Cardiovascular Systems Inc
Form 10-Q
February 02, 2016
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UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
Washington, DC 20549

FORM 10-Q

QUARTERLY REPORT PURSUANT TO SECTION 13 OR 15(d) OF
THE SECURITIES EXCHANGE ACT OF 1934
For the quarterly period ended December 31, 2015
Commission File No. 000-52082

CARDIOVASCULAR SYSTEMS, INC.
(Exact name of registrant as specified in its charter)

Delaware	No. 41-1698056
(State or other jurisdiction of incorporation or organization)	(IRS Employer Identification No.)

1225 Old Highway 8 Northwest
St. Paul, Minnesota 55112-6416
(Address of principal executive offices, including zip code)
Registrant's telephone number, including area code: (651) 259-1600

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. (Check one):

Large accelerated filer	x	Accelerated filer	¨
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

The number of shares outstanding of the registrant's common stock as of January 29, 2016 was: Common Stock, $0.001 par value per share, 32,697,125 shares.

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PART I. — FINANCIAL INFORMATION

ITEM 1. CONSOLIDATED FINANCIAL STATEMENTS (UNAUDITED)

Cardiovascular Systems, Inc.
Consolidated Balance Sheets
(Dollars in thousands, except per share and share amounts)
(Unaudited)

	December 31, 2015	June 30, 2015
ASSETS		
Current assets		
Cash and cash equivalents	$65,329	$83,842
Accounts receivable, net	25,752	30,830
Inventories	18,237	13,966
Marketable securities	1,871	1,876
Prepaid expenses and other current assets	1,577	3,380
Total current assets	112,766	133,894
Property and equipment, net	33,564	32,883
Patents, net	4,759	4,511
Other assets	136	40
Total assets	$151,225	$171,328
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities		
Accounts payable	$8,313	$9,763
Accrued expenses	19,651	20,125
Total current liabilities	27,964	29,888
Long-term liabilities		
Other liabilities	1,986	2,005
Total liabilities	29,950	31,893
Commitments and contingencies	—	—
Common stock, $0.001 par value; authorized 100,000,000 common shares at December 31, 2015 and June 30, 2015; issued and outstanding 32,734,918 at December 31, 2015 and 31,898,124 at June 30, 2015, respectively	33	32
Additional paid in capital	421,005	410,700
Accumulated other comprehensive income	48	90
Accumulated deficit	(299,811)	(271,387)
Total stockholders' equity	121,275	139,435
Total liabilities and stockholders' equity	$151,225	$171,328

The accompanying notes are an integral part of these unaudited consolidated financial statements.

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Cardiovascular Systems, Inc.
Consolidated Statements of Operations
(Dollars in thousands, except per share and share amounts)
(Unaudited)

	Three Months Ended December 31,		Six Months Ended December 31,	
	2015	2014	2015	2014
Net revenues	$41,392	$44,732	$85,263	$86,086
Cost of goods sold	8,071	9,346	16,842	18,231
Gross profit	33,321	35,386	68,421	67,855
Expenses:				
Selling, general and administrative	41,258	32,553	82,653	66,060
Research and development	7,206	8,085	14,147	15,237
Total expenses	48,464	40,638	96,800	81,297
Loss from operations	(15,143)	(5,252)	(28,379)	(13,442)
Interest and other, net	(20)	(21)	(45)	(55)
Net loss	$(15,163)	$(5,273)	$(28,424)	$(13,497)
Net loss per common share:				
Basic and diluted	$(0.47)	$(0.17)	$(0.88)	$(0.43)
Weighted average common shares used in computation:				
Basic and diluted	32,553,991	31,487,358	32,382,433	31,399,234

The accompanying notes are an integral part of these unaudited consolidated financial statements.

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Cardiovascular Systems, Inc.
Consolidated Statements of Comprehensive Loss
(Dollars in thousands)
(Unaudited)

	Three Months Ended December 31,		Six Months Ended December 31,	
	2015	2014	2015	2014
Net loss	$(15,163)	$(5,273)	$(28,424)	$(13,497)
Other comprehensive income (loss):				
Unrealized gain (loss) on available for sale securities	57	67	(42)	81
Comprehensive loss	$(15,106)	$(5,206)	$(28,466)	$(13,416)

The accompanying notes are an integral part of these unaudited consolidated financial statements.

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Cardiovascular Systems, Inc.
Consolidated Statements of Cash Flows
(Dollars in thousands)
(Unaudited)

	Six Months Ended December 31,	
	2015	2014
Cash flows from operating activities		
Net loss	$(28,424)	$(13,497)
Adjustments to reconcile net loss to net cash used in operations		
Depreciation of property and equipment	1,810	751
Amortization and write-off of patents	144	82
Provision for doubtful accounts	525	846
Stock-based compensation	7,219	7,083
Changes in assets and liabilities		
Accounts receivable	4,903	(5,527)
Inventories	(4,271)	(1,067)
Prepaid expenses and other assets	2,117	287
Accounts payable	(1,086)	(796)
Accrued expenses and other liabilities	(492)	721
Net cash used in operating activities	(17,555)	(11,117)
Cash flows from investing activities		
Expenditures for property and equipment	(2,792)	(11,258)
Issuance of convertible note receivable	(350)	—
Purchases of marketable securities	(37)	(2,084)
Costs incurred in connection with patents	(455)	(543)
Net cash used in investing activities	(3,634)	(13,885)
Cash flows from financing activities		
Proceeds from employee stock purchase plan	1,670	1,360
Exercise of stock options	1,006	794
Payments on debt	—	(2,400)
Net cash provided by (used in) financing activities	2,676	(246)
Net change in cash and cash equivalents	(18,513)	(25,248)
Cash and cash equivalents		
Beginning of period	83,842	126,592
End of period	$65,329	$101,344
Noncash investing activities		
Property and equipment included in accounts payable	$—	$5,136

The accompanying notes are an integral part of these unaudited consolidated financial statements.

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CARDIOVASCULAR SYSTEMS, INC.
NOTES TO CONSOLIDATED FINANCIAL STATEMENTS
(For the Six Months Ended December 31, 2015 and 2014)
(Dollars in thousands, except per share and share amounts)
(Unaudited)

1. Business Overview

Company Description

Cardiovascular Systems, Inc. (the "Company") was incorporated as Replidyne, Inc. ("Replidyne") in Delaware in 2000. On February 25, 2009, Replidyne completed its business combination with Cardiovascular Systems, Inc., a Minnesota corporation, in accordance with the terms of the Agreement and Plan of Merger and Reorganization, dated as of November 3, 2008. At the effective time of the merger, Replidyne changed its name to Cardiovascular Systems, Inc.

The Company develops, manufactures and markets devices for the treatment of vascular diseases. The Company's peripheral arterial disease products, the Stealth 360°® Peripheral Orbital Atherectomy System ("OAS"), the Diamondback 360® Peripheral OAS, the Diamondback 360® 60cm Peripheral OAS access device and the Diamondback 360 4 French 1.25 Peripheral OAS access device, are catheter-based platforms capable of treating a broad range of plaque types, including calcified plaque, in leg arteries both above and below the knee and address many of the limitations associated with existing surgical, catheter and pharmacological treatment alternatives. These devices use smaller access sheaths that can provide procedural benefits and allow physicians to treat PAD patients in the small and tortuous vessels located below the knee through alternative access sites in the ankle and foot as well as in the groin.

