CERUS CORP
Form 10-Q
May 06, 2016
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UNITED STATES

SECURITIES AND EXCHANGE COMMISSION

WASHINGTON, D.C. 20549

FORM 10-Q

(Mark One)

x **QUARTERLY REPORT PURSUANT TO SECTION 13 OR 15 (d) OF THE SECURITIES EXCHANGE ACT OF 1934**

For the quarterly period ended March 31, 2016

or

¨ **TRANSITION REPORT PURSUANT TO SECTION 13 OR 15 (d) OF THE SECURITIES EXCHANGE ACT OF 1934**

For the transition period from: _____ to _____

Commission File Number 000-21937

CERUS CORPORATION

(Exact name of registrant as specified in its charter)

Delaware	**68-0262011**
(State or other jurisdiction of	**(I.R.S. Employer**
incorporation or organization)	**Identification No.)**
2550 Stanwell Dr.	
Concord, California	**94520**
(Address of principal executive offices)	**(Zip Code)**

(925) 288-6000

(Registrant s telephone number, including area code)

Indicate by check mark whether the registrant (1) has filed all reports required to be filed by Section 13 or 15 (d) of the Securities Exchange Act of 1934 during the preceding 12 months (or for such shorter period that the registrant was required to file such reports), and (2) has been subject to such filing requirements for the past 90 days. YES x NO ¨

Indicate by check mark whether the registrant has submitted electronically and posted on its corporate Web site, if any, every Interactive Data File required to be submitted and posted pursuant to Rule 405 of Regulation S-T (§232.405 of this chapter) during the preceding 12 months (or for such shorter period that the registrant was required to submit and post such files). YES x NO ¨

Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, a non-accelerated filer, or a smaller reporting company. See the definitions of large accelerated filer, accelerated filer and smaller reporting company in Rule 12b-2 of the Exchange Act.

Large accelerated filer ¨	Accelerated filer x
Non-accelerated filer ¨ (Do not check if a smaller reporting company)	Smaller reporting company ¨

Indicate by check mark whether the registrant is a shell company (as defined in Rule 12b-2 of the Exchange Act). YES ¨ NO x

As of April 28, 2016, there were 101,710,815 shares of the registrant s common stock outstanding.

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CERUS CORPORATION

QUARTERLY REPORT ON FORM 10-Q

THREE MONTHS ENDED MARCH 31, 2016

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PART I: FINANCIAL INFORMATION

ITEM 1. FINANCIAL STATEMENTS

CERUS CORPORATION

CONDENSED CONSOLIDATED BALANCE SHEETS

(in thousands)

	March 31, 2016 (Unaudited)	December 31, 2015
ASSETS		
Current assets:		
Cash and cash equivalents	$ 20,791	$ 71,018
Short-term investments	70,513	25,698
Investment in marketable equity securities	5,082	11,163
Accounts receivable	4,086	5,794
Inventories	11,255	10,812
Prepaid expenses	1,377	1,166
Other current assets	6,333	4,755
Total current assets	119,437	130,406
Non-current assets:		
Property and equipment, net	3,380	3,549
Goodwill	1,316	1,316
Intangible assets, net	890	940
Restricted cash	574	612
Other assets	2,341	2,579
Total assets	$ 127,938	$ 139,402
LIABILITIES AND STOCKHOLDERS EQUITY		
Current liabilities:		
Accounts payable	$ 6,238	$ 5,217
Accrued liabilities	9,221	9,853
Manufacturing and development obligations current	2,219	3,282
Debt current	4,527	2,956
Deferred revenue current	613	554
Total current liabilities	22,818	21,862
Non-current liabilities:		
Debt non-current	15,301	16,848
Deferred income taxes	131	122

Manufacturing and development obligations non-current	4,840	4,542
Other non-current liabilities	1,314	1,263
Total liabilities	44,404	44,637
Commitments and contingencies		
Stockholders equity:		
Common stock	101	99
Additional paid-in capital	694,741	685,189
Accumulated other comprehensive income	3,367	7,289
Accumulated deficit	(614,675)	(597,812)
Total stockholders equity	83,534	94,765
Total liabilities and stockholders equity	$ 127,938	$ 139,402

See accompanying Notes to Unaudited Condensed Consolidated Financial Statements.

