Cardiovascular Systems Inc Form 10-Q November 12, 2010

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 September 30, 2010 Commission File No. 000-52082

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

Delaware (State or Other Jurisdiction of Incorporation or Organization)

**Table of Contents** 

No. 41-1698056 (IRS Employer Identification No.)

**651 Campus Drive** 

St. Paul, Minnesota 55112-3495 (Address of Principal Executive Offices) Registrant s telephone number (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 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 b NO o

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 o NO o

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 o	Accelerated filer o	Non-accelerated filer o	Smaller reporting
		(Do not check if a smaller	company þ
		reporting company)	
Indicate by check mark wh	hether the registrant is a she	ell company (as defined in Rule 1'	$2h_2$ of the Exchange Act)

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

The number of shares outstanding of the registrant s common stock as of November 9, 2010 was: Common Stock, \$0.001 par value per share, 15,811,068 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)

	S	eptember 30, 2010	J	une 30, 2010
ASSETS				
Current assets	¢	22.000	¢	02 717
Cash and cash equivalents	\$	22,006	\$	23,717
Accounts receivable, net		10,579		9,394
Inventories		4,456		4,319
Prepaid expenses and other current assets		1,448		1,048
Total current assets		38,489		38,478
Property and equipment, net		2,015		1,964
Patents, net		1,817		1,712
Other assets		106		180
Total assets	\$	42,427	\$	42,334
LIABILITIES AND STOCKHOLDERS EQUITY				
Current liabilities				
Current maturities of long-term debt	\$	4,600	\$	3,613
Accounts payable	Ψ	5,038	Ψ	3,353
Deferred grant incentive		1,535		1,181
Accrued expenses		6,869		6,569
		0,009		0,507
Total current liabilities		18,042		14,716
Long-term liabilities				
Long-term debt, net of current maturities		6,366		7,286
Deferred grant incentive		2,218		2,208
Other liabilities		365		409
Total long-term liabilities		8,949		9,903
Total liabilities		26,991		24,619
Commitments and contingencies				
Stockholders equity Common stock, \$0.001 par value; authorized 100,000,000 common shares at September 30, 2010 and June 30, 2010; issued and outstanding 15,709,508 at				1.5
September 30, 2010 and 15,148,549 at June 30, 2010, respectively Additional paid in capital		16 159,710		15 157,718

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Common stock warrants Accumulated deficit	11,301 (155,591)	11,305 (151,323)
Total stockholders equity	15,436	17,715
Total liabilities and stockholders equity	\$ 42,427	\$ 42,334

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

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

		Three Months Ended September 30,		
		2010		2009
Revenues	\$	18,165	\$	15,198
Cost of goods sold		4,141		3,488
Gross profit		14,024		11,710
Expenses				
Selling, general and administrative		15,496		14,856
Research and development		2,422		2,781
Total expenses		17,918		17,637
Loss from operations		(3,894)		(5,927)
Other (expense) income				
Interest expense		(365)		(371)
Interest income		7		98
Other		(16)		
Total other expense		(374)		(273)
Net loss	\$	(4,268)	\$	(6,200)
Net loss per common share:				
Basic and diluted	\$	(0.28)	\$	(0.43)
Weighted average common shares used in computation:				
Basic and diluted	1	5,369,157	14	4,516,843
The accompanying notes are an integral part of these unaudited consolid	lated financial at	atomonta		