In October 2013, the Company received premarket approval from the U.S. Food and Drug Administration to market the Diamondback 360® Coronary OAS as a treatment for severely calcified coronary arteries.

The Company is evaluating options for international expansion to maximize the coronary and peripheral market opportunities.

2. Summary of Significant Accounting Policies

Interim Financial Statements

The Company prepared the unaudited interim consolidated financial statements and related unaudited financial information in the footnotes in accordance with accounting principles generally accepted in the United States of America ("GAAP") and the rules and regulations of the Securities and Exchange Commission ("SEC") for interim financial statements. The year-end consolidated balance sheet was derived from the Company's audited consolidated financial statements, but does not include all disclosures as required by GAAP. These interim consolidated financial statements reflect all adjustments consisting of normal recurring accruals, which, in the opinion of management, are necessary to state fairly the Company's consolidated financial position, the results of its operations and its cash flows for the interim periods. These interim consolidated financial statements should be read in conjunction with the consolidated annual financial statements and the notes thereto included in the Form 10-K filed by the Company with the SEC on August 27, 2015. The nature of the Company's business is such that the results of any interim period may not be indicative of the results to be expected for the entire year.

Use of Estimates

The preparation of the Company's consolidated financial statements in conformity with GAAP requires management to make estimates and assumptions that affect the reported amounts of assets and liabilities and disclosure of contingent assets and liabilities at the date of the financial statements and the reported amounts of revenues and expenses during the reporting period. Actual results could differ from those estimates.

Prior Year Revision

During the fourth quarter of fiscal 2015, the Company evaluated the presentation of its accounts payable and accrued expenses line items on the consolidated balance sheet and determined that a reclassification of amounts from accounts payable to accrued expenses would provide a more meaningful presentation. There were no changes to total current liabilities and net cash used in operations as a result of these reclassifications. The Company reclassified $4,259 from accounts payable to accrued expenses as of December 31, 2014. In addition, the Company reclassified the changes in accounts payable and accrued expenses in the

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operating activities section of the consolidated statement of cash flows by $1,263 for the six months ended December 31, 2014. The Company has concluded that these reclassifications are not material.

Stock-Based Compensation

The Company has stock-based compensation plans, which include stock options, nonvested share awards, and an employee stock purchase plan. Fair value of option awards is determined using option-pricing models, fair value of nonvested share awards with market conditions is determined using the Monte Carlo simulation, and fair value of nonvested share awards that vest based upon performance or service conditions is determined by the closing market price of the Company's stock on the date of grant. Stock-based compensation expense is recognized ratably over the requisite service period for the awards expected to vest.

Revenue Recognition

The Company sells the majority of its products via direct shipment to hospitals or clinics. The Company recognizes revenue when all of the following criteria are met: persuasive evidence of an arrangement exists; delivery has occurred; the sales price is fixed or determinable; and collectability is reasonably assured. The Company records estimated sales returns, discounts and rebates as a reduction of net sales.

Costs related to products delivered are recognized in the period revenue is recognized. Cost of goods sold consists primarily of raw materials, direct labor, and manufacturing overhead.

Recent Accounting Pronouncements

In May 2014, the Financial Accounting Standards Board (“FASB”) issued Accounting Standards Update (“ASU”) 2014-09, “Revenue From Customers With Contracts.” The guidance requires an entity to recognize revenue to depict the transfer of goods or services to customers in an amount that reflects the consideration to which an entity expects to be entitled in exchange for those goods or services. The guidance also requires expanded disclosures relating to the nature, amount, timing, and uncertainty of revenue and cash flows arising from contracts with customers. Additionally, qualitative and quantitative disclosures are required about customer contracts, significant judgments and changes in judgments, and assets recognized from the costs to obtain or fulfill a contract. ASU 2014-09 was initially to be effective for annual periods beginning after December 15, 2016, including interim periods within that reporting period, using one of two prescribed retrospective methods. Early adoption was not to be permitted. In August 2015, the FASB issued ASU 2015-14 to defer the effective date of ASU 2014-09 by one year and allow early adoption for all entities but not before the original public entity effective date. The Company is evaluating the impact of the amended revenue recognition guidance on its financial statements.

In August 2014, the FASB issued ASU No. 2014-15, “Disclosure of Uncertainties about an Entity's Ability to Continue as a Going Concern.” The guidance requires management to perform interim and annual assessments of an entity's ability to continue as a going concern within one year of the date of issuance of the entity's financial statements. The entity must also provide certain disclosures if there is substantial doubt about the entity's ability to continue as a going concern. ASU 2014-15 is effective for annual periods ending after December 15, 2016, and interim periods thereafter. Early adoption is permitted. The Company does not anticipate a material impact on its financial statements upon adoption.

In April 2015, the FASB issued ASU No. 2015-05, “Customer's Accounting for Fees Paid in a Cloud Computing Arrangement.” The ASU provides guidance to customers about whether a cloud computing arrangement includes a software license. ASU 2015-05 is effective for annual periods, including interim periods within those annual periods, beginning after December 15, 2015. Early adoption is permitted and companies can elect to adopt the guidance

prospectively to all arrangements entered into or materially modified after the effective date, or retrospectively. The Company does not anticipate a material impact on its financial statements upon adoption.

In July 2015, the FASB issued ASU No. 2015-11, “Simplifying the Measurement of Inventory.” The guidance requires an entity to measure inventory within the scope of the ASU at the lower of cost and net realizable value. ASU 2015-11 is effective for annual periods, including interim periods within those annual periods, beginning after December 15, 2016 and should be applied prospectively. Early adoption is permitted. The Company does not anticipate a material impact on its financial statements upon adoption.

In November 2015, the FASB issued ASU 2015-17, “Balance Sheet Classification of Deferred Taxes.” The guidance requires that all deferred tax assets and liabilities, along with any related valuation allowance, be classified as noncurrent on the balance sheet. ASU 2015-17 is effective for annual periods, including interim periods within those annual periods, beginning after

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December 15, 2016 and can be applied either prospectively or retrospectively. Early adoption is permitted. The Company does not anticipate a material impact on its financial statements upon adoption.

3. Selected Consolidated Financial Statement Information

Accounts Receivable, Net

Accounts receivable consists of the following:

	December 31, 2015	June 30, 2015
Accounts receivable	$27,326	$32,267
Less: Allowance for doubtful accounts	(1,574)	(1,437)
Total Accounts receivable	$25,752	$30,830

Inventories, Net

Inventories consist of the following:

	December 31, 2015	June 30, 2015
Raw materials	$8,119	$7,292
Work in process	453	1,108
Finished goods	9,665	5,566
Total Inventories	$18,237	$13,966

Property and Equipment, Net

Property and equipment consists of the following:

	December 31, 2015	June 30, 2015
Land	$500	$500
Building	22,576	22,468
Equipment	12,827	11,745
Furniture	2,715	2,581
Leasehold improvements	116	110
Construction in progress	2,379	1,218
	41,113	38,622
Less: Accumulated depreciation	(7,549)	(5,739)
Total Property and equipment, net	$33,564	$32,883

Accrued Expenses

Accrued expenses consist of the following:

	December 31, 2015	June 30, 2015
Salaries and bonus	$3,606	$3,961
Commissions	5,775	5,387
Vacation	3,775	3,770
Excise, sales and other taxes	3,534	3,217
Clinical studies	2,162	2,446

Other	799	1,344
Total Accrued expenses	$ 19,651	$ 20,125

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4. Deferred Compensation Plan

The Company offers certain members of management and highly compensated employees the opportunity to defer up to 100% of their base salary (after 401(k), payroll tax and other deductions), performance bonus and discretionary bonus and elect to receive the deferred compensation at a fixed future date of participant’s choosing. Each participant may, at the time of his or her deferral election, choose to allocate the deferred compensation into investment alternatives set by the Human Resources and Compensation Committee. The amount payable to each participant under the plan will change in value based upon the investment selected by that participant and is classified as current or long-term on the Company's balance sheet based on the disbursement elections made by the participants. As of December 31, 2015, the amount payable is all classified as long-term and is included in other liabilities on the consolidated balance sheet.