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CERUS CORPORATION

CONDENSED CONSOLIDATED STATEMENTS OF OPERATIONS

UNAUDITED

(in thousands, except per share data)

	Three Months Ended March 31,	
	2016	**2015**
Revenue	$ 7,632	$ 7,692
Cost of revenue	4,263	4,714
Gross profit	3,369	2,978
Operating expenses:		
Research and development	6,917	5,581
Selling, general and administrative	11,747	11,718
Amortization of intangible assets	50	50
Total operating expenses	18,714	17,349
Loss from operations	(15,345)	(14,371)
Non-operating (expense) income, net:		
Gain from revaluation of warrant liability		6,296
Foreign exchange loss	(117)	(1,113)
Interest expense	(655)	(255)
Other income, net	66	2
Total non-operating (expense) income, net	(706)	4,930
Loss before income taxes	(16,051)	(9,441)
Provision for income taxes	812	19
Net loss	$ (16,863)	$ (9,460)
Net loss per share:		
Basic	$ (0.17)	$ (0.10)
Diluted	$ (0.17)	$ (0.17)
Weighted average shares outstanding used for calculating net loss per share:		
Basic	99,471	93,411
Diluted	99,471	94,662

See accompanying Notes to Unaudited Condensed Consolidated Financial Statements.

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CERUS CORPORATION

CONDENSED CONSOLIDATED STATEMENTS OF COMPREHENSIVE LOSS

UNAUDITED

(in thousands)

	Three Months Ended March 31,	
	2016	**2015**
Net loss	$ (16,863)	$ (9,460)
Other comprehensive (loss) income:		
Unrealized (losses) gains on available-for-sale investments, net of taxes of ($2,058) and zero for the three months ended March 31, 2016 and 2015, respectively	(3,922)	19
Comprehensive loss	$ (20,785)	$ (9,441)

See accompanying Notes to Unaudited Condensed Consolidated Financial Statements.

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CERUS CORPORATION

CONDENSED CONSOLIDATED STATEMENTS OF CASH FLOWS

UNAUDITED

(in thousands)

	Three Months Ended March 31,	
	2016	**2015**
Operating activities		
Net loss	$ (16,863)	$ (9,460)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation and amortization	476	443
Stock-based compensation	1,776	1,474
Changes in valuation of warrant liability		(6,296)
Non-cash interest expense	300	64
Deferred income taxes	9	1
Non-cash tax expense from other unrealized loss on available-for-sale securities	768	
Changes in operating assets and liabilities:		
Accounts receivable	1,708	340
Inventories	(488)	(1,220)
Other assets	(213)	(116)
Accounts payable	995	484
Accrued liabilities	(639)	(1,488)
Manufacturing and development obligations	(924)	
Deferred revenue	52	23
Net cash used in operating activities	(13,043)	(15,751)
Investing activities		
Capital expenditures	(43)	(59)
Purchases of investments	(50,544)	(69,982)
Proceeds from maturities of investments	5,500	4,400
Restricted cash	38	47
Net cash used in investing activities	(45,049)	(65,594)
Financing activities		
Net proceeds from the issuance of common stock in connection with equity incentive plans	698	999
Net proceeds from public offering	7,199	75,527
Repayment of debt	(32)	(28)
Net cash provided by financing activities	7,865	76,498

Net decrease in cash and cash equivalents	(50,227)	(4,847)
Cash and cash equivalents, beginning of year	71,018	22,781
Cash and cash equivalents, end of year	$ 20,791	$ 17,934

See accompanying Notes to Unaudited Condensed Consolidated Financial Statements.

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CERUS CORPORATION

NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS

UNAUDITED

Note 1. Summary of Significant Accounting Policies

Principles of Consolidation and Basis of Presentation

The accompanying unaudited condensed consolidated financial statements include those of Cerus Corporation and its subsidiary, Cerus Europe B.V. (together with Cerus Corporation, hereinafter Cerus or the Company) after elimination of all intercompany accounts and transactions. These unaudited condensed consolidated financial statements have been prepared in accordance with accounting principles generally accepted in the United States of America (GAAP) for interim financial information and pursuant to the rules and regulations of the Securities and Exchange Commission (SEC). Accordingly, they do not include all of the information and footnotes required by GAAP for complete financial statements. In the opinion of management, all adjustments, consisting of normal recurring entries, considered necessary for a fair presentation have been made. Operating results for the three months ended March 31, 2016, are not necessarily indicative of the results that may be expected for the year ending December 31, 2016, or for any future periods.

