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 incorporation or organization)	**(I.R.S. Employer 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	Three Months Ended March 31, 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 value of such assets will be recovered through the undiscounted expected future cash flows. If the expected undiscounted future cash flows are less than the carrying amount of these assets, the Company then measures the amount of the impairment loss based on the excess of the carrying amount over the fair value of the assets. The Company did not recognize impairment charges related to its long-lived assets during the three months ended March 31, 2016 and 2015.

Foreign Currency Remeasurement

The functional currency of the Company s foreign subsidiary is the U.S. dollar. Monetary assets and liabilities denominated in foreign currencies are remeasured in U.S. dollars using the exchange rates at the balance sheet date. Non-monetary assets and liabilities denominated in foreign currencies are remeasured in U.S. dollars using historical exchange rates. Revenues and expenses are remeasured using average exchange rates prevailing during the period. Remeasurements are recorded in the Company s consolidated statements of operations.

Stock-Based Compensation

The Company accounts for stock-based compensation in accordance with ASC Topic 718, *Compensation Stock Compensation.* Stock-based compensation expense is measured at the grant-date based on the fair value of the award and is recognized as expense on a straight-line basis over the requisite service period, which is the vesting period, and is adjusted for estimated forfeitures. To the extent that stock options contain performance criteria for vesting, stock-based compensation is recognized once the performance criteria are probable of being achieved.

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For stock-based awards issued to non-employees, the Company follows ASC Topic 505-50, *Equity Based Payment to Non-Employees* and considers the measurement date at which the fair value of the stock-based award is measured to be the earlier of (i) the date at which a commitment for performance by the grantee to earn the equity instrument is reached or (ii) the date at which the grantee s performance is complete. The Company recognizes stock-based compensation expense for the fair value of the vested portion of the non-employee stock-based awards in its consolidated statements of operations.

See Note 11 in the Notes to Unaudited Condensed Consolidated Financial Statements for further information regarding the Company s stock-based compensation expenses.

Income Taxes

The Company accounts for income taxes using an asset and liability approach in accordance with ASC Topic 740, *Accounting for Income Taxes*. Under this method, deferred tax assets and liabilities are determined based on differences between the financial reporting and tax bases of assets and liabilities and are measured using the enacted tax rates and laws that will be in effect when the differences are expected to reverse. ASC Topic 740 requires derecognition of tax positions that do not have a greater than 50% likelihood of being recognized upon review by a taxing authority having full knowledge of all relevant information. Use of a valuation allowance as described in ASC Topic 740 is not an appropriate substitute for derecognition of a tax position. The Company recognizes accrued interest and penalties related to unrecognized tax benefits in its income tax expense. To date, the Company has not recognized any interest and penalties in its unaudited condensed consolidated statements of operations, nor has it accrued for or made payments for interest and penalties. Although the Company believes it more likely than not that a taxing authority would agree with its current tax positions, there can be no assurance that the tax positions the Company has taken will be substantiated by a taxing authority if reviewed. The Company s U.S. federal and California tax years through 2015 remain subject to examination by the taxing jurisdictions due to unutilized net operating losses and research credits. The Company continues to carry a full valuation allowance on all of its net deferred tax assets, except for its indefinite lived intangibles.

Net Loss Per Share

Basic net loss per share is computed by dividing net loss by the weighted average number of common shares outstanding for the period. Diluted net loss per share gives effect to all potentially dilutive common shares outstanding for the period. The potentially dilutive securities include stock options, employee stock purchase plan rights, warrants and restricted stock units, which are calculated using the treasury stock method, and convertible preferred stock, which is calculated using the if-converted method. Diluted net loss per share also gives effect to potential adjustments to the numerator for gains resulting from the revaluation of warrants to fair value for the period, even if the Company is in a net loss position if the effect would result in more dilution.

Certain potential dilutive securities were excluded from the dilution calculation for the three months ended March 31, 2016 and 2015, as their inclusion would have been anti-dilutive.