Beginning in August 2014, the Company acquired available-for-sale marketable securities under the deferred compensation plan. These available-for-sale marketable securities are primarily comprised of investments with a fixed income and equity investments.

Investments consisted of the following:

	As of December 31, 2015			
	Amortized Cost	Unrealized Gains	Unrealized Losses	Fair Value
Mutual funds	$1,823	$48	$—	$1,871
Total short-term investments	$1,823	$48	$—	$1,871
	As of June 30, 2015			
	Amortized Cost	Unrealized Gains	Unrealized Losses	Fair Value
Mutual funds	$1,786	$90	$—	$1,876
Total short-term investments	$1,786	$90	$—	$1,876

During the six months ended December 31, 2015 and 2014, there were $37 and $2,084, respectively, in purchases of available-for-sale securities. There were no sales or other-than-temporary impairments during the six months ended December 31, 2015 and 2014.

The following table provides information by level for the Company's available-for-sale marketable securities that were measured at fair value on a recurring basis:

		Fair Value Measurements as of December 31, 2015 Using Inputs Considered as		
	Fair Value	Level 1	Level 2	Level 3
Mutual funds	$1,871	$1,261	$610	$—
Total short-term investments	$1,871	$1,261	$610	$—
		Fair Value Measurements as of June 30, 2015 Using Inputs Considered as		
	Fair Value	Level 1	Level 2	Level 3
Mutual funds	$1,876	$1,275	$601	$—
Total short-term investments	$1,876	$1,275	$601	$—

The Company's marketable securities classified within Level 1 are valued primarily using real-time quotes for transactions in active exchange markets. Marketable securities within Level 2 are valued using readily available pricing sources. There were no transfers of assets between Level 1 and Level 2 of the fair value measurement hierarchy during the six months ended December 31, 2015. Any transfers between levels would be recognized on the

date of the event or when a change in circumstances causes a transfer.

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5. Stock Options and Restricted Stock Awards

The Company maintains the 2014 Equity Incentive Plan (the “2014 Plan”) for the purpose of granting equity awards to employees, directors and consultants. The 2014 Plan was approved by the Company's stockholders and became effective in November 2014. The 2014 Plan was amended in May 2015. The 2014 Plan replaced the 2007 Equity Incentive Plan (the “2007 Plan”), and no further equity awards may be granted under the 2007 Plan. The Company also maintains a terminated plan, the 2003 Stock Option Plan (the “2003 Plan”) (the 2014 Plan, the 2007 Plan, and the 2003 Plan are collectively referred to as the “Plans”).

Stock Options

All options granted under the Plans become exercisable over periods established at the date of grant. The option exercise price is generally not less than the estimated fair market value of the Company’s common stock at the date of grant, as determined by the Company’s management and Board of Directors. In addition, the Company has granted nonqualified stock options to a director outside of the Plans. An employee's vested options must be exercised at or within 90 days of termination to avoid forfeiture. As of December 31, 2015, all outstanding options were fully vested.

Stock option activity for the six months ended December 31, 2015 is as follows:

	Number of Options[(a)]	Weighted Average Exercise Price
Options outstanding at June 30, 2015	699,872	$10.32
Options exercised	(87,817)	$11.46
Options forfeited or expired	(5,176)	$12.37
Options outstanding at December 31, 2015	606,879	$10.14

(a) Includes the effect of options granted, exercised, forfeited or expired from the 2003 Plan and 2007 Plan, and options granted outside such plans.

Restricted Stock

The fair value of each restricted stock award is equal to the fair market value of the Company’s common stock at the date of grant. Vesting of restricted stock awards generally ranges from one to three years. The estimated fair value of restricted stock awards, including the effect of estimated forfeitures, is recognized on a straight-line basis over the restricted stock’s vesting period.

On August 10, 2015, the Company granted performance based restricted stock awards to its executives and management. The performance based awards included grants of a maximum aggregate of 156,509 shares that vest based upon achievement of certain thresholds measuring total shareholder return during periods within fiscal 2016 compared to a pre-determined peer group of companies, and grants of a maximum aggregate of 156,520 shares that vest based upon achievement of certain thresholds measuring annual revenue growth during fiscal 2016 compared to a pre-determined peer group of companies. Management adjusts expense as required based on expected revenue growth performance for those awards.

Restricted stock award activity for the six months ended December 31, 2015 is as follows:

	Number of Shares	Weighted Average Fair Value
Restricted stock awards outstanding at June 30, 2015	995,323	$21.31

Restricted stock awards granted [1]	768,243	$21.82
Restricted stock awards forfeited	(154,754)	$27.30
Restricted stock awards vested	(435,244)	$22.63
Restricted stock awards outstanding at December 31, 2015	1,173,568	$24.15

(1) Includes both time-based and performance-based restricted stock awards.

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6. Commitment and Contingencies

Operating Leases

The Company leases manufacturing and office space and equipment under various lease agreements that expire at various dates through March 2020. Rental expenses were $299 and $412 for the three months ended December 31, 2015 and 2014, respectively, and $641 and $797 for the six months ended December 31, 2015 and 2014, respectively.

Future minimum lease payments under the agreements as of December 31, 2015 are as follows:

Six months ended June 30, 2016	$288
Fiscal 2017	555
Fiscal 2018	523
Fiscal 2019	471
Fiscal 2020	353
	$2,190

Department of Justice Investigation

On May 8, 2014, the Company received a letter from the U.S. Attorney's Office for the Western District of North Carolina (the "Department of Justice") stating that it is investigating the Company to determine whether it had violated the False Claims Act ("FCA"), and on July 8, 2015, the complaint underlying the Department of Justice's investigation was unsealed. On November 2, 2015, the Company agreed to waive service of the complaint. The Company's response to the complaint is due on March 25, 2016. The government has the option to intervene in an FCA case and take over the prosecution if it concludes that the claims have merit. As of the date hereof, the Department of Justice has not chosen to intervene in this case. The Company continues to cooperate with the Department of Justice in its investigation and is discussing the allegations in the case and possible resolution with the government. The Company cannot predict when the Department of Justice's investigation or this litigation will be resolved, the outcome of the investigation or this litigation, or the potential impact of either on the Company.

Other Matters

In the ordinary conduct of business, the Company is subject to various lawsuits and claims covering a wide range of matters including, but not limited to, employment claims and commercial disputes. While the outcome of these matters is uncertain, the Company does not believe there are any significant matters as of December 31, 2015 that are probable or estimable, for which the outcome could have a material adverse impact on its consolidated balance sheets or statements of operations.