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

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

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	Three Months Ended September 30,	
	2010	2009
Cash flows from operating activities	¢ (1 <b>2</b> (9)	¢ (( <b>2</b> 00)
Net loss	\$ (4,268)	\$ (6,200)
Adjustments to reconcile net loss to net cash used in operations	164	126
Depreciation and amortization Amortization of debt discount	164 67	136 72
Stock-based compensation Litigation settlement promissory note	1,989 250	2,221
Changes in assets and liabilities	250	
Accounts receivable	(1,185)	293
Inventories	(1,183) (137)	(713)
Prepaid expenses and other assets	(326)	(394)
Accounts payable	1,685	(383)
Accrued expenses and other liabilities	370	2,981
Active expenses and other natifices	570	2,901
Net cash used in operations	(1,391)	(1,987)
Cash flows from investing activities		
Expenditures for property and equipment	(200)	(41)
Sales of investments		100
Costs incurred in connection with patents	(120)	(139)
Net cash used in investing activities	(320)	(80)
Cash flows from financing activities		
Exercise of stock options and warrants		285
Payments on long-term debt		(875)
Net cash used in financing activities		(590)
Net change in cash and cash equivalents	(1,711)	(2,657)
Cash and cash equivalents		
Beginning of period	23,717	33,411
End of period	\$ 22,006	\$ 30,754
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The accompanying notes are an integral part of these unaudited consolidated financial statements.

## CARDIOVASCULAR SYSTEMS, INC. NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (For the three months ended September 30, 2010 and 2009) (dollars in thousands, except per share and share amounts) (unaudited)

## 1. Business Overview

# **Company Description and Merger**

Cardiovascular Systems, Inc. was incorporated as Replidyne, Inc. in Delaware in 2000. On February 25, 2009, Replidyne, Inc. completed its reverse merger with Cardiovascular Systems, Inc., a Minnesota corporation incorporated in 1989 (CSI-MN), in accordance with the terms of the Agreement and Plan of Merger and Reorganization, dated as of November 3, 2008 (the Merger Agreement). Pursuant to the Merger Agreement, CSI-MN continued after the merger as the surviving corporation and a wholly-owned subsidiary of Replidyne. At the effective time of the merger, Replidyne, Inc. changed its name to Cardiovascular Systems, Inc. (CSI) and CSI-MN merged with and into CSI, with CSI continuing after the merger as the surviving corporation.

The Company develops, manufactures and markets devices for the treatment of vascular diseases. The Company s primary products, the Diamondback 360° PAD System and the Diamondback Predator 360° PAD System, 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 treatment alternatives. Prior to the merger, Replidyne was a biopharmaceutical company focused on discovering, developing, in-licensing and commercializing innovative anti-infective products.

## 2. Summary of Significant Accounting Policies

## Interim Financial Statements

The Company has 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 audited consolidated financial statements, but does not include all disclosures as required by accounting principles generally accepted in the United States of America. These interim consolidated financial statements reflect all adjustments consisting of normal recurring accruals, which, in the opinion of management, are necessary to present fairly the Company's 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 September 28, 2010. 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.

## Fair Value of Financial Instruments

Effective July 1, 2008, the Company adopted fair value guidance issued by the FASB, which provides a framework for measuring fair value under Generally Accepted Accounting Principles and expands disclosures about fair value measurements. In February 2008, the FASB provided a one-year deferral on the effective date of the guidance for non-financial assets and non-financial liabilities, except those that are recognized or disclosed in the financial statements at least annually.

The fair value guidance classifies inputs into the following hierarchy:

Level 1 Inputs quoted prices in active markets for identical assets and liabilities

*Level 2 Inputs* observable inputs other than quoted prices in active markets for identical assets and liabilities unobservable inputs

The following table sets forth the fair value of the Company s financial instruments that were measured on a recurring basis as of September 30, 2010. Assets are measured on a recurring basis if they are remeasured at least annually:

Balance at June 30, 2010 Change in conversion option valuation	\$	224 52
Balance at September 30, 2010	\$	276

The conversion option is related to the loan and security agreement with Partners for Growth. The option pricing model used to determine the value of the conversion option included various inputs including historical volatility, stock price simulations, and assessed behavior of the Company and Partners for Growth based on those simulations.

As of September 30, 2010, the Company believes that the carrying amounts of its other financial instruments, including accounts receivable, accounts payable and accrued liabilities approximate their fair value due to the short-term maturities of these instruments. The carrying amount of long-term debt approximates fair value based on interest rates currently available for debt with similar terms and maturities.

#### Use of Estimates

The preparation of the Company s consolidated financial statements in conformity with accounting principles generally accepted in the United States of America 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.