The following table sets forth the reconciliation of the numerator and denominator used in the computation of basic and diluted net loss per share for the three months ended March 31, 2016 and 2015 (in thousands, except per share amounts):

	Three Months Ended March 31,	
	2016	**2015**
Numerator for Basic and Diluted:		
Net loss used for basic calculation	$ (16,863)	$ (9,460)
Effect of revaluation of warrant liability		(6,296)
Adjusted net loss used for diluted calculation	$ (16,863)	$ (15,756)
Denominator:		
Basic weighted average number of shares outstanding	99,471	93,411
Effect of dilutive potential shares		1,251
Diluted weighted average number of shares outstanding	99,471	94,662
Net loss per share:		
Basic	$ (0.17)	$ (0.10)
Diluted	$ (0.17)	$ (0.17)

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The table below presents shares underlying stock options, employee stock purchase plan rights, restricted stock units and/or convertible preferred stock that were excluded from the calculation of the weighted average number of shares outstanding used for the calculation of diluted net loss per share. These are excluded from the calculation due to their anti-dilutive effect for the three months ended March 31, 2016 and 2015 (shares in thousands):

	Three Months Ended March 31,	
	2016	**2015**
Weighted average number of anti-dilutive potential shares outstanding options	14,986	13,439

Guarantee and Indemnification Arrangements

The Company recognizes the fair value for guarantee and indemnification arrangements issued or modified by the Company. In addition, the Company monitors the conditions that are subject to the guarantees and indemnifications in order to identify if a loss has occurred. If the Company determines it is probable that a loss has occurred, then any such estimable loss would be recognized under those guarantees and indemnifications. Some of the agreements that the Company is a party to contain provisions that indemnify the counter party from damages and costs resulting from claims that the Company s technology infringes the intellectual property rights of a third party or claims that the sale or use of the Company s products have caused personal injury or other damage or loss. The Company has not received any such requests for indemnification under these provisions and has not been required to make material payments pursuant to these provisions.

The Company generally provides for a one-year warranty on certain of its INTERCEPT blood-safety products covering defects in materials and workmanship. The Company accrues costs associated with warranty obligations when claims become known and are estimable. The Company has not experienced significant or systemic warranty claims nor is it aware of any existing current warranty claims. Accordingly, the Company had not accrued for any future warranty costs for its products at March 31, 2016 and December 31, 2015.

Fair Value of Financial Instruments

The Company applies the provisions of fair value relating to its financial assets and liabilities. The carrying amounts of accounts receivables, accounts payable, and other accrued liabilities approximate their fair value due to the relative short-term maturities. Based on the borrowing rates currently available to the Company for loans with similar terms, the Company believes the fair value of its debt approximates their carrying amounts. The Company measures and records certain financial assets and liabilities at fair value on a recurring basis, including its available-for-sale securities and warrant liability prior to the expiration and exercise of the warrants in November 2015. The Company classifies instruments within Level 1 if quoted prices are available in active markets for identical assets, which include the Company s cash accounts and money market funds. The Company classifies instruments in Level 2 if the instruments are valued using observable inputs to quoted market prices, benchmark yields, reported trades, broker/dealer quotes or alternative pricing sources with reasonable levels of price transparency. These instruments include the Company s corporate debt and U.S. government agency securities holdings. The available-for-sale securities are held by a custodian who obtains investment prices from a third party pricing provider that uses standard inputs (observable in the market) to models which vary by asset class. The Company classifies instruments in Level 3 if one or more significant inputs or significant value drivers are unobservable. The Company assesses any transfers among fair value measurement levels at the end of each reporting period.

See Notes 2 in the Notes to Unaudited Condensed Consolidated Financial Statements for further information regarding the Company s valuation of financial instruments.