7. Earnings Per Share

The following table presents a reconciliation of the numerators and denominators used in the basic and diluted earnings per common share computations (in thousands except share and per share amounts):

	Three Months Ended December 31,		Six Months Ended December 31,	
	2015	2014	2015	2014
Numerator				
Net loss	$(15,163)	$(5,273)	$(28,424)	$(13,497)
Denominator				
Weighted average common shares – basic	32,553,991	31,487,358	32,382,433	31,399,234
Effect of dilutive stock options[a][b]	—	—	—	—

Weighted average common shares outstanding – diluted	32,553,991	31,487,358	32,382,433	31,399,234
Net loss per common share — basic and diluted	$(0.47)	$(0.17)	$(0.88)	$(0.43)

(a) At December 31, 2015 and 2014, 606,879 and 835,234 stock options, respectively, were outstanding. The effect of the shares that would be issued upon exercise of these options has been excluded from the calculation of diluted loss per share because those shares are anti-dilutive.

(b) At December 31, 2015 and 2014, 305,031 and 336,176 additional shares of common stock, respectively, were issuable upon the settlement of outstanding restricted stock units. The effect of the shares that would be issued upon settlement of these restricted stock units has been excluded from the calculation of diluted loss per share because those shares are anti-dilutive.

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ITEM 2. MANAGEMENT'S DISCUSSION AND ANALYSIS OF FINANCIAL CONDITION AND RESULTS OF OPERATIONS

You should read the following discussion and analysis of our financial condition and results of operations together with our financial statements and the related notes appearing under Item 1 of Part I of this Quarterly Report on Form 10-Q. Some of the information contained in this discussion and analysis or set forth elsewhere in this quarterly report, including information with respect to our plans and strategy for our business and expected financial results, includes forward-looking statements that involve risks and uncertainties. You should review the "Risk Factors" discussed in our Form 10-K for the year ended June 30, 2015 and subsequent reports on Form 10-Q for a discussion of important factors that could cause actual results to differ materially from the results described in or implied by the forward-looking statements contained in the following discussion and analysis.

OVERVIEW

We are a medical device company focused on developing and commercializing innovative solutions for vascular and coronary disease. Our peripheral arterial disease ("PAD") products, the Stealth 360® Peripheral Orbital Atherectomy System ("OAS")(the "Stealth 360"), the Diamondback 360® Peripheral OAS (the "Diamondback 360 Peripheral"), the Diamondback 360® 60cm Peripheral OAS access device, and the Diamondback 360 4 French 1.25 Peripheral OAS access device, are catheter-based platforms capable of treating a broad range of plaque types in leg arteries both above and below the knee and address many of the limitations associated with existing surgical, catheter and pharmacological treatment alternatives. These devices use smaller access sheaths that can provide procedural benefits and allow physicians to treat PAD patients in the small and tortuous vessels located below the knee through alternative access sites in the ankle and foot as well as in the groin. We refer to the Stealth 360, Diamondback 360 Peripheral, Diamondback 360 60cm Peripheral OAS, Diamondback 360 4 French 1.25 Peripheral OAS, and Predator 360 collectively in this report as the "PAD Systems."

Our coronary arterial disease ("CAD") product, Diamondback 360® Coronary OAS ("CAD System"), is marketed as a treatment for severely calcified coronary arteries. The CAD System is a catheter-based platform designed to facilitate stent delivery in patients with CAD who are acceptable candidates for percutaneous transluminal coronary angioplasty or stenting due to de novo, severely calcified coronary artery lesions. The CAD System design is similar to technology used in our PAD Systems, customized specifically for the coronary application.

From 1989 to 1997, we engaged in research and development on several different product concepts. Since 1997, we have devoted substantially all of our resources to the development and commercialization of the PAD Systems and, since 2007, to the development, approval and commercialization of our CAD System.

From 2003 to 2005, we conducted numerous bench and animal tests in preparation for application submissions to the U.S. Food and Drug Administration ("FDA"). In 2006, we obtained an investigational device exemption from the FDA to conduct our pivotal OASIS PAD clinical trial, which was completed in January 2007. The OASIS clinical trial was a prospective 20-center study that involved 124 patients with 201 lesions.

In August 2007, the FDA granted us 510(k) clearance for the use of the Diamondback 360 Peripheral as a therapy in patients with PAD. We commenced commercial introduction of the Diamondback 360 Peripheral in the United States in September 2007. We were granted 510(k) clearance of the Predator 360 in March 2009, which we no longer market, and the Stealth 360 in March 2011. We received 510(k) clearance of the Diamondback 360 60cm Peripheral OAS in March 2014, and in April 2015, we received 510(k) clearance of the Diamondback 360 4 French 1.25 Peripheral OAS. We market the PAD Systems in the United States through a direct sales force and expend significant capital on our sales and marketing efforts to expand our customer base and utilization per customer. We assemble at our facilities the saline infusion pump and the single-use catheter used in the PAD Systems with components

purchased from third-party suppliers, as well as with components manufactured in-house. We purchase supplemental products from third-party suppliers.

We have developed modified versions of the PAD System to treat coronary arteries. A coronary application required us to conduct a clinical trial and file a premarket approval ("PMA") application, and obtain approval from the FDA. In March 2013, we completed submission of our PMA application to the FDA for our orbital atherectomy system to treat calcified coronary arteries. In October 2013, we received PMA from the FDA to market the CAD System as a treatment for severely calcified coronary arteries. We commenced the commercial launch of our CAD System following receipt of PMA.

We are currently pursuing coronary approval for Japan and are evaluating options for additional international expansion to maximize the coronary and peripheral market opportunities.

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As of December 31, 2015, we had an accumulated deficit of $299.8 million. We generally expect our losses to decline as revenues grow. To date, we have financed our operations primarily from the issuance of common and preferred stock, convertible promissory notes, and debt.

CRITICAL ACCOUNTING POLICIES AND SIGNIFICANT JUDGMENTS AND ESTIMATES

Our management's discussion and analysis of our financial condition and results of operations are based on our consolidated financial statements, which have been prepared in accordance with accounting principles generally accepted in the United States. The preparation of our consolidated financial statements requires us to make estimates, assumptions and judgments that affect amounts reported in those statements. Our estimates, assumptions and judgments, including those related to revenue recognition, allowance for doubtful accounts, excess and obsolete inventory, and stock-based compensation, are updated as appropriate at least quarterly. We use authoritative pronouncements, our technical accounting knowledge, cumulative business experience, judgment and other factors in the selection and application of our accounting policies. While we believe that the estimates, assumptions and judgments that we use in preparing our consolidated financial statements are appropriate, these estimates, assumptions and judgments are subject to factors and uncertainties regarding their outcome. Therefore, actual results may materially differ from these estimates.

Some of our significant accounting policies require us to make subjective or complex judgments or estimates. An accounting estimate is considered to be critical if it meets both of the following criteria: (1) the estimate requires assumptions about matters that are highly uncertain at the time the accounting estimate is made, and (2) different estimates that reasonably could have been used, or changes in the estimate that are reasonably likely to occur from period to period, would have a material impact on the presentation of our financial condition, results of operations, or cash flows.

Our critical accounting policies are identified in our Annual Report on Form 10-K for the fiscal year ended June 30, 2015 in Management's Discussion and Analysis of Financial Condition and Results of Operations under the heading "Critical Accounting Policies and Significant Judgments and Estimates." There were no significant changes to our critical accounting policies during the six months ended December 31, 2015.

