

Cardiovascular Systems Inc
Form 10-Q
November 04, 2016
Table of Contents

UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
Washington, D.C. 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 September 30, 2016
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 (IRS Employer
incorporation or organization) 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 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 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 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

The number of shares outstanding of the registrant's common stock as of October 28, 2016 was: Common Stock, \$0.001 par value per share, 33,063,243 shares.

Table of Contents

Cardiovascular Systems, Inc.

Table of Contents

	PAGE
<u>PART I. FINANCIAL INFORMATION</u>	
<u>ITEM 1. Consolidated Financial Statements (unaudited)</u>	<u>3</u>
<u>Consolidated Balance Sheets as of September 30, 2016 and June 30, 2016</u>	<u>3</u>
<u>Consolidated Statements of Operations for the three months ended September 30, 2016 and 2015</u>	<u>4</u>
<u>Consolidated Statements of Comprehensive Loss for the three months ended September 30, 2016 and 2015</u>	<u>5</u>
<u>Consolidated Statements of Cash Flows for the three months ended September 30, 2016 and 2015</u>	<u>6</u>
<u>Notes to Consolidated Financial Statements</u>	<u>7</u>
<u>ITEM 2. Management's Discussion and Analysis of Financial Condition and Results of Operations</u>	<u>15</u>
<u>ITEM 3. Quantitative and Qualitative Disclosures About Market Risk</u>	<u>22</u>
<u>ITEM 4. Controls and Procedures</u>	<u>22</u>
<u>PART II. OTHER INFORMATION</u>	
<u>ITEM 1. Legal Proceedings</u>	<u>23</u>
<u>ITEM 1A. Risk Factors</u>	<u>23</u>
<u>ITEM 2. Unregistered Sales of Equity Securities and Use of Proceeds</u>	<u>23</u>
<u>ITEM 3. Defaults Upon Senior Securities</u>	<u>23</u>
<u>ITEM 4. Mine Safety Disclosures</u>	<u>23</u>
<u>ITEM 5. Other Information</u>	<u>23</u>
<u>ITEM 6. Exhibits</u>	<u>23</u>
<u>Signatures</u>	<u>24</u>
<u>Exhibit Index</u>	<u>25</u>

Table of Contents

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)

	September 30, 2016	June 30, 2016
ASSETS		
Current assets		
Cash and cash equivalents	\$ 58,194	\$60,638
Accounts receivable, net	24,308	23,128
Inventories	16,887	17,440
Marketable securities	705	684
Prepaid expenses and other current assets	1,998	2,992
Total current assets	102,092	104,882
Property and equipment, net	31,820	32,471
Patents, net	4,352	5,013
Other assets	70	40
Total assets	\$ 138,334	\$ 142,406
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities		
Accounts payable	\$ 8,763	\$8,506
Accrued expenses	21,688	26,993
Total current liabilities	30,451	35,499
Long-term liabilities		
Other liabilities	4,939	6,010
Total liabilities	35,390	41,509
Commitments and contingencies (see Note 6)	—	—
Common stock, \$0.001 par value; authorized 100,000,000 common shares at September 30, 2016 and June 30, 2016; issued and outstanding 33,046,180 at September 30, 2016 and 32,792,497 at June 30, 2016, respectively	33	33
Additional paid in capital	432,119	428,235
Accumulated other comprehensive income	61	40
Accumulated deficit	(329,269) (327,411)
Total stockholders' equity	102,944	100,897
Total liabilities and stockholders' equity	\$ 138,334	\$ 142,406

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

Table of Contents

Cardiovascular Systems, Inc.

Consolidated Statements of Operations

(Dollars in thousands, except per share and share amounts)

(Unaudited)

	Three Months Ended September 30,	
	2016	2015
Net revenues	\$49,800	\$43,871
Cost of goods sold	9,466	8,771
Gross profit	40,334	35,100
Expenses:		
Selling, general and administrative	36,866	41,395
Research and development	5,335	6,941
Total expenses	42,201	48,336
Loss from operations	(1,867)	(13,236)
Other (income) and expense, net	(33)	2
Loss before income taxes	(1,834)	(13,238)
Provision for income taxes	24	23
Net loss	\$(1,858)	\$(13,261)

Net loss per common share:

Basic and diluted \$(0.06) \$(0.41)

Weighted average common shares used in computation:

Basic and diluted 32,985,082 2,210,874

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

Table of Contents

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

	Three Months Ended September 30,	
	2016	2015
Net loss	\$(1,858)	\$(13,261)
Other comprehensive income (loss):		
Unrealized gain (loss) on available for sale securities	21	(99)
Comprehensive loss	\$(1,837)	\$(13,360)