#### **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. These criteria are met at the time of delivery when the risk of loss and title passes to the customer. The Company records estimated sales returns, discounts and rebates as a reduction of net sales in the same period revenue is recognized.

## **Recent Accounting Pronouncements**

In January 2010, the FASB issued further guidance regarding additional disclosures relating to fair value of transfers in and out of input Levels 1 and 2 and for activity in Level 3 and clarifies certain other existing disclosure requirements. This guidance had no impact on the Company s consolidated financial position, results of operations or cash flows for the three months ended September 30, 2010.

In October 2009, the FASB issued guidance providing principles for allocation of consideration among multiple-elements, and accounting for separate deliverables under such an arrangement. The guidance introduces an estimated selling price method for valuing the elements of a bundled arrangement if vendor-specific objective evidence or third-party evidence of selling price is not available, and significantly expands related disclosure requirements. This standard is effective on a prospective basis for revenue arrangements entered into or materially modified in fiscal years beginning on or after June 15, 2010. Alternatively, adoption may be on a retrospective basis, and early application is permitted. The Company adopted this guidance on July 1, 2010, and it had no impact on the Company s consolidated financial position, results of operations or cash flows for the three months ended September 30, 2010.

## 3. Selected Consolidated Financial Statement Information

### Inventories

Inventories are stated at the lower of cost or market with cost determined on a first-in, first-out (FIFO) method of valuation. The establishment of inventory allowances for excess and obsolete inventories is based on estimated exposure on specific inventory items.

At September 30, 2010 and June 30, 2010, respectively, inventories were comprised of the following:

	Se	ptember 30, 2010	June 30, 2010
Inventories			
Raw materials	\$	1,268	\$ 1,256
Work in process		194	282
Finished goods		2,994	2,781
	\$	4,456	\$ 4,319

#### 4. Debt

### Loan and Security Agreement with Silicon Valley Bank

On March 29, 2010, the Company entered into an amended and restated loan and security agreement with Silicon Valley Bank. The agreement includes a \$10,000 term loan and a \$15,000 line of credit. The terms of each of these loans are as follows:

The \$10,000 term loan has a fixed interest rate of 9.0% and a final payment amount equal to 1.0% of the loan amount due at maturity. This term loan has a 36 month maturity, with repayment terms that include interest only payments during the first six months followed by 30 equal principal and interest payments. This term loan also includes an acceleration provision that requires the Company to pay the entire outstanding balance, plus a penalty ranging from 1.0% to 3.0% of the principal amount, upon prepayment or the occurrence and continuance of an event of default. In connection with entering into the agreement, the Company amended a warrant previously granted to Silicon Valley Bank. The warrants provide an option to purchase 8,493 shares of common stock at an exercise price of \$5.48 per share. This warrant is immediately exercisable and expires ten years after the date of amendment. The balance outstanding on the term loan at September 30, 2010 was \$9,625, net of the unamortized discount associated with the warrants.

The \$15,000 line of credit has a two year maturity and a floating interest rate equal to Silicon Valley Bank s prime rate, plus 2.0%, with an interest rate floor of 6.0%. Interest on borrowings is due monthly and the principal balance is due at maturity. Borrowings on the line of credit are based on (a) 80% of eligible domestic receivables, plus (b) the lesser of 40% of eligible inventory or 25% of eligible domestic receivables or \$2,500, minus (c) to the extent in effect, certain loan reserves as defined in the agreement. Accounts receivable receipts are deposited into a lockbox account in the name of Silicon Valley Bank. The accounts receivable line of credit is subject to non-use fees, annual fees, and cancellation fees. The agreement provides that initially 50% of the outstanding principal balance of the \$10,000 term loan reduces available borrowings under the line of credit. Upon the achievement of certain financial covenants, the amount reducing available borrowings will be reduced to zero. There was not an outstanding balance on the line of credit at September 30, 2010.