RESULTS OF OPERATIONS

The following table sets forth our results of operations expressed as dollar amounts (in thousands) and the changes between the specified periods expressed as percent increases or decreases:

	Three Months Ended December 31,			Six Months Ended December 31,		
	2015	2014	Percent Change	2015	2014	Percent Change
Net revenues	$41,392	$44,732	(7.5)%	$85,263	$86,086	(1.0)%
Cost of goods sold	8,071	9,346	(13.6)	16,842	18,231	(7.6)
Gross profit	33,321	35,386	(5.8)	68,421	67,855	0.8
Expenses:						
Selling, general and administrative	41,258	32,553	26.7	82,653	66,060	25.1
Research and development	7,206	8,085	(10.9)	14,147	15,237	(7.2)
Total expenses	48,464	40,638	19.3	96,800	81,297	19.1
Loss from operations	(15,143)	(5,252)	188.3	(28,379)	(13,442)	111.1
Interest and other, net	(20)	(21)	(4.8)	(45)	(55)	(18.2)
Net loss	$(15,163)	$(5,273)	187.6	$(28,424)	$(13,497)	110.6

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Comparison of Three Months Ended December 31, 2015 with Three Months Ended December 31, 2014

Net revenues. Net revenues decreased by $3.3 million, or 7.5%, from $44.7 million for the three months ended December 31, 2014 to $41.4 million for the three months ended December 31, 2015. This decrease was primarily attributable to lower sales of our PAD Systems, which decreased approximately $3.7 million, due to 8.5% fewer devices sold in the three months ended December 31, 2015 than during the three months ended December 31, 2014, primarily resulting from challenges associated with the expansion of our sales force and the transition to a dual-franchise sales organization. In addition, revenues decreased $1.8 million due to the expiration in June 2015 of our exclusive distribution agreement with Asahi to market its peripheral guidewire line in the United States. Partially offsetting the decreases in PAD Systems were sales of our CAD Systems, which increased $1.8 million, or 30.6%, reflecting a 31.9% increase in the number of devices sold. Other CAD product revenue increased by $278,000, or 64.3%, primarily driven by increased sales of our CAD Systems, which the other CAD products support.

Currently, all of our revenues are in the United States; however, we intend to sell internationally in the future and have commenced the process of seeking approval to do so in both Europe and Japan. In November 2014, we received CE Mark for the Stealth 360 and are currently evaluating the timing and structure of our plans to commercialize products in Europe. We expect our revenue in the third quarter of fiscal 2016 to be similar to the three months ended December 31, 2015, due primarily to challenges associated with the expansion and transition of our sales force. Implementation of our dual-franchise sales strategy, including the development and maturation of our sales representatives, is progressing, and we expect this progress to begin favorably impacting revenue after third quarter of this fiscal year.

Cost of Goods Sold. Cost of goods sold decreased $1.2 million, or 13.6%, from $9.3 million for the three months ended December 31, 2014 to $8.1 million for the three months ended December 31, 2015. Cost of goods sold represents the cost of materials, labor and overhead for single-use catheters, guidewires, saline pumps, and other ancillary products. Cost of goods sold for the three months ended December 31, 2015 and 2014 includes $189,000 and $241,000, respectively, for stock-based compensation. The decrease in cost of goods sold is primarily due to decreased sales levels, as well as lower costs per unit from higher production volumes and manufacturing efficiencies. Gross margin increased to 80.5% for the three months ended December 31, 2015 from 79.1% for the three months ended December 31, 2014 due to lower costs per unit discussed above. We expect that gross margin in the third quarter of fiscal 2016 will be comparable to gross margin in the three months ended December 31, 2015. Quarterly margin fluctuations could occur based on production volumes, timing of new product introductions, sales mix, pricing changes, or other unanticipated circumstances.

Selling, General and Administrative Expenses. Our selling, general and administrative expenses increased by $8.7 million, or 26.7%, from $32.6 million for the three months ended December 31, 2014 to $41.3 million for the three months ended December 31, 2015. The increase was due primarily to the expansion of our sales and administrative organizations, as well as increased tradeshow and heathcare policy activities. Selling, general and administrative expenses for the three months ended December 31, 2015 and 2014 include $2.5 million and $2.9 million, respectively, for stock-based compensation. We expect our selling, general and administrative expenses in the third quarter of fiscal 2016 to be at or below amounts incurred for the three months ended December 31, 2015 as a result of cost reduction initiatives.

Research and Development Expenses. Research and development expenses decreased by $879,000, or 10.9%, from $8.1 million for the three months ended December 31, 2014 to $7.2 million for the three months ended December 31, 2015. Research and development expenses relate to specific projects to develop new products or expand into new markets, such as the development of new versions of the PAD and CAD Systems, shaft designs, crown designs, and PAD and CAD clinical trials. The decrease primarily related to the completion of enrollment in several of our clinical studies. Research and development expenses for the three months ended December 31, 2015 and 2014 include $449,000 and $368,000, respectively, for stock-based compensation. For the third quarter in fiscal 2016, we generally

expect to incur quarterly research and development expenses at or below amounts incurred for the three months ended December 31, 2015. Fluctuations could occur based on the number of projects and studies and the timing of expenditures.

Comparison of Six Months Ended December 31, 2015 with Six Months Ended December 31, 2014

Net revenues. Net revenues decreased by $823,000, or 1.0%, from $86.1 million for the six months ended December 31, 2014 to $85.3 million for the six months ended December 31, 2015. This decrease was attributable to the expiration in June 2015 of our exclusive distribution agreement with Asahi to market its peripheral guidewire line in the United States, which contributed $3.7 million in revenues during the six months ended December 31, 2014. In addition, sales of our PAD Systems decreased $3.0 million, or 4.6%, which primarily reflects a 4.3% decrease in the average selling price. Partially offsetting these decreases were sales of our CAD System, which increased approximately $5.2 million, due to 51.1% more devices sold in the six months ended December 31, 2015 than during the six months ended December 31, 2014 as we continue our commercial launch of our

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CAD System. Other product revenue, excluding Asahi sales, increased $658,000, or 11.1%, primarily driven by increased sales of our CAD Systems, which the other products support.

Cost of Goods Sold. Cost of goods sold decreased by $1.4 million, or 7.6%, from $18.2 million for the six months ended December 31, 2014 to $16.8 million for the six months ended December 31, 2015. Cost of goods sold represents the cost of materials, labor and overhead for single-use catheters, guidewires, saline pumps, and other ancillary products. Cost of goods sold for the six months ended December 31, 2015 and 2014 includes $404,000 and $463,000, respectively, for stock-based compensation. Gross margin increased to 80.2% for the six months ended December 31, 2015 from 78.8% for the six months ended December 31, 2014. The decrease in cost of goods sold and the increase in gross margin was primarily due to lower costs per unit from higher production volumes and manufacturing efficiencies, partially offset by lower average selling prices.

Selling, General and Administrative Expenses. Our selling, general and administrative expenses increased by $16.6 million, or 25.1%, from $66.1 million for the six months ended December 31, 2014 to $82.7 million for the six months ended December 31, 2015. The increase was due primarily to the expansion of our sales and administrative organizations, increased healthcare policy activities, and higher expenses related to our new corporate headquarters. Selling, general and administrative expenses for the six months ended December 31, 2015 and 2014 include $6.0 million and $5.9 million, respectively, for stock-based compensation.

Research and Development Expenses. Research and development expenses decreased by $1.1 million, or 7.2%, from $15.2 million for the six months ended December 31, 2014 to $14.1 million for the six months ended December 31, 2015. Research and development expenses relate to specific projects to develop new products or expand into new markets, such as the development of new versions of the PAD and CAD Systems, shaft designs, crown designs, and PAD and CAD clinical trials. The decrease primarily related to the completion of enrollment in several of our clinical studies. Research and development expenses for the six months ended December 31, 2015 and 2014 include $822,000 and $688,000, respectively, for stock-based compensation.