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

Table of Contents

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

	Three Months Ended September 30,	
	2016	2015
Cash flows from operating activities		
Net loss	\$(1,858)	\$(13,261)
Adjustments to reconcile net loss to net cash used in operations		
Depreciation of property and equipment	957	887
Amortization and write-off of patents	807	86
Provision for doubtful accounts	150	175
Stock-based compensation	3,450	4,107
Changes in assets and liabilities		
Accounts receivable	(1,330)	3,791
Inventories	553	(1,480)
Prepaid expenses and other assets	1,314	1,043
Accounts payable	257	(18)
Accrued expenses and other liabilities	(6,376)	(166)
Net cash used in operating activities	(2,076)	(4,836)
Cash flows from investing activities		
Purchases of property and equipment	(282)	(1,847)
Issuance of convertible note receivable	—	(350)
Purchases of marketable securities	—	(17)
Costs incurred in connection with patents	(170)	(160)
Net cash used in investing activities	(452)	(2,374)
Cash flows from financing activities		
Exercise of stock options	84	19
Net cash provided by financing activities	84	19
Net change in cash and cash equivalents	(2,444)	(7,191)
Cash and cash equivalents		
Beginning of period	60,638	83,842
End of period	\$58,194	\$76,651

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

Table of Contents

CARDIOVASCULAR SYSTEMS, INC.
NOTES TO CONSOLIDATED FINANCIAL STATEMENTS
(For the Three Months Ended September 30, 2016 and 2015)
(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 (“PAD”) products, the Diamondback 360[®] Peripheral Orbital Atherectomy System (“OAS”) and the Stealth 360[®] Peripheral OAS, 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 other 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 a variety of vessel sizes, including 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 United States Food and Drug Administration to market the Diamondback 360[®] Coronary OAS as a treatment for severely calcified coronary arteries.

The Company is currently selling only in the United States and evaluating options for international expansion to maximize the coronary and peripheral market opportunities. In June 2016, the Company submitted an application to Japan’s Pharmaceuticals and Medical Devices Agency for approval of our Diamondback 360[®] Coronary OAS Micro Crown. Pending approval, Japan would become the first international market for any of the Company’s products.

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 for a fair statement of 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 25, 2016. 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.

Table of Contents

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 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 December 15, 2016 and can be applied either prospectively or retrospectively. Early adoption is permitted. The Company is currently evaluating the impact of the deferred tax guidance on its financial statements upon adoption.

In February 2016, the FASB issued ASU 2016-02, "Leases." The guidance requires lessees to recognize the assets and liabilities that arise from leases on the balance sheet. ASU 2016-02 is effective for annual periods beginning after December 15, 2018, including interim periods within those annual periods, and should be applied using a modified retrospective approach. Early adoption is permitted. The Company is currently evaluating the impact of the new lease guidance on its financial statements.

Table of Contents

In March 2016, the FASB issued ASU 2016-09, “Stock Compensation.” The guidance simplifies several aspects related to the accounting for share-based payment transactions, including the accounting for income taxes, classification on the statement of cash flows, forfeitures, and statutory withholding requirements. ASU 2016-09 is effective for annual periods beginning after December 15, 2016, and interim periods within those annual periods. Early adoption is permitted and transition requirements vary based on the amendments adopted. The Company is currently evaluating the impact of the stock compensation guidance on its financial statements.

In April 2016, the FASB issued ASU 2016-10, “Identifying Performance Obligations and Licensing,” which amends ASU 2014-09, “Revenue from Contracts with Customers.” The guidance clarifies how entities would determine whether promised goods or services are separately identifiable from other promises in a contract and, therefore, would be accounted for separately. The guidance would also allow entities to disregard goods or services that are immaterial in the context of a contract and provides an accounting policy election to account for shipping and handling activities as fulfillment costs rather than as additional promised services. ASU 2016-10 has the same effective date and transition requirements as ASU 2014-09, as amended by 2015-14. The Company is currently evaluating the impact on its financial statements.

In May 2016, the FASB issued ASU No. 2016-12, “Narrow-Scope Improvements and Practical Expedients,” which amends ASU 2014-09, “Revenue from Contracts with Customers,” to address implementation issues relative to transition (adding a practical expedient for contract modifications and clarifying what constitutes a completed contract when employing ASU 2014-09’s full or modified retrospective transition methods), collectability, noncash consideration, and the presentation of sales and other similar-type taxes (allowing entities to exclude sales-type taxes collected from transaction price). This ASU has the same effective date and transition requirements as ASU 2014-09, as amended by ASU 2015-14. The Company is currently evaluating the impact on its financial statements.