Borrowings from Silicon Valley Bank are secured by all of the Company s assets. The borrowings are subject to prepayment penalties and financial covenants, including maintaining certain liquidity and fixed charge coverage ratios, and certain three-month EBITDA targets. The Company was in compliance with all financial covenants as of September 30, 2010. The agreement also includes subjective acceleration clauses which permit Silicon Valley Bank to accelerate the due date under certain circumstances, including, but not limited to, material adverse effects on the Company s financial status or otherwise. Any non-compliance by the Company under the terms of debt arrangements could result in an event of default under the Silicon Valley Bank loan, which, if not cured, could result in the acceleration of this debt.

Loan and Security Agreement with Partners for Growth

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On April 14, 2010, the Company entered into a loan and security agreement with Partners for Growth III, L.P. (PFG). The agreement provides that PFG will make loans to the Company up to \$4,000. The agreement has a maturity date of April 14, 2015. The loans bear interest at a floating per annum rate equal to 2.75% above Silicon Valley Bank s prime rate, and such interest is payable monthly. The principal balance of and any accrued and unpaid interest on any notes are due on the maturity date and may not be prepaid by the Company at any time in whole or in part.

Under the agreement, PFG provided the Company with an initial loan of \$1,500 on April 15, 2010. In addition, for a period of one year until April 14, 2011, the Company may request up to \$2,500 of additional proceeds from time to time, in minimum increments of \$250. After this period, the Company may only request additional proceeds (in increments of not less than \$250) set forth in the debt agreement with PFG only to the extent of any aggregate principal amount converted into the Company s common stock through an optional conversion or mandatory conversion. At any time prior to the maturity date, PFG may at its option convert any amount into the Company s common stock at the conversion price set forth in each note, which conversion price will be subject to adjustment upon certain events as

provided in such note. The initial note has a conversion price of \$5.43, which equaled the ten-day volume weighted average price per share of the Company s common stock prior to the date of the agreement. The Company may also effect at any time a mandatory conversion of amounts, subject to certain terms, conditions and limitations provided in the agreement, including a requirement that the ten-day volume weighted average price of the Company s common stock prior to the date of conversion is at least 15% greater than the conversion price. The Company may reduce the conversion price to a price that represents a 15% discount to the ten-day volume weighted average price of our common stock to satisfy this condition and effect a mandatory conversion.

The loans are secured by certain of the Company s assets, and the agreement contains customary covenants limiting the Company s ability to, among other things, incur debt or liens, make certain investments and loans, effect certain redemptions of and declare and pay certain dividends on its stock, permit or suffer certain change of control transactions, dispose of collateral, or change the nature of its business. In addition, the PFG loan and security agreement contains financial covenants requiring the Company to maintain certain liquidity and fixed charge coverage ratios, and certain three-month EBITDA targets. The Company was in compliance with all financial covenants at September 30, 2010. If the Company does not comply with the various covenants, PFG may, subject to various customary cure rights, decline to provide additional loans, require amortization of the loan over its remaining term, or require the immediate payment of all amounts outstanding under the loan and foreclose on any or all collateral, depending on which financial covenants are not maintained.

In connection with the execution of the PFG loan and security agreement, the Company issued a warrant to PFG on April 14, 2010, which allows PFG to purchase 147,330 shares of the Company s common stock at a price per share of \$5.43, which price was based on the ten-day volume weighted average price per share of the Company s common stock prior to the date of the agreement. The warrant vests with respect to 50% on the issue date, and thereafter, vests pro rata from time to time according to a percentage equal to (a) the additional loans actually drawn until April 14, 2011, divided by (b) \$2,500. The warrant expires on the fifth anniversary of the issue date, subject to earlier expiration in accordance with the terms. The balance outstanding on the convertible loan at September 30, 2010 was \$1,341, net of the unamortized discount associated with the warrants.