These unaudited condensed consolidated financial statements and notes thereto should be read in conjunction with the Company s audited consolidated financial statements and notes thereto for the year ended December 31, 2015, which were included in the Company s 2015 Annual Report on Form 10-K, filed with the SEC on March 9, 2016. The accompanying condensed consolidated balance sheet as of December 31, 2015, has been derived from the Company s audited consolidated financial statements as of that date, except as described in the New Accounting Pronouncement section below related to the adoption of Accounting Standards Update (ASU) No. 2015-03, *Interest Imputation of Interest (Subtopic 835-30): Simplifying the Presentation of Debt Issuance Costs*.

Use of Estimates

The preparation of financial statements requires management to make estimates, assumptions and judgments that affect the reported amounts of assets, liabilities, revenue and expenses, and related disclosures of contingent assets and liabilities. On an ongoing basis, management evaluates its estimates, which are based on historical experience and on various other assumptions that are believed to be reasonable under the circumstances. Actual results may differ from those estimates under different assumptions or conditions.

Revenue

The Company recognizes revenue in accordance with Accounting Standards Codification (ASC) Topic 605-25, *Revenue Recognition Arrangements with Multiple Deliverables,* as applicable. Revenue is recognized when (i) persuasive evidence of the arrangement exists; (ii) delivery has occurred or services have been rendered; (iii) pricing is fixed or determinable; and (iv) collectability is reasonably assured. The Company s main sources of revenues for the three months ended March 31, 2016 and 2015 were product revenue from sales of the INTERCEPT Blood System for platelets and plasma (platelet and plasma systems or disposable kits) and UVA illumination devices (illuminators).

Revenue related to product sales is generally recognized when the Company fulfills its obligations for each element of an agreement. For all sales of the Company s INTERCEPT Blood System products, the Company uses a binding purchase order or signed sales contract as evidence of an arrangement. The Company sells its platelet and plasma systems directly to blood banks, hospitals, universities, government agencies, as well as to distributors in certain regions. Generally, the Company s contracts with its customers do not provide for open return rights, except within a reasonable time after receipt of goods in the case of defective or non-conforming product. Deliverables and the units of accounting vary according to the provisions of each purchase order or sales contract. For revenue arrangements with multiple elements, the Company determines whether the delivered elements meet the criteria as separate units of accounting. Such criteria require that the deliverable have stand-alone value to the customer and that if a general right of return exists relative to the delivered item, delivery or performance of the undelivered item(s) is considered probable and substantially in the control of the Company. Once the Company determines if the deliverable meets the criteria for a separate unit of accounting, the Company must determine how the consideration should be allocated between the deliverables and how the separate units of accounting should be recognized as revenue. Consideration received is allocated to elements that are identified as discrete units of accounting. Because the Company has no vendor specific objective evidence or third party evidence for its systems due to the Company s variability in its pricing across the regions into which it sells its products, the allocation of revenue is based on best estimated selling price for the products sold. The objective of best estimated selling price is to determine the price at which the Company would transact a sale, had the product been sold on a stand-alone basis. The Company determines best estimated selling price for its systems by considering multiple factors. The Company regularly reviews best estimated selling price.

Freight costs charged to customers are recorded as a component of revenue. Taxes that the Company invoices to its customers and remits to governments are recorded on a net basis, which excludes such tax from product revenue.

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Research and Development Expenses

In accordance with ASC Topic 730, *Accounting for Research and Development Expenses,* research and development (R&D) expenses are charged to expense when incurred, including cost incurred under each grant that has been awarded to the Company by the U.S. government or development contracts. Research and development expenses include salaries and related expenses for scientific and regulatory personnel, payments to consultants, supplies and chemicals used in in-house laboratories, costs of R&D facilities, depreciation of equipment and external contract research expenses, including clinical trials, preclinical safety studies, other laboratory studies, process development and product manufacturing for research use.

The Company s use of estimates in recording accrued liabilities for R&D activities (see Use of Estimates above) affects the amounts of R&D expenses recorded. Actual results may differ from those estimates under different assumptions or conditions.

Cash Equivalents

The Company considers all highly liquid investments with original maturities of three months or less from the date of purchase to be classified as cash equivalents. These investments primarily consist of money market instruments, and are classified as available-for-sale.