In June 2016, the FASB issued ASU No. 2016-13, “Measurement of Credit Losses on Financial Instruments,” which revises guidance for the accounting for credit losses on financial instruments within its scope. The new standard introduces an approach, based on expected losses, to estimate credit losses on certain types of financial instruments and modifies the impairment model for available-for-sale debt securities. The new approach to estimating credit losses (referred to as the current expected credit losses model) applies to most financial assets measured at amortized cost and certain other instruments, including trade and other receivables, loans, held-to-maturity debt securities, net investments in leases and off-balance-sheet credit exposures. ASU 2016-13 is effective for annual periods beginning after December 15, 2019, including interim periods within those fiscal years. Early adoption is permitted and should be applied as a cumulative-effect adjustment to retained earnings as of the beginning of the first reporting period in which the guidance is adopted. The Company is currently assessing the impact of the credit loss guidance on its financial statements.

3. Selected Consolidated Financial Statement Information

Accounts Receivable, Net

Accounts receivable consists of the following:

	September 30, 2016	June 30, 2016
Accounts receivable	\$ 25,133	\$ 23,840
Less: Allowance for doubtful accounts	(825)	(712)
Accounts receivable, net	\$ 24,308	\$ 23,128

Inventories

Inventories consist of the following:

	September 30, 2016	June 30, 2016
Raw materials	\$ 7,404	\$7,439
Work in process	728	1,142
Finished goods	8,755	8,859
Inventories	\$ 16,887	\$17,440

Table of Contents

Property and Equipment, Net

Property and equipment consists of the following:

	September 30, 2016	June 30, 2016
Land	\$ 500	\$500
Building	22,575	22,575
Equipment	15,566	14,141
Furniture	2,709	2,709
Leasehold improvements	86	86
Construction in progress	414	1,533
	41,850	41,544
Less: Accumulated depreciation (10,030)		(9,073)
Property and equipment, net	\$ 31,820	\$ 32,471

Accrued Expenses

Accrued expenses consist of the following:

	September 30, 2016	June 30, 2016
Salaries and bonus	\$ 3,698	\$4,305
Commissions	5,809	7,788
Accrued vacation	3,452	3,498
Accrued excise, sales and other taxes	3,399	3,372
Clinical studies	874	1,757
Legal settlement	1,322	3,872
Restructuring	939	1,337
Other accrued expenses	2,195	1,064
Total Accrued expenses	\$ 21,688	\$ 26,993

Legal Settlement

On June 28, 2016, the Company entered into a Settlement Agreement (the "Settlement Agreement") with the United States of America, acting through the Department of Justice (the "DOJ") and on behalf of the Office of Inspector General of the Department of Health and Human Services, and Travis Thams, to resolve the investigation by the DOJ and the Civil Action underlying such investigation. Under the Settlement Agreement, the Company will pay \$8,000, as follows: an initial payment of \$3,000, which the Company paid on July 1, 2016, with the remaining \$5,000, which bears interest at 1.8% per annum, payable in 11 equal quarterly installments, beginning January 1, 2017. The amount payable within the next twelve months is included in accrued expenses as noted in the table above.

Restructuring

On March 31, 2016, the Company announced a restructuring to reduce costs as a part of its plan to progress towards profitability and positive cash flow. As a result, the Company recorded a restructuring expense of \$2,364 during the year ended June 30, 2016, which was comprised of severance and other employee related costs.

The following table provides information regarding the restructuring accrual:

Edgar Filing: Cardiovascular Systems Inc - Form 10-Q

	Severance
Restructuring accrual at June 30, 2016	\$ 1,521
Cash payments	(495)
Restructuring accrual at September 30, 2016	\$ 1,026

10

Table of Contents

The Company anticipates that \$939 of the restructuring accrual at September 30, 2016 will be paid within the next twelve months and is therefore recorded in accrued expenses on the consolidated balance sheet. Estimated payments of \$87 are recorded in other liabilities on the consolidated balance sheet. The Company does not anticipate additional restructuring costs.

CEO Departure

On February 29, 2016, the Company's former Chief Executive Officer ("CEO") resigned from his positions as President and CEO of the Company and as a director of the Company. The Company and the former CEO entered into a Separation Agreement with benefits consistent with the Company's Amended and Restated Executive Officer Severance Plan. The total expense related to the former CEO's departure was \$1,507 and was recorded in selling, general and administrative expenses for the year ended June 30, 2016. As of September 30, 2016, \$701 of the package benefits is recorded in accrued expenses and \$238 is recorded in other liabilities on the consolidated balance sheet, representing the long-term portion of the former CEO's benefits.

Other Liabilities

Other non-current liabilities consist of the following:

	September 30, 2016	June 30, 2016
Legal settlement	\$ 3,678	\$4,128
Deferred compensation	358	684
Accrued severance	325	610
Other liabilities	578	588
Total Other liabilities	\$ 4,939	\$6,010

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 September 30, 2016, \$347 of the amount payable is included in accrued liabilities and \$358 is included in other liabilities on the consolidated balance sheet. Future distribution dates are July 1, 2017 and January 1, 2020.