LIQUIDITY AND CAPITAL RESOURCES

We had cash and cash equivalents of $65.3 million and $83.8 million at December 31, 2015 and June 30, 2015, respectively. During the six months ended December 31, 2015, net cash used in operations amounted to $17.6 million. As of December 31, 2015, we had an accumulated deficit of $299.8 million. We have historically funded our operating losses primarily from the issuance of common and preferred stock, convertible promissory notes, and debt.

Changes in Liquidity

Cash and Cash Equivalents. Cash and cash equivalents were $65.3 million at December 31, 2015 and $83.8 million at June 30, 2015. The decrease is primarily attributable to net cash used in operations and investing activities during the six months ended December 31, 2015.

Operating Activities. Net cash used in operations was $17.6 million and $11.1 million for the six months ended December 31, 2015 and 2014, respectively. For the six months ended December 31, 2015 and 2014, we had a net loss of $28.4 million and $13.5 million, respectively. Significant changes in working capital during these periods included:

- Cash provided by (used in) accounts receivable of $4.9 million and $(5.5) million during the six months ended December 31, 2015 and 2014, respectively, was primarily due to the amount and timing of revenue during the six months ended December 31, 2015 and 2014.
- Cash used in inventories was $4.3 million and $1.1 million during the six months ended December 31, 2015 and 2014, respectively. For the six months ended December 31, 2015, the amount of cash used in inventories was

primarily due to higher levels of finished goods for future sales. For the six months ended December 31, 2014, the amount of cash used in inventories primarily related to higher levels of raw materials for the manufacture of products, including the CAD System commercial launch and finished goods for future sales.

- Cash provided by prepaid expenses and other current assets was $2.1 million and $287,000 during the six months ended December 31, 2015 and 2014, respectively, primarily due to payment timing of vendor deposits and other expenditures.
- Cash used in accounts payable was $1.1 million and $0.8 million during the six months ended December 31, 2015 and 2014, respectively, due to the amount and timing of purchases and vendor payments.

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- Cash (used in) provided by accrued expenses and other liabilities of $(492,000) and $721,000 during the six months ended December 31, 2015 and 2014, respectively, was primarily due to the amount and timing of compensation payments and clinical study expense accruals.

Investing Activities. Net cash used in investing activities was $3.6 million and $13.9 million for the six months ended December 31, 2015 and 2014, respectively. During the six months ended December 31, 2015, cash was used primarily for the purchase of property and equipment and patents, and for the issuance of a convertible note receivable. Cash used during the six months ended December 31, 2014 related to the purchase of property and equipment and patents, construction of our new headquarters, and purchases of available-for-sale marketable securities for the deferred compensation plans. During the six months ended December 31, 2014, we paid $8.9 million towards the construction of our new corporate headquarters.

Financing Activities. Net cash provided by (used in) financing activities was $2.7 million and $(246,000) for the six months ended December 31, 2015 and 2014, respectively. For the six months ended December 31, 2015, cash provided by financing activities was due to proceeds from employee stock purchases of $1.7 million and proceeds from the exercise of stock options of $1.0 million. For the six months ended December 31, 2014, cash used in financing activities was due to payments on debt of $2.4 million, partially offset by proceeds from employee stock purchases of $1.4 million and proceeds from the exercise of stock options of $794,000.

Our future liquidity and capital requirements will be influenced by numerous factors, including the extent and duration of future operating losses, the level and timing of future sales and expenditures, the results and scope of ongoing research and product development programs, working capital required to support our sales growth, the receipt of and time required to obtain regulatory clearances and approvals, our sales and marketing programs, the continuing acceptance of our products in the marketplace, competing technologies, market and regulatory developments, ongoing facility requirements, potential strategic transactions (including the potential acquisition of businesses, technologies and products), and the existence, defense and resolution of legal proceedings, including the Department of Justice investigation and related litigation. As of December 31, 2015, we believe our current cash and cash equivalents will be sufficient to fund working capital requirements, capital expenditures and operations for the foreseeable future, including at least the next twelve months. We also believe we have debt capacity and the potential ability to finance our new Minnesota facility, which could further supplement funds if warranted. We intend to retain any future earnings to support operations and to finance the growth and development of our business and we do not anticipate paying any dividends in the foreseeable future.

NON-GAAP FINANCIAL INFORMATION

To supplement our consolidated financial statements prepared in accordance with GAAP, our management uses a non-GAAP financial measure referred to as “Adjusted EBITDA.” The following table sets forth, for the periods indicated, a reconciliation of Adjusted EBITDA to the most comparable U.S. GAAP measure expressed as dollar amounts (in thousands):

	Six Months Ended December 31,	
	2015	2014
Loss from operations	$(28,379)	$(13,442)
Add: Stock-based compensation	7,219	7,083
Add: Depreciation and amortization	1,921	833
Adjusted EBITDA	$(19,239)	$(5,526)

Adjusted EBITDA declined as compared to the prior year period due to the higher loss from operations, partially offset by increased depreciation and stock-based compensation expense. The increase in depreciation expense was the

result of the completion of our new headquarters in March 2015.

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Use and Economic Substance of Non-GAAP Financial Measures Used and Usefulness of Such Non-GAAP Financial Measures to Investors

We use Adjusted EBITDA as a supplemental measure of performance and believe this measure facilitates operating performance comparisons from period to period and company to company by factoring out potential differences caused by depreciation and amortization expense and non-cash charges such as stock-based compensation. Our management uses Adjusted EBITDA to analyze the underlying trends in our business, assess the performance of our core operations, establish operational goals and forecasts that are used to allocate resources and evaluate our performance period over period and in relation to our competitors' operating results. Additionally, our management is partially evaluated on the basis of Adjusted EBITDA when determining achievement of their incentive compensation performance targets.

We believe that presenting Adjusted EBITDA provides investors greater transparency to the information used by our management for its financial and operational decision-making and allows investors to see our results "through the eyes" of management. We also believe that providing this information better enables our investors to understand our operating performance and evaluate the methodology used by our management to evaluate and measure such performance.

The following is an explanation of each of the items that management excluded from Adjusted EBITDA and the reasons for excluding each of these individual items:

- Stock-based compensation. We exclude stock-based compensation expense from our non-GAAP financial measure primarily because such expense, while constituting an ongoing and recurring expense, is not an expense that requires cash settlement. Our management also believes that excluding this item from our non-GAAP results is useful to investors to understand the application of stock-based compensation guidance and its impact on our operational performance, liquidity and ability to make additional investments in the Company, and it allows for greater transparency to certain line items in our financial statements.
- Depreciation and amortization expense. We exclude depreciation and amortization expense from our non-GAAP financial measure primarily because such expenses, while constituting ongoing and recurring expenses, are not expenses that require cash settlement and are not used by our management to assess the core profitability of our business operations. Our management also believes that excluding these items from our non-GAAP results is useful to investors to understand our operational performance, liquidity and ability to make additional investments in the company.

Material Limitations Associated with the Use of Non-GAAP Financial Measures and Manner in Which We Compensate for these Limitations

Non-GAAP financial measures have limitations as analytical tools and should not be considered in isolation or as a substitute for our financial results prepared in accordance with GAAP. Some of the limitations associated with our use of these non-GAAP financial measures are:

- Items such as stock-based compensation do not directly affect our cash flow position; however, such items reflect economic costs to us and are not reflected in our Adjusted EBITDA, and therefore these non-GAAP measures do not reflect the full economic effect of these items.
- Non-GAAP financial measures are not based on any comprehensive set of accounting rules or principles and therefore other companies may calculate similarly titled non-GAAP financial measures differently than we do, limiting the usefulness of those measures for comparative purposes.
- Our management exercises judgment in determining which types of charges or other items should be excluded from the non-GAAP financial measures we use.