New Accounting Pronouncements

In May 2014, the Financial Accounting Standards Board (FASB) issued ASU No. 2014-09, *Revenue from Contracts with Customers (Topic 606),* which provides a single comprehensive model for entities to use in accounting for revenue arising from contracts with customers and will supersede most current revenue recognition guidance. This ASU is based on the principle that revenue is recognized to depict the transfer of goods or services to customers in an amount that reflects the consideration to which the entity expects to be entitled in exchange for those goods or services. The ASU also requires additional disclosure about the nature, amount, timing and uncertainty of revenue and cash flows arising from customer contracts, including significant judgments and changes in judgments and assets recognized from costs incurred to obtain or fulfill a contract. In August 2015, the FASB issued ASU No. 2015-14, *Revenue from Contracts with Customers (Topic 606), Deferral of the Effective Date*, which defers by one year the effective date of ASU No. 2014-09 to annual reporting periods beginning after December 15, 2017 (including interim periods within those periods). Early adoption is permitted to the original effective date of December 15, 2016 (including interim periods within those periods). In March 2016, the FASB issued ASU No. 2016-08, *Revenue from Contracts with Customers (Topic 606): Principal versus Agent Considerations (Reporting Revenue Gross versus Net)*, which clarifies how to identify the unit of accounting for the principal versus agent evaluation and how to apply the control principle to certain types of arrangements. In April 2016, the FASB issued ASU No. 2016-10, *Revenue from Contracts with Customers (Topic 606): Identifying Performance Obligations and Licensing*, which clarifies the implementation guidance on identifying performance obligations and licensing. These ASUs will be effective for the Company in the first quarter of fiscal year 2018, using one of two retrospective application methods. The Company has not selected a transition method and is currently assessing the potential effects of this ASU on the Company s condensed consolidated financial statements.

In August 2014, the FASB issued ASU No. 2014-15, *Presentation of Financial Statements Going Concern* (Subtopic 205-40): Disclosure of Uncertainties about an Entity s Ability to Continue as a Going Concern, which requires management to evaluate, in connection with preparing financial statements for each annual and interim reporting period, whether there are conditions or events, considered in the aggregate, that raise substantial doubt about an entity s ability to continue as a going concern within one year after the date that the financial statements are issued and provide related disclosures. This ASU will be effective for the Company in fiscal year 2017. Early adoption is permitted. The adoption of this ASU is not expected to have a material impact on the Company s condensed consolidated financial statements.

In April 2015, the FASB issued ASU No. 2015-03, *Interest Imputation of Interest (Subtopic 835-30): Simplifying the Presentation of Debt Issuance Costs*, which requires debt issuance costs related to a recognized debt liability to be presented in the balance sheet as a direct deduction from the corresponding debt liability rather than as an asset. The Company has adopted this ASU effective January 1, 2016 under the retrospective application method. To conform to the current period presentation, the Company reclassified $32,000 and $36,000, which were previously included in the Other current assets and Other assets, respectively, in the Company s condensed consolidated balance sheet as of December 31, 2015, as a reduction of Debt-current and Debt-non-current, respectively. As a result of the reclassifications, Other current assets and Debt-current decreased by $32,000, and Other assets and Debt- non-current decreased by $36,000, in the Company s condensed consolidated balance sheet as of December 31, 2015.

In January 2016, the FASB issued ASU No. 2016-01, *Financial Instruments-Overall (Subtopic 825-10),* which requires all equity investments to be measured at fair value with changes in the fair value recognized through net income (other than those accounted for under equity method of accounting or those that result in consolidation of the investee). The amendments also require an entity to present separately in other comprehensive income the portion of the total change in the fair value of a liability resulting from a change in the instrument-specific credit risk when the entity has elected to measure the liability at fair value in accordance with the fair value option for financial instruments. In addition, this ASU eliminates the requirement to disclose the fair value of financial instruments measured at amortized cost for entities that are not public business entities and the requirement to disclose the method(s) and significant assumptions used to estimate the fair value that is required to be disclosed for financial instruments measured at amortized cost on the balance sheet for public business entities. This ASU will be effective for the Company in fiscal year 2018. Early adoption is permitted. The Company is currently assessing the future impact of this ASU on the Company s condensed consolidated financial statements.