The available-for-sale marketable securities are primarily comprised of investments with a fixed income and equity investments and consist of the following:

	As of September 30, 2016			
	Amortized Cost	Unrealized Gains	Unrealized Losses	Fair Value
Mutual funds	\$644	\$ 61	\$	—\$ 705
Total short-term investments	\$644	\$ 61	\$	—\$ 705
	As of June 30, 2016			
	Amortized Cost	Unrealized Gains	Unrealized Losses	Fair Value

Edgar Filing: Cardiovascular Systems Inc - Form 10-Q

Mutual funds	\$644	\$ 40	\$	—\$ 684
Total short-term investments	\$644	\$ 40	\$	—\$ 684

During the three months ended September 30, 2016 and 2015, there were \$0 and \$17, respectively, in purchases of available-for-sale securities. There were no sales or other-than-temporary impairments during the three months ended September 30, 2016.

Table of Contents

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 September 30, 2016 Using Inputs Considered as		
	Fair Value	Level 1	Level 2	Level 3
Mutual funds	\$ 705	\$ 444	\$ 261	\$ —
Total short-term investments	\$ 705	\$ 444	\$ 261	\$ —

	Fair Value	Measurements as of June 30, 2016 Using Inputs Considered as		
	Fair Value	Level 1	Level 2	Level 3
Mutual funds	\$ 684	\$ 425	\$ 259	\$ —
Total short-term investments	\$ 684	\$ 425	\$ 259	\$ —

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 three months ended September 30, 2016. Any transfers between levels would be recognized on the date of the event or when a change in circumstances causes a transfer.

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 and subsequently 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 one other 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 September 30, 2016, all outstanding options were fully vested.

Stock option activity for the three months ended September 30, 2016 is as follows:

	Number of Options ^(a)	Weighted Average Exercise Price
Options outstanding at June 30, 2016	606,879	\$ 10.14

Edgar Filing: Cardiovascular Systems Inc - Form 10-Q

Options exercised	(9,645)	\$ 8.64
Options outstanding at September 30, 2016	597,234	\$ 10.17

(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

For restricted stock awards which vest solely based on time, 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.

Table of Contents

On August 8, 2016 and August 17, 2016, the Company granted restricted stock awards to its executives and management. These awards included grants of an aggregate maximum 336,826 shares that vest based on the Company's total shareholder return relative to total shareholder return of the Company's peer group, as measured by the closing prices of the stock of the Company and the peer group members for the 90 trading days preceding July 1, 2016 compared to the closing prices of the stock of the Company and the peer group members for the 90 trading days preceding July 1, 2019. Vesting of these awards will be determined on the date that the Company's Annual Report on Form 10-K for the fiscal year ending June 30, 2019 is filed.

To calculate the estimated fair value of these restricted stock awards with market conditions, the Company uses a Monte Carlo simulation, which uses the expected average stock prices to estimate the expected number of shares that will vest. The Monte Carlo simulation resulted in a fair value of approximately \$4,032, which the Company will recognize as expense using the straight-line method over the period that the awards are expected to vest. Stock-based compensation expense related to an award with a market condition will be recognized regardless of whether the market condition is satisfied, provided that the requisite service has been provided.

Restricted stock award activity for the three months ended September 30, 2016 is as follows:

	Number of Shares	Weighted Average Fair Value
Restricted stock awards outstanding at June 30, 2016	957,689	\$ 22.99
Restricted stock awards granted - time based	239,286	\$ 21.56
Restricted stock awards granted - market conditions	336,826	\$ 11.97
Restricted stock awards forfeited	(338,550)	\$ 23.61
Restricted stock awards vested	(169,909)	\$ 24.21
Restricted stock awards outstanding at September 30, 2016	1,025,342	\$ 18.63

6. Commitment and Contingencies

Operating Leases

The Company leases manufacturing and other space, as well as equipment, under lease agreements that expire at various dates through March 2020. Rental expenses were \$172 and \$342 for the three months ended September 30, 2016 and 2015, respectively.

Future minimum lease payments under the agreements as of September 30, 2016 are as follows:

Nine months ended June 30, 2017	\$459
Fiscal 2018	523
Fiscal 2019	471
Fiscal 2020	353
	\$1,806

Stockholder Securities Litigation

With respect to Shoemaker v. Cardiovascular Systems, Inc. et al., 0:16-cv-00568 (D. Minn.) described in Note 9 of the notes to the consolidated annual financial statements, included in the Form 10-K filed by the Company with the SEC on August 25, 2016., the Company filed a motion to dismiss the complaint in this action on August 29, 2016.

Stockholder Derivative Action

With respect to the stockholder derivative action described in Note 9 of the notes to the consolidated annual financial statements, included in the Form 10-K filed by the Company with the SEC on August 25, 2016, the plaintiff amended its complaint on September 19, 2016. On October 19, 2016, the plaintiff filed a notice of voluntary dismissal of the complaint.