As of September 30, 2010, debt maturities (including debt discount) were as follows:

Nine months ending June 30, 2011	\$ 3,680
2012	3,812
2013	3,474
Total	\$ 10,966
Less: Current Maturities	(4,600)
Long-term debt	\$ 6,366

### 5. Stock Options and Restricted Stock Awards

The Company has a 2007 Equity Incentive Plan (the 2007 Plan ), under which options to purchase common stock and restricted stock awards have been granted to employees, directors and consultants at exercise prices determined by the board of directors; and a 1991 Stock Option Plan (the 1991 Plan ) and a 2003 Stock Option Plan (the

2003 Plan ) (the 2007 Plan, the 1991 Plan and the 2003 Plan collectively, the Plans ). The 1991 Plan and 2003 Plan permitted the granting of incentive stock options and nonqualified options. A total of 485,250 shares of common stock were originally reserved for issuance under the 1991 Plan, but with the execution of the 2003 Plan no additional options are available for grant under the 1991 Plan. A total of 2,458,600 shares of common stock were originally reserved for issuance under the 2003 Plan but with the approval of the 2007 Plan no additional options are available for grant under the 2003 Plan, but with the approval of the 2007 Plan no additional options are available for grant under the 2003 Plan originally allowed for the granting of up to 1,941,000 shares of common stock as approved by the board of directors in the form of nonqualified or incentive stock options, restricted stock awards, restricted stock unit awards, performance share awards, performance unit awards or stock appreciation rights to officers, directors, consultants and employees of the Company. The Plan was amended in February 2009 to increase

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the number of authorized shares to 2,509,969. The amended 2007 Plan includes a renewal provision whereby the number of shares shall automatically be increased on the first day of each fiscal year ending July 1, 2017, by the lesser of (i) 970,500 shares, (ii) 5% of the outstanding common shares on such date, or (iii) a lesser amount determined by the board of directors. On July 1, 2010, the number of shares available for grant was increased by 757,427 under the 2007 Plan renewal provision. The Company also maintains the 2006 Equity Incentive Plan (the 2006 Plan ), relating to Replidyne activity prior to the merger in February 2009. A total of 794,641 shares were originally reserved under the 2006 Plan, but effective with the merger no additional options will be granted under it.

All options granted under the Plans become exercisable over periods established at the date of grant. The option exercise price is generally based upon the market price for the Company s common stock on the date of grant. In addition, the Company has granted nonqualified stock options to a director outside of the Plans.

Stock option activity for the three months ended September 30, 2010 is as follows:

	Number of Options(a)	A	Weighted Average Exercise Price	
Options outstanding at June 30, 2010	3,356,993	\$	10.49	
Options forfeited or expired	(51,591)	\$	12.34	
Options outstanding at September 30, 2010	3,305,402	\$	10.47	

(a) Includes the effect of options granted, exercised, forfeited or expired from the 1991 Plan, 2003 Plan, 2007 Plan, and options granted outside the stock option plans described above.

Options typically vest over two to three years. An employee s unvested options are forfeited when employment is terminated; vested options must be exercised at or within 90 days of termination to avoid forfeiture. The Company determines the fair value of options using the Black-Scholes option pricing model. The estimated fair value of options, including the effect of estimated forfeitures, is recognized as expense on a straight-line basis over the options vesting periods.

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 range 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. Restricted stock award activity for the three months ended September 30, 2010 is as follows:

	Number of Shares	Weighted Average Fair Value		
Restricted stock awards outstanding at June 30, 2010	1,105,883	\$	7.69	
Restricted stock awards granted	617,630	\$	4.77	
Restricted stock awards forfeited	(56,401)	\$	6.78	
Restricted stock awards vested	(229,448)	\$	4.19	
Restricted stock awards outstanding at September 30, 2010	1,437,394	\$	6.40	

#### 6. Texas Production Facility

Effective on September 9, 2009, the Company entered into an agreement with the Pearland Economic Development Corporation (the PEDC) for the construction and lease of an approximately 46,000 square foot production facility located in Pearland, Texas. The facility will primarily serve as an additional manufacturing location for the Company.