In February 2016, the FASB issued ASU No. 2016-02, *Leases,* which, for operating leases, requires a lessee to recognize a right-of-use asset and a lease liability, initially measured at the present value of the lease payments, in its balance sheet. The standard also requires a lessee to recognize a single lease cost, calculated so that the cost of the lease is allocated over the lease term, on a generally straight-line basis. This ASU will be effective for the Company in fiscal year 2019. Early adoption is permitted. The Company is currently assessing the future impact of this ASU on its consolidated financial statements and anticipates the new guidance will significantly impact the Company s condensed consolidated financial statements.

In March 2016, the FASB issued ASU No. 2016-09, *Compensation-Stock Compensation (Topic 718): Improvements to Employee Share-Based Payment Accounting,* which requires entities to record all excess tax benefits and tax deficiencies as income tax expense or benefit in the income statement when awards vest or are settled, and eliminates additional paid-in capital (APIC) pools. The ASU also changes the accounting for an employee s use of shares to satisfy the employer s statutory income tax withholding obligation, and the accounting for forfeitures, and provides two practical expedients for nonpublic entities. This ASU will be effective for the Company in fiscal year 2017. Early adoption is permitted. The Company is currently assessing the future impact of this ASU on the Company s condensed consolidated financial statements.

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Note 2. Fair Value on Financial Instruments

The Company uses certain assumptions that market participants would use to determine the fair value of an asset or liability in pricing the asset or liability in an orderly transaction between market participants at the measurement date. The identification of market participant assumptions provides a basis for determining what inputs are to be used for pricing each asset or liability. A fair value hierarchy has been established which gives precedence to fair value measurements calculated using observable inputs over those using unobservable inputs. This hierarchy prioritized the inputs into three broad levels as follows:

Level 1: Quoted prices in active markets for identical instruments

Level 2: Other significant observable inputs (including quoted prices in active markets for similar instruments)

Level 3: Significant unobservable inputs (including assumptions in determining the fair value of certain investments)

Money market funds are highly liquid investments and are actively traded. The pricing information on these investment instruments are readily available and can be independently validated as of the measurement date. This approach results in the classification of these securities as Level 1 of the fair value hierarchy.

To estimate the fair value of Level 2 debt securities as of March 31, 2016, the Company s primary service relies on inputs from multiple industry-recognized pricing sources to determine the price for each investment. Corporate debt and U.S. government agency securities are systematically priced by this service as of the close of business each business day. If the primary pricing service does not price a specific asset a secondary pricing service is utilized.

The fair values of the Company s financial assets and liabilities were determined using the following inputs at March 31, 2016 (in thousands):

	Balance sheet classification	Total	Quoted Prices in Active Markets for Identical Assets (Level 1)	Significant Other Observable Inputs (Level 2)	Significant Unobservable Inputs (Level 3)
Money market funds	Cash and cash equivalents	$ 6,648	$ 6,648	$	$
United States government agency securities	Short-term investments	9,997		9,997	
Corporate debt securities	Short-term investments	60,516		60,516	
Marketable equity securities	Marketable equity securities	5,082	5,082		
Total financial assets		$ 82,243	$ 11,730	$ 70,513	$

The fair values of the Company s financial assets and liabilities were determined using the following inputs at December 31, 2015 (in thousands):

	Balance sheet classification	Total	Quoted Prices in Active Markets for Identical Assets (Level 1)	Significant Other Observable Inputs (Level 2)	Significant Unobservable Inputs (Level 3)
Money market funds	Cash and cash equivalents	$ 59,302	$ 59,302	$	$
Corporate debt securities	Short-term investments	25,698		25,698	
Marketable equity securities	Marketable equity securities	11,163	11,163		
Total financial assets		$ 96,163	$ 70,465	$ 25,698	$

The Company did not have any transfers among fair value measurement levels during the three months ended March 31, 2016 or the year ended December 31, 2015. The Company did not have any financial assets or liabilities classified as level 3 financial instruments at March 31, 2016 and December 31, 2015.