Table of Contents

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 September 30, 2016 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 September 30,	
	2016	2015
Numerator		
Net loss	\$(1,858)	\$(13,261)
Denominator		
Weighted average common shares – basic	32,985,083	32,210,874
Effect of dilutive stock options ^{(a)(b)}	—	—
Weighted average common shares outstanding – diluted	32,985,083	32,210,874
Net loss per common share — basic and diluted	\$(0.06)	\$(0.41)

At September 30, 2016 and 2015, 597,234 and 697,372 stock options, respectively, were outstanding. The effect of (a) 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.

At September 30, 2016 and 2015, 350,771 and 297,044 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 (b) upon settlement of these restricted stock units has been excluded from the calculation of diluted loss per share because those shares are anti-dilutive.

Table of Contents

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, 2016 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 Diamondback 360 Peripheral Orbital Atherectomy System ("OAS") ("Diamondback 360 Peripheral"), the Diamondback 360 60cm Peripheral OAS, the Diamondback 360 4 French 1.25 Peripheral OAS, the Diamondback 360 1.50 Peripheral OAS, the Diamondback 360 2.00 Peripheral OAS, and the Stealth 360[®] Peripheral OAS ("Stealth 360"), are catheter-based platforms capable of treating a broad range of plaque types in leg arteries both above and below the knee, including calcified plaque, and address many of the limitations associated with existing surgical, catheter and pharmacological treatment alternatives. The micro-invasive devices use smaller access sheaths that can provide procedural benefits and allow physicians to treat PAD patients in even 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 each of the products above in this report as the "Peripheral OAS."

Our coronary arterial disease ("CAD") product, Diamondback 360 Coronary OAS ("Coronary OAS"), is marketed as a treatment for severely calcified coronary arteries. The Coronary OAS 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 Coronary OAS design is similar to technology used in our Peripheral OAS, 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 of the Peripheral OAS and, since 2007, to the approval of our Coronary OAS.

In 2006, we obtained an investigational device exemption from the U.S. Food and Drug Administration ("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 and Stealth 360 in March 2011. We no longer market the Predator 360. We received 510(k) clearance of the Diamondback 360 60cm Peripheral OAS in March 2014; in April 2015, we received 510(k) clearance of the Diamondback 360 4 French 1.25 Peripheral OAS, and in October 2015, we received 510(k) clearance of the Diamondback 360 1.50 and 2.00 Peripheral OAS.

We have developed modified versions of the Peripheral OAS 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 Coronary OAS as a treatment for severely calcified coronary arteries. We commenced a commercial launch of our Coronary OAS following receipt of PMA.

We market the Peripheral and Coronary OAS 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. At our facilities, we assemble the saline infusion pump and the single-use catheter used in the Peripheral OAS and Coronary OAS with components purchased from third-party suppliers, as well as with components manufactured in-house. Supplemental products are purchased from third-party suppliers.

Table of Contents

In October 2014, we received CE Mark for our Stealth 360 device and are currently evaluating the timing and structure of our plans to commercialize our products in Europe.

In July 2016, we submitted an application to Japan's Pharmaceuticals and Medical Devices Agency ("PMDA") for approval of our Diamondback 360[®] Coronary OAS Micro Crown, our second generation coronary device. Pending approval, Japan would become the first international market for any CSI products.

CRITICAL ACCOUNTING POLICIES AND SIGNIFICANT JUDGMENTS AND ESTIMATES

Our management's discussion and analysis of our financial condition and results of operations is 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, 2016 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 three months ended September 30, 2016.

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			Percent Change
	September 30,			
	2016	2015		
Net revenues	\$49,800	\$43,871	13.5	%
Cost of goods sold	9,466	8,771	7.9	
Gross profit	40,334	35,100	14.9	
Expenses:				
Selling, general and administrative	36,866	41,395	(10.9)
Research and development	5,335	6,941	(23.1)
Total expenses	42,201	48,336	(12.7)
Loss from operations	(1,867	(13,236	(85.9)

Edgar Filing: Cardiovascular Systems Inc - Form 10-Q

Other (income) and expense, net	(33)	2	(1,750.0)
Loss before income taxes	(1,834)	(13,238)	(86.1)
Provision for income taxes	24	23	4.3
Net loss	\$(1,858)	\$(13,261)	(86.0)

16

Table of Contents

Comparison of Three Months Ended September 30, 2016 with Three Months Ended September 30, 2015

Net revenues. Net revenues increased by \$5.9 million, or 13.5%, from \$43.9 million for the three months ended September 30, 2015 to \$49.8 million for the three months ended September 30, 2016. This increase was attributable to higher sales of both our PAD and CAD Systems. CAD System revenues increased approximately \$2.6 million, or 32.8%, due to 31.5% more devices sold in the three months ended September 30, 2016 than during the three months ended September 30, 2015. Sales of our PAD System also increased \$2.6 million, or 8.1%, due to 5.8% more devices sold in the three months ended September 30, 2016 than during the three months ended September 30, 2015, as well as an increase in average selling prices. Other product revenue increased by \$653,000, or 19.8%, primarily driven by increased sales of our PAD and CAD Systems, which the other 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 Japan and Europe. In July 2016, we submitted an application to Japan's PMDA for approval of our Diamondback 360[®] Coronary OAS Micro Crown. In October 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 to increase as we continue to increase the number of physicians using the devices, increase the usage per physician, introduce new and improved products, generate additional clinical data, and expand into new geographies.