The lease agreement provides that the PEDC will lease the facility and the land immediately surrounding the facility to the Company for an initial term of ten years, which began April 1, 2010. Monthly fixed rent payments are \$35 for each of the first five years of the initial term and \$38 for each of the last five years of the initial term. The Company is also responsible for paying the taxes and operating expenses related to the facility. The lease has been classified as an operating lease for financial statement purposes. Upon an event of default under the agreement, the

Company will be liable for the difference between the balance of the rent owed for the remainder of the term and the fair market rental value of the leased premises for such period.

The Company has the option to renew the lease for up to two additional periods of five years each. If the Company elects to exercise one or both of these options, the rent for such extended terms will be set at the prevailing market rental rates at such times, as determined in the agreement. After the commencement date and until shortly before the tenth anniversary of the commencement date, the Company will have the option to purchase all, but not less than all, of the leased premises at fair market value, as determined in the agreement. Further, within six years of the commencement date and subject to certain conditions, the Company has options to cause the PEDC to make two additions or expansions to the facility of a minimum of 34,000 and 45,000 square feet each.

The Company and the PEDC previously entered into a Corporate Job Creation Agreement dated June 17, 2009. The Job Creation Agreement provided the Company with \$2,975 in net cash incentive funds. The Company believes it will be able to comply with the conditions specified in the grant agreement. The PEDC will provide the Company with an additional \$1,700 of net cash incentive funds in the following amounts and upon achievement of the following milestones:

\$1,020, upon the hiring of the 75th full-time employee at the facility; and

\$680, upon the hiring of the 125<sup>th</sup> full-time employee at the facility.

In order to retain all of the cash incentives, beginning one year and 90 days after the commencement date, the Company must not have fewer than 25 full-time employees at the facility for more than 120 consecutive days. Failure to meet this requirement will result in an obligation to make reimbursement payments to the PEDC as outlined in the agreement. The Company will not have any reimbursement requirements after 60 months from the effective date of the agreement.

The Job Creation Agreement also provides the Company with a net \$1,275 award, of which \$510 will be funded by a grant from the State of Texas for which the Company has applied through the Texas Enterprise Fund program. As of September 30, 2010, \$340 has been received. The PEDC has committed, by resolution, to guarantee the award and will make payment to the Company for the remaining \$765. As of September 30, 2010, \$255 has been received. The grant from the State of Texas is subject to reimbursement if the Company fails to meet certain job creation targets through 2014 and maintain these positions through 2020.

The Company has presented the net cash incentive funds as a current and long-term liability on the balance sheet. The liabilities will be reduced over a 60 month period and recorded as an offset to expenditures incurred using a systematic methodology that is intended to reduce the majority of the liabilities in the first 24 months of the agreement. As of September 30, 2010, \$327 in expenses has reduced the deferred grant incentive liabilities, resulting in a remaining current liability of \$1,535 and long-term liability of \$2,218.

### 7. Commitment and Contingencies

## ev3 Legal Proceedings

The Company was a party to a legal proceeding with ev3 Inc., ev3 Endovascular, Inc. and FoxHollow Technologies, Inc., together referred to as the Plaintiffs, which filed a complaint on December 28, 2007 in the Ramsey County District Court for the State of Minnesota against the Company and former employees of FoxHollow currently employed by the Company, which complaint was subsequently amended.

On October 27, 2010, the Company entered into a settlement agreement with the Plaintiffs. The agreement dismisses all claims and counterclaims in the legal proceeding between the two parties, with neither party admitting any liability or wrongdoing. Pursuant to the agreement, the Company paid ev3 \$1,000, in the form of \$750 cash and a \$250 promissory note. The promissory note bears interest at 3.5% per annum, with principal and cumulative interest due and payable on or before January 1, 2014. The Company has received insurance proceeds of \$500 related to the settlement, and has recorded a net expense of \$500 in selling, general, and administrative expenses related to the settlement during the three months ended September 30, 2010.