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Note 3. Available-for-sale Securities

The following is a summary of available-for-sale securities at March 31, 2016 (in thousands):

	March 31, 2016			
	Amortized Cost	Gross Unrealized Gain	Gross Unrealized Loss	Fair Value
Money market funds	$ 6,648	$	$	$ 6,648
United States government agency securities	9,996	1		9,997
Corporate debt securities	60,465	72	(21)	60,516
Marketable equity securities		5,082		5,082
Total available-for-sale securities	$ 77,109	$ 5,155	$ (21)	$ 82,243

The following is a summary of available-for-sale securities at December 31, 2015 (in thousands):

	December 31, 2015			
	Amortized Cost	Gross Unrealized Gain	Gross Unrealized Loss	Fair Value
Money market funds	$ 59,302	$	$	$ 59,302
Corporate debt securities	25,747		(49)	25,698
Marketable equity securities		11,163		11,163
Total available-for-sale securities	$ 85,049	$ 11,163	$ (49)	$ 96,163

Available-for-sale securities at March 31, 2016 and December 31, 2015, consisted of the following by contractual maturity (in thousands):

	March 31, 2016		December 31, 2015	
	Amortized Cost	Fair Value	Amortized Cost	Fair Value
One year or less	$ 56,934	$ 56,934	$ 85,049	$ 85,000
Marketable equity securities		5,082		11,163
Greater than one year and less than five years	20,175	20,227		
Total available-for-sale securities	$ 77,109	$ 82,243	$ 85,049	$ 96,163

The following tables show all available-for-sale marketable securities in an unrealized loss position for which an other-than-temporary impairment has not been recognized and the related gross unrealized losses and fair value, aggregated by investment category and length of time that individual securities have been in a continuous unrealized loss position (in thousands):

	March 31, 2016					
	Less than 12 Months		12 Months or Greater		Total	
	Fair Value	Unrealized Loss	Fair Value	Unrealized Loss	Fair Value	Unrealized Loss
Corporate debt securities	$ 18,137	$ (21)	$	$	$ 18,137	$ (21)
Total available-for-sale securities	$ 18,137	$ (21)	$	$	$ 18,137	$ (21)

	December 31, 2015					
	Less than 12 Months		12 Months or Greater		Total	
	Fair Value	Unrealized Loss	Fair Value	Unrealized Loss	Fair Value	Unrealized Loss
Corporate debt securities	$ 20,170	$ (46)	$ 5,528	$ (3)	$ 25,698	$ (49)
Total available-for-sale securities	$ 20,170	$ (46)	$ 5,528	$ (3)	$ 25,698	$ (49)

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As of March 31, 2016, the Company considered the declines in market value of its marketable securities investment portfolio to be temporary in nature and did not consider any of its investments other-than-temporarily impaired. The Company typically invests in highly-rated securities, and its investment policy limits the amount of credit exposure to any one issuer. The policy generally requires investments to be investment grade, with the primary objective of minimizing the potential risk of principal loss. Fair values were determined for each individual security in the investment portfolio. When evaluating an investment for other-than-temporary impairment, the Company reviews factors such as the length of time and extent to which fair value has been below its cost basis, the financial condition of the issuer and any changes thereto, changes in market interest rates, and the Company s intent to sell, or whether it is more likely than not it will be required to sell, the investment before recovery of the investment s cost basis. During the three months ended March 31, 2016 and 2015, the Company did not recognize any other-than-temporary impairment loss. The Company has no current requirement or intent to sell the securities in an unrealized loss position. The Company expects to recover up to (or beyond) the initial cost of investment for securities held.