We compensate for these limitations by relying primarily upon our GAAP results and using non-GAAP financial measures only supplementally.

INFLATION

We do not believe that inflation had a material impact on our business and operating results during the periods presented.

OFF-BALANCE SHEET ARRANGEMENTS

Since inception, we have not engaged in any off-balance sheet activities as defined in Item 303(a)(4) of Regulation S-K.

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RECENT ACCOUNTING PRONOUNCEMENTS

In May 2014, the Financial Accounting Standards Board (“FASB”) issued Accounting Standards Update (“ASU”) 2014-09, “Revenue From Customers With Contracts.” The guidance requires an entity to recognize revenue to depict the transfer of goods or services to customers in an amount that reflects the consideration to which an entity expects to be entitled in exchange for those goods or services. The guidance also requires expanded disclosures relating to the nature, amount, timing, and uncertainty of revenue and cash flows arising from contracts with customers. Additionally, qualitative and quantitative disclosures are required about customer contracts, significant judgments and changes in judgments, and assets recognized from the costs to obtain or fulfill a contract. ASU 2014-09 was originally to be effective for annual periods beginning after December 15, 2016, including interim periods within that reporting period, using one of two prescribed retrospective methods. Early adoption was not to be permitted. In August 2015, the FASB issued ASU 2015-14 to defer the effective date of ASU 2014-09 by one year and allow early adoption for all entities but not before the original public entity effective date. We are evaluating the impact of the amended revenue recognition guidance on our consolidated financial statements.

In August 2014, the FASB issued ASU No. 2014-15, “Disclosure of Uncertainties about an Entity's Ability to Continue as a Going Concern.” The guidance requires management to perform interim and annual assessments of an entity's ability to continue as a going concern within one year of the date of issuance of the entity's financial statements. The entity must also provide certain disclosures if there is substantial doubt about the entity's ability to continue as a going concern. ASU 2014-15 is effective for annual periods ending after December 15, 2016, and interim periods thereafter. Early adoption is permitted. We do not anticipate a material impact on our financial statements upon adoption.

In April 2015, the FASB issued ASU No. 2015-05, “Customer's Accounting for Fees Paid in a Cloud Computing Arrangement.” The guidance provides guidance to customers about whether a cloud computing arrangement includes a software license. ASU 2015-05 is effective for annual periods, including interim periods within those annual periods, beginning after December 15, 2015. Early adoption is permitted and companies can elect to adopt the guidance prospectively to all arrangements entered into or materially modified after the effective date, or retrospectively. We do not anticipate a material impact on our financial statements upon adoption.

In July 2015, the FASB issued ASU No. 2015-11, “Simplifying the Measurement of Inventory.” The guidance requires an entity to measure inventory within the scope of the ASU at the lower of cost and net realizable value. ASU 2015-11 is effective for annual periods, including interim periods within those annual periods, beginning after December 15, 2016 and should be applied prospectively. Early adoption is permitted. We do not anticipate a material impact on our financial statements upon adoption.

In November 2015, the FASB issued ASU 2015-17, “Balance Sheet Classification of Deferred Taxes.” The guidance requires that all deferred tax assets and liabilities, along with any related valuation allowance, be classified as noncurrent on the balance sheet. ASU 2015-17 is effective for annual periods, including interim periods within those annual periods, beginning after December 15, 2016 and can be applied either prospectively or retrospectively. Early adoption is permitted. We do not anticipate a material impact on our financial statements upon adoption.

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PRIVATE SECURITIES LITIGATION REFORM ACT

The Private Securities Litigation Reform Act of 1995 provides a “safe harbor” for forward-looking statements. Such “forward-looking” information is included in this Form 10-Q, including Item 2 of Part I, and in other materials filed or to be filed by the Company with the Securities and Exchange Commission (as well as information included in oral statements or other written statements made or to be made by the Company). Forward-looking statements include all statements based on future expectations. This Form 10-Q contains forward-looking statements that involve risks and uncertainties, including (i) our expectation that our losses will decline as our revenues grow; (ii) the expectation of selling our products internationally in the future and the timing and structure of our plans to do so; (iii) our expectation of our revenue in the third quarter of fiscal 2016; (iv) our expectation that the progress of our dual-franchise sales strategy will begin favorably impacting revenue after the third quarter of this fiscal year; (v) our expectation that gross margin in the third quarter of fiscal 2016 will be comparable to gross margin in the three months ended December 31, 2015; (vi) our expectation that selling, general and administrative expenses in the third quarter of fiscal 2016 will be at or below amounts incurred for the three months ended December 31, 2015; (vii) our expectation that we will incur research and development expenses in the third quarter of fiscal 2016 at amounts at or below the amounts incurred for the three months ended December 31, 2015; (viii) our belief that our current cash and cash equivalents will be sufficient to fund working capital requirements, capital expenditures and operations for the foreseeable future; (ix) our belief that we have debt capacity and the potential ability to finance our new Minnesota facility, which could further supplement funds if warranted; (x) our intention to retain any future earnings to support operations and to finance the growth and development of our business; (xi) our dividend expectations; (xii) the potential to raise additional capital in the future; and (xiii) the anticipated impact of adoption of recent accounting pronouncements on the Company's financial statements.
In some cases, you can identify forward-looking statements by the following words: “anticipate,” “believe,” “continue,” “could,” “estimate,” “expect,” “intend,” “may,” “ongoing,” “plan,” “potential,” “predict,” “project,” “should,” “will,” “would,” these terms or other comparable terminology, although not all forward-looking statements contain these words. Forward-looking statements are only predictions and are not guarantees of performance. These statements are based on our management’s beliefs and assumptions, which in turn are based on their interpretation of currently available information.

These statements involve known and unknown risks, uncertainties and other factors that may cause our results or our industry’s actual results, levels of activity, performance or achievements to be materially different from the information expressed or implied by these forward-looking statements. These factors include regulatory developments in the U.S. and foreign countries; FDA and similar foreign clearances and approvals; approval of our products for distribution in foreign countries; approval of products for reimbursement and the level of reimbursement; dependence on market growth; agreements with third parties to sell their products; the experience of physicians regarding the effectiveness and reliability of the PAD and CAD Systems; the reluctance of physicians, hospitals and other organizations to accept new products; the potential for unanticipated delays in enrolling medical centers and patients for clinical trials; actual clinical trial and study results; the impact of competitive products and pricing; unanticipated developments affecting our estimates regarding expenses, future revenues and capital requirements; the difficulty of successfully managing operating costs; our inability to sustain growth in our sales and marketing organization; our ability to manage employee turnover, growth and training; our ability to manage our sales force expansion and dual franchise strategy; our actual research and development efforts and needs; our ability to obtain and maintain intellectual property protection for product candidates; our actual financial resources and our ability to obtain additional financing; fluctuations in results and expenses based on new product introductions, sales mix, unanticipated warranty claims, and the timing of project expenditures; investigations or litigation threatened or initiated against us; our ability to manage costs; and general economic conditions. These and additional risks and uncertainties are described more fully in our Form 10-K filed with the SEC on August 27, 2015 and subsequent reports on Form 10-Q. Copies of filings made with the SEC are available through the SEC’s electronic data gathering analysis and retrieval system (EDGAR) at www.sec.gov.