## 8. 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:

	Three Months Ended March 31,			
		2010	2009	
Numerator	¢	$(\mathbf{A} \mathbf{O} \mathbf{O})$	¢	$\langle \langle \mathbf{a} \mathbf{a} \mathbf{a} \rangle \rangle$
Net loss	\$	(4,268)	\$	(6,200)
Denominator				
Weighted average common shares basic Effect of dilutive stock options and warrants (a)(b)	15	,369,157	14	,516,843
Weighted average common shares outstanding diluted	15,369,157		14,516,84	
Net loss per common share basic and diluted	\$	(0.28)	\$	(0.43)

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- (a) At September 30, 2010 and 2009, 3,234,626 and 3,115,246 warrants, respectively, were outstanding. The effect of the shares that would be issued upon exercise of these warrants has been excluded from the calculation of diluted loss per share because those shares are anti-dilutive.
- (b) At September 30, 2010 and 2009, 3,305,402 and 3,650,296 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.

# 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 1. 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, 2010 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 interventional treatment systems for vascular disease. Our primary products, the Diamondback  $360^{\circ}$  PAD System (the Diamondback  $360^{\circ}$ ) and the Diamondback Predator  $360^{\circ}$  (the Predator  $360^{\circ}$ ), 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 treatment alternatives. We also are pursuing approval of our products for coronary use. We refer to the Diamondback  $360^{\circ}$  and the Predator  $360^{\circ}$  collectively in this report as the Diamondback Systems.

We were incorporated as Replidyne, Inc. in Delaware in 2000. On February 25, 2009, Replidyne, Inc. completed its business combination with Cardiovascular Systems, Inc., a Minnesota corporation (CSI-MN), in accordance with the terms of the Agreement and Plan of Merger and Reorganization, dated as of November 3, 2008 (the Merger Agreement). Pursuant to the Merger Agreement, CSI-MN continued after the merger as the surviving corporation and a wholly-owned subsidiary of Replidyne. Replidyne changed its name to Cardiovascular Systems, Inc. (CSI) and CSI-MN merged with and into CSI, with CSI continuing after the merger as the surviving corporation. These transactions are referred to herein as the merger. Replidyne was a biopharmaceutical company focused on discovering, developing, in-licensing and commercializing anti-infective products.

At the closing of the merger, Replidyne s net assets, as calculated pursuant to the terms of the Merger Agreement, were approximately \$36.6 million as adjusted. As of immediately following the effective time of the merger, former CSI stockholders owned approximately 80.2% of the outstanding common stock of the combined company, and Replidyne stockholders owned approximately 19.8% of the outstanding common stock of the combined company.

CSI was incorporated in Minnesota in 1989. From 1989 to 1997, we engaged in research and development on several different product concepts that were later abandoned. Since 1997, we have devoted substantially all of our resources to the development of the Diamondback Systems.

From 2003 to 2005, we conducted numerous bench and animal tests in preparation for application submissions to the FDA. We initially focused our testing on providing a solution for coronary in-stent restenosis, but later changed the focus to PAD. In 2006, we obtained an investigational device exemption from the FDA to conduct our pivotal OASIS 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° as a therapy in patients with PAD. We commenced commercial introduction of the Diamondback 360° in the United States in September 2007. We were granted 510(k) clearance of the Predator 360° in March 2009. We market the Diamondback 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 single-use catheter used in the Diamondback Systems with components purchased from third-party suppliers, as well as with components manufactured in-house. A control unit and guidewires are purchased from third-party suppliers.

As of September 30, 2010, we had an accumulated deficit of \$155.6 million. We expect our losses to continue but generally decline as revenue grows from continued commercialization activities, development of additional product enhancements, accumulation of clinical data on our products, and further regulatory approvals. To date, we have financed our operations primarily through the private placement of equity securities and completion of the merger.

### 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, investments, 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.