Cost of Goods Sold. Cost of goods sold increased \$695,000, or 7.9%, from \$8.8 million for the three months ended September 30, 2015 to \$9.5 million for the three months ended September 30, 2016. 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 September 30, 2016 and 2015 includes \$200,000 and \$215,000, respectively, for stock-based compensation. The increase in cost of goods sold was primarily due to increased sales levels, partially offset by lower material costs. Gross margin increased to 81.0% for the three months ended September 30, 2016 from 80.0% for the three months ended September 30, 2015 due to lower material costs and an increase in average selling prices. We expect that gross margin in the second quarter of fiscal 2017 will be comparable to gross margin in the three months ended September 30, 2016. 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 decreased by \$4.5 million, or 10.9%, from \$41.4 million for the three months ended September 30, 2015 to \$36.9 million for the three months ended September 30, 2016. The decrease was primarily due to lower payroll-related expenses from a 6.3% decrease in headcount from the three months ended September 30, 2015, lower commissions expense, and a reduction in medical device excise tax expense due to the suspension of the tax effective January 1, 2016. Partially offsetting the decreases was an increase in bonus expense due to our performance and increased legal fees. Selling, general and administrative expenses for the three months ended September 30, 2016 and 2015 includes \$3.0 million and \$3.5 million, respectively, for stock-based compensation, which decreased due to the decreased headcount. We expect our selling, general and administrative expenses to decrease in the second quarter of fiscal 2017 as compared to amounts incurred for the three months ended September 30, 2016 due to lower event costs.

Research and Development Expenses. Research and development expenses decreased by \$1.6 million, or 23.1%, from \$6.9 million for the three months ended September 30, 2015 to \$5.3 million for the three months ended September 30, 2016. 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 to 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 September 30, 2016 and 2015 includes \$289,000 and \$373,000, respectively, for stock-based compensation. We expect research and development expenses in

the second quarter of fiscal 2017 to be slightly higher than amounts incurred for the three months ended September 30, 2016 due to the timing of projects and studies. Fluctuations could occur based on the number of projects and studies and the timing of expenditures.

LIQUIDITY AND CAPITAL RESOURCES

We had cash and cash equivalents of \$58.2 million and \$60.6 million at September 30, 2016 and June 30, 2016, respectively. During the three months ended September 30, 2016, net cash used in operations amounted to \$2.1 million. As of September 30, 2016, we had an accumulated deficit of \$329.3 million. We have historically funded our operating losses primarily from the issuance of common and preferred stock, convertible promissory notes, and debt.

Table of Contents

Changes in Liquidity

Cash and Cash Equivalents. Cash and cash equivalents were \$58.2 million at September 30, 2016 and \$60.6 million at June 30, 2016. The decrease is primarily attributable to net cash used in operations and investing activities during the three months ended September 30, 2016.

Operating Activities. Net cash used in operations was \$2.1 million and \$4.8 million for the three months ended September 30, 2016 and 2015, respectively. For the three months ended September 30, 2016 and 2015, we had a net loss of \$1.9 million and \$13.3 million, respectively. Significant changes in working capital during these periods included:

Cash (used in) provided by accounts receivable of \$(1.3) million and \$3.8 million during the three months ended September 30, 2016 and 2015, respectively, was primarily due to the amount and timing of revenue and collections during the three months ended September 30, 2016 and 2015.

Cash provided by (used in) inventories was \$553,000 and \$(1.5) million during the three months ended September 30, 2016 and 2015, respectively. For the three months ended September 30, 2016, the amount of cash provided by inventories was primarily due to lower inventory levels. For the three months ended September 30, 2015, the amount of cash used in inventories was primarily due to higher levels of finished goods for future sales.

Cash provided by prepaid expenses and other current assets was \$1.3 million and \$1.0 million during the three months ended September 30, 2016 and 2015, respectively, primarily due to payment timing of vendor deposits and other expenditures.

Cash provided by (used in) accounts payable was \$257,000 and \$(18,000) during the three months ended September 30, 2016 and 2015, respectively, due to the amount and timing of purchases and vendor payments.

Cash (used in) provided by accrued expenses and other liabilities was \$(6.4) million and \$166,000 during the three months ended September 30, 2016 and 2015, respectively. For the three months ended September 30, 2016, the change in accrued expenses was primarily due to the initial \$3.0 million Department of Justice settlement payment (discussed below), severance payments, and the amount and timing of compensation payments. For the three months ended September 30, 2015, the change in accrued expenses and other liabilities was primarily due to the amount and timing of compensation payments.