You should read these risk factors and the other cautionary statements made in this Form 10-Q as being applicable to all related forward-looking statements wherever they appear in this Form 10-Q. We cannot assure you that the forward-looking statements in this Form 10-Q will prove to be accurate. Furthermore, if our forward-looking statements prove to be inaccurate, the inaccuracy may be material. You should read this Form 10-Q completely. Other than as required by law, we undertake no obligation to update these forward-looking statements, even though our situation may change in the future.

ITEM 3. QUANTITATIVE AND QUALITATIVE DISCLOSURES ABOUT MARKET RISK

The primary objective of our investment activity is to preserve our capital for the purpose of funding operations, while at the same time maximizing the income we receive from our investments without significantly increasing risk or decreasing availability. To achieve these objectives, our investment policy allows us to maintain a portfolio of cash equivalents and investments in a variety of marketable securities, including money market funds, U.S. government securities, and certain bank obligations. Our cash and cash equivalents as of December 31, 2015 include liquid money market accounts. Due to the short-term nature of these investments, we believe that there is no material exposure to interest rate risk.

Additionally, we have acquired certain available-for-sale marketable securities under our deferred compensation plan. See Note 4 to our Consolidated Financial Statements included in Part 1 of Item I of this Quarterly Report on Form 10-Q for additional information on these available-for-sale marketable securities and the related risks.

ITEM 4. CONTROLS AND PROCEDURES

Evaluation of Disclosure Controls and Procedures

Our Chief Executive Officer and Chief Financial Officer, referred to collectively herein as the Certifying Officers, are responsible for establishing and maintaining our disclosure controls and procedures. The Certifying Officers have reviewed and evaluated the effectiveness of the Company’s disclosure controls and procedures (as defined in Rules 13a-15(e) and 15d-15(e) promulgated under the Securities Exchange Act of 1934 (the “Exchange Act”)) as of December 31, 2015. Based on that review and evaluation, which included inquiries made to certain other employees of the Company, the Certifying Officers have concluded that, as of the end of the period covered by this Report, the Company’s disclosure controls and procedures, as designed and implemented, are effective.

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Changes in Internal Control Over Financial Reporting

There were no changes in our internal control over financial reporting (as defined in Rules 13a-15(f) and 15d-15(f) under the Exchange Act) during the three months ended December 31, 2015 that have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

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PART II. — OTHER INFORMATION

ITEM 1. LEGAL PROCEEDINGS

Refer to Part I, Item 3 (Legal Proceedings) of the Company's Form 10-K for the year ended June 30, 2015, as filed with the SEC on August 27, 2015, and Part II, Item 1 (Legal Proceedings) of the Company's Form 10-Q for the three months ended September 30, 2015, as filed with the SEC on November 6, 2015. The Company's response to the relator's complaint underlying the Department of Justice investigation referred to in such filings was due on January 4, 2016. On December 14, 2015, the United States District Court for the Western District of North Carolina, Charlotte Division, granted the Company's motion to extend the time to file a response to the complaint. The Company's response to the complaint is now due on March 25, 2016.

ITEM 1A. RISK FACTORS

In addition to the other information set forth in this report, including the important information in the section entitled "Private Securities Litigation Reform Act," you should carefully consider the "Risk Factors" discussed in our Form 10-K for the year ended June 30, 2015 filed with the SEC on August 27, 2015 for a discussion of important factors that could cause actual results to differ materially from the results described in or implied by the forward-looking statements contained in this report, and materially adversely affect our financial condition or future results. Additional risks and uncertainties not currently known to us or that we currently deem to be immaterial might materially adversely affect our actual business, financial condition and/or operating results. In addition, you should consider the following risk factor:

We currently are involved in litigation, and may face future claims, that could adversely affect our business and financial results, divert management's attention from our business, and subject us to significant liabilities.

As discussed elsewhere in this Report, on May 8, 2014, we received a letter from the U.S. Attorney's Office for the Western District of North Carolina (the "Department of Justice") stating that it is investigating the Company to determine whether we had violated the False Claims Act ("FCA"), and on July 8, 2015, the complaint underlying the Department of Justice's investigation was unsealed. Our response to the relator's complaint underlying the Department of Justice investigation referred to in such filings was due on January 4, 2016. On December 14, 2015, the United States District Court for the Western District of North Carolina, Charlotte Division, granted our motion to extend the time to file a response to the complaint. Our response to the complaint is now due on March 25, 2016. We cannot predict when the Department of Justice's investigation or this litigation will be resolved, the outcome of the investigation or this litigation, or the potential impact of either on us.

Additionally, the market price of our common stock recently has been subject to significant fluctuations, and several law firms have issued press releases announcing the commencement of investigations on behalf of our investors regarding possible violations of federal securities laws by us and our directors and officers and breaches of fiduciary duties by our directors and officers. These press releases could lead to the filing of lawsuits against us and our directors and officers.

Litigation is expensive and could divert management's attention and resources from our primary business, which could adversely affect our operating results. Any adverse determination in any such litigation or any settlements of such actual or threatened litigation could require us to make significant payments or require us to take, or refrain from taking, actions, either of which could negatively affect our operations or financial condition. Any litigation initiated against us and any adverse determinations in such litigation could have a material impact on how investors view our company and result in a decline in our stock price.

ITEM 2. UNREGISTERED SALES OF EQUITY SECURITIES AND USE OF PROCEEDS

None.

ITEM 3. DEFAULTS UPON SENIOR SECURITIES

None.

ITEM 4. MINE SAFETY DISCLOSURES

None.

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ITEM 5. OTHER INFORMATION

None.

ITEM 6. EXHIBITS

(a)Exhibits — See Exhibit Index on page following signatures

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SIGNATURES

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 thereunto duly authorized.

Dated: February 2, 2016

CARDIOVASCULAR SYSTEMS, INC.

By /s/ Scott R. Ward
Scott R. Ward
Interim President and Chief Executive Officer
(Principal Executive Officer)

By /s/ Laurence L. Betterley
Laurence L. Betterley
Chief Financial Officer
(Principal Financial and Accounting Officer)

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EXHIBIT INDEX
CARDIOVASCULAR SYSTEMS, INC.
FORM 10-Q

Exhibit No.	Description
10.1	Cardiovascular Systems, Inc. 2015 Employee Stock Purchase Plan (previously filed with the SEC as Exhibit 10.1 to and incorporated herein by reference from the Company's Report on Form 8-K filed on November 19, 2015).
10.2*	Employment Letter, dated November 30, 2015, by and between the Company and Scott R. Ward.
10.3*	Confidentiality and Assignment of Inventions Agreement, dated November 30, 2015, by and between the Company and Scott R. Ward.
31.1*	Certification of Interim President and Chief Executive Officer Pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.
31.2*	Certification of Chief Financial Officer Pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.
32.1**	Certification of Interim President and Chief Executive Officer Pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.
32.2**	Certification of Chief Financial Officer Pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.
101	Financial statements from the quarterly report on Form 10-Q of the Company for the quarter ended December 31, 2015, formatted in XBRL: (i) the Consolidated Balance Sheets, (ii) the Consolidated Statements of Operations, (iii) the Consolidated Statements of Comprehensive Loss, (iv) the Consolidated Statements of Cash Flows, and (v) the Notes to Financial Statements.

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*Filed herewith.
**Furnished herewith.