilities	1,278	1,303
Total liabilities	31,419	29,812
Stockholders' equity	60,788	19,107
Total liabilities and stockholders' equity	$92,207	$ 48,919