Investing Activities. Net cash used in investing activities was \$452,000 and \$2.4 million for the three months ended September 30, 2016 and 2015, respectively. During the three months ended September 30, 2016, cash was used primarily for the purchase of property and equipment and patents. Cash used during the three months ended September 30, 2015 related to the purchase of property and equipment and patents, as well as for the issuance of a convertible note receivable.

Financing Activities. Net cash provided by financing activities was \$84,000 and \$19,000 for the three months ended September 30, 2016 and 2015, respectively, due to proceeds from the exercise of stock options.

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 business operations, 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. As of September 30, 2016, we believe our current cash and cash equivalents will be sufficient to fund working capital requirements, capital expenditures, operations for the foreseeable future, including at least the next twelve months, as well as to fund payments related to the Department of Justice settlement, expenses relating to implementation and compliance with our Corporate

Integrity Agreement, and payments related to our restructuring and departure of our former CEO. We also believe we have the potential ability to finance our new Minnesota facility and obtain debt financing, 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.

Table of Contents

Legal Settlement

As previously discussed in our Annual Report on Form 10-K, filed with the SEC on August 25, 2016, on June 28, 2016, we entered into a Settlement Agreement with the Department of Justice, pursuant to which we will pay \$8.0 million as follows: an initial payment of \$3.0 million, which we paid in July 2016, with the remaining \$5.0 million, which bears interest at 1.8% per annum, payable in 11 equal quarterly installments, beginning in January 2017.

In connection with the resolution of this matter, we entered into a five-year corporate integrity agreement (the “Corporate Integrity Agreement”) with the Office of Inspector General of the Department of Health and Human Services. The Corporate Integrity Agreement requires that we maintain our existing compliance programs and imposes certain expanded compliance-related requirements during the term of the Corporate Integrity Agreement, including establishment of specific procedures and requirements regarding consulting activities, co-marketing activities and other interactions with healthcare professionals and healthcare institutions and the sale and marketing of our products; ongoing monitoring, reporting, certification and training obligations; and the engagement of an independent review organization to perform certain auditing and reviews and prepare certain reports regarding our compliance with federal health care programs. In the event of a breach of the Corporate Integrity Agreement, we could become liable for payment of certain stipulated penalties or could be excluded from participation in federal health care programs. The Corporate Integrity Agreement will require us to invest additional amounts in our compliance program and pay fees and expenses of the independent review organization.

Restructuring

In March 2016, we announced a broad-based restructuring to reduce costs as a part of our plan to progress towards profitability and positive cash flow. As a result, we recorded a restructuring expense of \$2.4 million during the year ended June 30, 2016, which was comprised of severance and other employee related costs. Approximately \$939,000 is payable over the next twelve months and \$87,000 payable in subsequent periods. We do not anticipate additional restructuring costs. See Note 3 to our Consolidated Financial Statements included in Item 1 of Part I of this Quarterly Report on Form 10-Q for additional discussion.

CEO Departure

In February 2016, our former Chief Executive Officer (“CEO”) resigned from his positions as President and CEO of the Company and as a director of the Company. The Company and the former CEO entered into a Separation Agreement with benefits consistent with our Amended and Restated Executive Officer Severance Plan, which requires payments of approximately \$701,000 that will be paid within the next twelve months and estimated payments of \$238,000 primarily payable in the subsequent twelve months. See Note 3 to our Consolidated Financial Statements included in Item 1 of Part I of this Quarterly Report on Form 10-Q for additional discussion.

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):

	Three Months Ended September 30, 2016 2015	
Net loss	\$(1,858)	\$(13,261)

Edgar Filing: Cardiovascular Systems Inc - Form 10-Q

Less: Other (income) and expense, net	(33)	2
Less: Provision for income taxes	24	23
Loss from operations	(1,867)	(13,236)
Add: Stock-based compensation	3,450	4,107
Add: Depreciation and amortization	1,017	940
Adjusted EBITDA	\$2,600	\$(8,189)

Adjusted EBITDA improved as compared to the prior year period due to the lower loss from operations as a result of higher revenues and lower costs and higher depreciation expense, slightly offset by lower stock-based compensation as a result of reduced headcount.

Table of Contents

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 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 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.

Table of Contents

RECENT ACCOUNTING PRONOUNCEMENTS

For a description of recent accounting pronouncements, see Note 2 to the consolidated financial statements.