Investments

Investments with original maturities of greater than three months primarily include corporate debt, U.S. government agency securities and marketable equity securities of Aduro Biotech, Inc. (Aduro), and are designated as available-for-sale and classified as short-term investments or investment in marketable equity securities, in accordance with ASC Topic 320, *Accounting for Certain Investments in Debt and Equity Securities* . Available-for-sale securities are carried at estimated fair value. The Company views its available-for-sale portfolio as available for use in its current operations. Unrealized gains and losses derived by changes in the estimated fair value of available-for-sale securities were recorded in Net unrealized (losses) gains on available-for-sale investments, net of taxes on the Company s unaudited condensed consolidated statements of comprehensive loss. Realized gains (losses) from the sale of available-for-sale investments were recorded in Other income, net on the Company s unaudited condensed consolidated statements of operations. The costs of securities sold are based on the specific identification method, if applicable. The Company reported the amortization of any premium and accretion of any discount resulting from the purchase of debt securities as a component of interest income.

The Company also reviews its available-for-sale securities on a regular basis to evaluate whether any security has experienced an other-than-temporary decline in fair value. Other-than-temporary declines in market value, if any, are recorded in Other income, net on the Company s unaudited condensed consolidated statements of operations.

Restricted Cash

The Company holds a certificate of deposit with a domestic bank for any potential decommissioning resulting from the Company s possession of radioactive material. The certificate of deposit is held to satisfy the financial surety requirements of the California Department of Health Services and is recorded in Other assets on the Company s unaudited condensed consolidated balance sheets. The Company also has certain non-U.S. dollar denominated deposits recorded as Restricted cash in compliance with certain foreign contractual requirements.

Concentration of Credit Risk

Financial instruments that potentially subject the Company to concentrations of credit risk consist primarily of cash equivalents, available-for-sale securities and accounts receivable.

Pursuant to the Company s investment policy, substantially all of the Company s cash, cash equivalents and available-for-sale securities are maintained at major financial institutions of high credit standing. The Company monitors the financial credit worthiness of the issuers of its investments and limits the concentration in individual securities and types of investments that exist within its investment portfolio. Generally, all of the Company s investments carry high credit quality ratings, which is in accordance with its investment policy. At March 31, 2016, the fair value of the Company s marketable equity securities of Aduro is subject to the underlying volatility of Aduro s stock price. At March 31, 2016, the Company does not believe there is significant financial risk from non-performance by the issuers of the Company s cash equivalents and short-term investments.

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Concentrations of credit risk with respect to trade receivables exist. On a regular basis, including at the time of sale, the Company performs credit evaluations of its significant customers that it expects to sell to on credit terms. Generally, the Company does not require collateral from its customers to secure accounts receivable. To the extent that the Company determines specific invoices or customer accounts may be uncollectible, the Company establishes an allowance for doubtful accounts against the accounts receivable on its unaudited condensed consolidated balance sheets and records a charge on its unaudited condensed consolidated statements of operations as a component of selling, general and administrative expenses.

The Company had two customers and three customers that accounted for more than 10% of the Company s outstanding trade receivables at March 31, 2016 and December 31, 2015, respectively. These customers cumulatively represented approximately 48% and 49% of the Company s outstanding trade receivables at March 31, 2016 and December 31, 2015, respectively. To date, the Company has not experienced collection difficulties from these customers.

Inventories

At March 31, 2016 and December 31, 2015, inventory consisted of work-in-process and finished goods only. Finished goods include INTERCEPT disposable kits, illuminators, and certain replacement parts for the illuminators. Platelet and plasma systems disposable kits generally have a two-year life from the date of manufacture. Illuminators and replacement parts do not have regulated expiration dates. Work-in-process includes certain components that are manufactured over a protracted length of time before being sold to, and ultimately incorporated and assembled by Fresenius Kabi Deutschland GmbH or Fresenius, Inc. (with their affiliates, Fresenius) into the finished INTERCEPT disposable kits. The Company maintains an inventory balance based on its current sales projections, and at each reporting period, the Company evaluates whether its work-in-process inventory would be sold to Fresenius for production of finished units in order to sell to existing and prospective customers within the next twelve-month period. It is not customary for the Company s production cycle for inventory to exceed twelve months. Instead, the Company uses its best judgment to factor in lead times for the production of its work-in-process and finished units to meet the Company s forecasted demands. If actual results differ from those estimates, work-in-process inventory could potentially accumulate for periods exceeding one year. At March 31, 2016 and December 31, 2015, the Company classified its work-in-process inventory as a current asset on its consolidated balance sheets based on its evaluation that the work-in-process inventory would be sold to Fresenius for finished disposable kit production within each respective subsequent twelve-month period.