The Company did not record any gross realized gains from the sale or maturity of available-for-sale investments during the three months ended March 31, 2016 and 2015. The Company did not record any gross realized losses from the sale or maturity of available-for-sale investments during the three months ended March 31, 2016 and 2015.

Note 4. Inventories

Inventories at March 31, 2016 and December 31, 2015, consisted of the following (in thousands):

	March 31, 2016	December 31, 2015
Work-in-process	$ 2,966	$ 3,187
Finished goods	8,289	7,625
Total inventories	$ 11,255	$ 10,812

Note 5. Goodwill and Intangible Assets, net

Goodwill

During the three months ended March 31, 2016, the Company did not dispose of or recognize additional goodwill. The Company expects to perform its annual review of goodwill on August 31, 2016, unless indicators of impairment are identified prior to that date. As of March 31, 2016, the Company has not identified any indicators of goodwill impairment.

Intangible Assets, net

The following is a summary of intangible assets, net at March 31, 2016 (in thousands):

	March 31, 2016		
	Gross Carrying	Accumulated Amortization	Net Carrying

	Amount			Amount
Acquisition-related intangible assets:				
Reacquired license INTERCEPT Asia	$ 2,017	$	(1,127)	$ 890
Total intangible assets	$ 2,017	$	(1,127)	$ 890

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The following is a summary of intangible assets, net at December 31, 2015 (in thousands):

	December 31, 2015		
	Gross Carrying Amount	Accumulated Amortization	Net Carrying Amount
Acquisition-related intangible assets:			
Reacquired license INTERCEPT Asia	$ 2,017	$ (1,077)	$ 940
Total intangible assets	$ 2,017	$ (1,077)	$ 940

The Company recognized $0.05 million in amortization expense related to intangible assets for each of the three months ended March 31, 2016 and 2015. During the three months ended March 31, 2016 and 2015, there were no impairment charges recognized related to the acquired intangible assets.

At March 31, 2016, the expected annual amortization expense of the intangible assets, net is $0.15 million for the remaining nine months of 2016, $0.2 million annually beginning with the year ending December 31, 2017 through the year ending December 31, 2019, and $0.1 million for the year ending December 31, 2020.

Note 6. Marketable Equity Investments

The Company held an investment in preferred shares of Aduro which it had historically accounted for under the cost method of accounting with a net carrying value of zero. In April 2015, Aduro s common stock began trading on the NASDAQ Global Select Market, under the symbol ADRO . At the time of Aduro s initial public offering (IPO), the Company s preferred shares in Aduro converted to 396,700 shares of common stock, and the fair value of the Company s investment became readily determinable and, as a result became a marketable equity security. Therefore, the Company no longer accounts for the investment in Aduro under the cost basis of accounting. The Company now reflects the investment in Aduro as an available-for-sale security included in investment in marketable equity securities on the Company s unaudited condensed consolidated balance sheet (Note 2) and will adjust the carrying value of this investment to fair value each quarterly reporting period, with changes in fair value recorded within other comprehensive income (loss), net of tax.

Note 7. Accrued Liabilities

Accrued liabilities at March 31, 2016 and December 31, 2015, consisted of the following (in thousands):

	March 31, 2016	December 31, 2015
Accrued compensation and related costs	$ 4,664	$ 5,198
Accrued professional services	2,808	2,337
Accrued customer costs	923	987
Accrued insurance premiums	220	438
Other accrued expenses	606	893

Total accrued liabilities	$ 9,221	$ 9,853

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Note 8. Debt

Debt consisted of the following (in thousands):

	March 31, 2016		
	Principal	Unamortized Discount	Total
Loan and Security Agreement	$ 20,000	$ (172)	$ 19,828
Less: debt current	(4,615)	88	(4,527)
Debt non-current	$ 15,385	$ (84)	$ 15,301

	December 31, 2015
	Principal