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-K and in other materials filed or to be filed by us with the Securities and Exchange Commission (as well as information included in oral statements or other written statements made or to be made by us). Forward-looking statements include all statements based on future expectations. This Form 10-K contains forward-looking statements that involve risks and uncertainties, including (i) the expectation of selling our products internationally in the future and the timing and structure of our plans to do so; (ii) our expectation that our losses will decline as our revenues grow; (iii) our plan to progress toward to profitability and positive cash flow; (iv) the stockholder litigation; (v) our expectation that our revenue will increase; (vi) our expectation of decreased selling, general and administrative expenses in the second quarter of fiscal 2017; (vii) our expectation that gross margin in the second quarter of fiscal 2017 will be comparable to the three months ended September 30, 2016; (viii) our expectation that we will incur research and development expenses in the second quarter of fiscal 2017 slightly higher than the amounts incurred for the three months ended September 30, 2016; (ix) our anticipation that we will not incur additional charges related to restructuring activities; (x) 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, as well as to fund certain other anticipated expenses; (xi) our intention to retain any future earnings to support operations and to finance the growth and development of our business; (xii) our dividend expectations; (xiii) our belief that we have debt capacity and the potential ability to finance our new Minnesota facility, which could further supplement funds if warranted; and (xiv) the anticipated impact of adoption of recent accounting pronouncements on our 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; our ability to negotiate and agree upon definitive documentation with a distribution partner in Japan; the experience of physicians regarding the effectiveness and reliability of our products; 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 ability to manage our sales force strategy; 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; our ability to manage costs; our actual financial resources and our ability to obtain additional financing; investigations or litigation threatened or initiated against us;

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 25, 2016. 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.

Table of Contents

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 September 30, 2016 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 Item 1 of Part 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 September 30, 2016. 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.

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 September 30, 2016 that have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

Table of Contents

PART II. — OTHER INFORMATION

ITEM 1. LEGAL PROCEEDINGS

Stockholder Securities Litigation

Refer to Part I, Item 3 (Legal Proceedings) of the Company's Form 10-K for the year ended June 30, 2016, as filed with the SEC on August 25, 2016. The Company's prior disclosures therein regarding Shoemaker v. Cardiovascular Systems, Inc. et al., 0:16-cv-00568 (D. Minn.) are incorporated herein by reference. The Company filed a motion to dismiss the complaint in this action on August 29, 2016.

Stockholder Derivative Action

Refer to Part I, Item 3 (Legal Proceedings) of the Company's Form 10-K for the year ended June 30, 2016, as filed with the SEC on August 25, 2016. The Company's prior disclosures therein regarding the stockholder derivative action are incorporated herein by reference. The plaintiff in the stockholder derivative action amended its complaint on September 19, 2016. On October 19, 2016, the plaintiff filed a notice of voluntary dismissal of the complaint.

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, 2016 filed with the SEC on August 25, 2016 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.

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.

ITEM 5. OTHER INFORMATION

None.

ITEM 6. EXHIBITS

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

Table of Contents

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: November 4, 2016 CARDIOVASCULAR SYSTEMS, INC.

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

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

Table of Contents

EXHIBIT INDEX
 CARDIOVASCULAR SYSTEMS, INC.
 FORM 10-Q

Exhibit No.	Description
10.1	Fiscal Year 2017 Executive Officer Base Salaries (previously filed with the SEC as Exhibit 10.5 to and incorporated herein by reference from the Company's Annual Report on Form 10-K for the year ended June 30, 2016).
10.2	Fiscal 2017 Executive Officer Bonus Plan and Equity Compensation (previously filed with the SEC as Exhibit 10.6 to and incorporated herein by reference from the Company's Annual Report on Form 10-K for the year ended June 30, 2016).
10.3	Fiscal Year 2017 Director Compensation Arrangements (previously filed with the SEC as Exhibit 10.7 to and incorporated herein by reference from the Company's Annual Report on Form 10-K for the year ended June 30, 2016).
10.4	Cardiovascular Systems, Inc. Amended Executive Officer Severance Plan (previously filed with the SEC as Exhibit 10.36 to and incorporated herein by reference from the Company's Annual Report on Form 10-K for the year ended June 30, 2016).
10.5	Form of Performance Unit Award (Cash Settled) under the 2014 Equity Incentive Plan (previously filed with the SEC as Exhibit 10.48 to and incorporated herein by reference from the Company's Annual Report on Form 10-K for the year ended June 30, 2016).
10.6	Form of Restricted Stock Agreement for Performance-Based Awards (3-year cliff vesting) under the 2014 Equity Incentive Plan (previously filed with the SEC as Exhibit 10.49 to and incorporated herein by reference from the Company's Annual Report on Form 10-K for the year ended June 30, 2016).
10.7	Employment Agreement, dated August 15, 2016, by and between Cardiovascular Systems, Inc. and Scott R. Ward (previously filed with the SEC as Exhibit 10.50 to and incorporated herein by reference from the Company's Annual Report on Form 10-K for the year ended June 30, 2016).
31.1*	Certification of Chairman, 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 Chairman, 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 September 30, 2016, 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.

* Filed herewith.

**Furnished herewith.

25