Inventory is recorded at the lower of cost, determined on a first-in, first-out basis, or net realizable value. The Company uses significant judgment to analyze and determine if the composition of its inventory is obsolete, slow-moving or unsalable and frequently reviews such determinations. The Company writes down specifically identified unusable, obsolete, slow-moving, or known unsalable inventory that has no alternative use in the period that it is first recognized by using a number of factors including product expiration dates, open and unfulfilled orders, and sales forecasts. Any write-down of its inventory to net realizable value establishes a new cost basis and will be maintained even if certain circumstances suggest that the inventory is recoverable in subsequent periods. Costs associated with the write-down of inventory are recorded in Cost of revenue on the Company s consolidated statements of operations. At March 31, 2016 and December 31, 2015, the Company had $1.6 million and $1.8 million, respectively, recorded for potential obsolete, expiring or unsalable product.

Property and Equipment, net

Property and equipment is comprised of furniture, equipment, leasehold improvements, information technology hardware and software and is recorded at cost. At the time the property and equipment is ready for its intended use, it is depreciated on a straight-line basis over the estimated useful lives of the assets (generally three to five years).

Leasehold improvements are amortized on a straight-line basis over the shorter of the lease term or the estimated useful lives of the improvements.

Capitalization of Software Costs

The Company capitalizes certain significant costs incurred in the acquisition and development of software for internal use, including the costs of the software, materials, and consultants during the application development stage. Costs incurred prior to the application development stage, costs incurred once the application is substantially complete and ready for its intended use, and other costs not qualifying for capitalization, including training and maintenance costs, are charged to expense as incurred. The capitalized costs associated with the enterprise resource planning system are being amortized over the estimated useful life of five years.

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Goodwill and Intangible Assets, net

Intangible assets, net, which include a license for the right to commercialize the INTERCEPT Blood System in Asia, are subject to ratable amortization over the original estimated useful life of ten years. The amortization of the Company s intangible assets, net, is recorded in Amortization of intangible assets on the Company s consolidated statements of operations. Goodwill is not amortized but instead is subject to an impairment test performed on an annual basis, or more frequently if events or changes in circumstances indicate that goodwill may be impaired. Such impairment analysis is performed on August 31 of each fiscal year, or more frequently if indicators of impairment exist. The test for goodwill impairment may be assessed using qualitative factors to determine whether it is more likely than not that the fair value of a reporting unit is less than the carrying amount. If the Company determines that it is more likely than not that the fair value of a reporting unit is less than the carrying amount, the Company must then proceed with performing the quantitative two-step process to test goodwill for impairment; otherwise, goodwill is not considered impaired and no further testing is warranted. The Company may choose not to perform the qualitative assessment to test goodwill for impairment and proceed directly to the quantitative two-step process; however, the Company may revert to the qualitative assessment to test goodwill for impairment in any subsequent period. The first step of the two-step process compares the fair value of each reporting unit with its respective carrying amount, including goodwill. The Company has determined that it operates in one reporting unit and estimates the fair value of its one reporting unit using the enterprise approach under which it considers the quoted market capitalization of the Company as reported on the Nasdaq Global Market. The Company considers quoted market prices that are available in active markets to be the best evidence of fair value. The Company also considers other factors, which include future forecasted results, the economic environment and overall market conditions. If the fair value of the reporting unit exceeds its carrying amount, goodwill of the reporting unit is not considered impaired and, therefore, the second step of the impairment test is unnecessary. The second step of the two-step process, which is used to measure the amount of impairment loss, compares the implied fair value of each reporting unit s goodwill, based on the present value of future cash flows, with the respective carrying amount of that goodwill. If the carrying amount of the reporting unit s goodwill exceeds the implied fair value of that goodwill, an impairment loss is recognized in an amount equal to that excess.

The Company performs an impairment test on its intangible assets, in accordance ASC Topic 360-10, *Property, Plant and Equipment,* if certain events or changes in circumstances occur which indicate that the carrying amounts of its intangible assets may not be recoverable. If the intangible assets are not recoverable, an impairment loss would be recognized by the Company based on the excess amount of the carrying value of the intangible assets over its fair value. For further details regarding the impairment analysis, reference is made to the section below under Long-lived Assets. See Note 5 in the Notes to Unaudited Condensed Consolidated Financial Statements for further information regarding the Company s impairment analysis and the valuation of goodwill and intangible assets, net.

Long-lived Assets

The Company evaluates its long-lived assets for impairment by continually monitoring events and changes in circumstances that could indicate carrying amounts of its long-lived assets may not be recoverable. When such events or changes in circumstances occur, the Company assesses recoverability by determining whether the carrying