### **RESULTS OF OPERATIONS**

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

	Three Mon	Three Months Ended September 30, Percent		
	2010	2009	Change	
Revenues	\$ 18,165	\$ 15,198	19.5%	
Cost of goods sold	4,141	3,488	18.7	
Gross profit	14,024	11,710	19.8	
Expenses:				
Selling, general and administrative	15,496	14,856	4.3	
Research and development	2,422	2,781	(12.9)	
Total expenses	17,918	17,637	1.6	
Loss from operations	(3,894)	(5,927)	(34.3)	
Other (expense) income:				
Interest expense	(365)	(371)	(1.6)	
Interest income	7	98	(92.9)	
State income taxes	(16)			
Total other expense	(374)	(273)	37.0	
Net loss	\$ (4,268)	\$ (6,200)	(31.1)	

Comparison of Three Months Ended September 30, 2010 with Three Months Ended September 30, 2009

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*Revenues*. Revenues increased by \$3.0 million, or 19.5%, from \$15.2 million for the three months ended September 30, 2009 to \$18.2 million for the three months ended September 30, 2010. This increase was attributable to a \$2.4 million, or 17.8%, increase in sales of Diamondback Systems and a \$544,000, or 34.9%, increase in sales of supplemental products and other revenue. Supplemental products include our Viper product line and distribution partner products. Currently, all of our revenues are in the United States; however, we may potentially sell internationally in the future. 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, and generate clinical data.

*Cost of Goods Sold.* Cost of goods sold increased by \$653,000, or 18.7%, from \$3.5 million for the three months ended September 30, 2009 to \$4.1 million for the three months ended September 30, 2010. Cost of goods sold represents the cost of materials, labor and overhead for single-use catheters, guidewires, control units, and other ancillary products. Cost of goods sold for the three months ended September 30, 2010 and 2009 includes \$277,000 and \$129,000, respectively, for stock-based compensation. We expect that the gross margin will stay fairly consistent in the future as sales volumes increase, although quarterly fluctuations could occur based on 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 \$640,000, or 4.3%, from \$14.9 million for the three months ended September 30, 2009 to \$15.5 million for the three months ended September 30, 2010. The primary reasons for the increase included the building of our sales and marketing team, and a net settlement charge of \$500,000 on the ev3 lawsuit. Selling, general and administrative expenses for the three months ended September 30, 2010 and 2009

includes \$1.4 million and \$1.8 million, respectively, for stock-based compensation. We expect our selling, general and administrative expenses to increase in the future due primarily to the costs associated with expanding our sales and marketing organization to further commercialize our products, but at a rate less than revenue growth.

*Research and Development Expenses.* Research and development expenses decreased by \$359,000, or 12.9%, from \$2.8 million for the three months ended September 30, 2009 to \$2.4 million for the three months ended September 30, 2010. Research and development expenses relate to specific projects to improve our product or expand into new markets, such as the development of new versions of the Diamondback Systems, shaft designs, crown designs, and PAD and coronary clinical trials. The reduction in these expenses related to the decreased numbers and sizes of development projects, as well as the timing of those projects. Research and development expenses for the three months ended September 30, 2010 and 2009 includes \$315,000 and \$281,000, respectively, for stock-based compensation. As we continue to expand our product portfolio within the market for the treatment of peripheral arteries and leverage our core technology into the coronary market, we generally expect to incur research and development expenses at amounts similar to the three months ended September 30, 2010. Fluctuations could occur based on the number of projects and studies and the timing of expenditures.

*Interest Expense*. Interest expense decreased by \$6,000, from \$371,000 for the three months ended September 30, 2009 to \$365,000 for the three months ended September 30, 2010. These amounts consisted primarily of interest on outstanding debt facilities and amortization of the debt discount.

*Interest Income.* Interest income decreased by \$91,000, from \$98,000 for the three months ended September 30, 2009 to \$7,000 for the three months ended September 30, 2010. The decrease was primarily due to the auction rate securities being redeemed by the issuers or repurchased by UBS AG at par value on or prior to June 30, 2010. **NON-GAAP FINANCIAL INFORMATION** 

To supplement our consolidated condensed 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,			
		2010		2009
Loss from operations	\$	(3,894)	\$	(5,927)
Add: Stock-based compensation		1,989		2,221
Add: Depreciation and amortization		164		136
Adjusted EBITDA	\$	(1,741)	\$	(3,570)

The improvement in Adjusted EBITDA of \$1.8 million, or 51.2%, is primarily the result of improvement in the loss from operations. The loss from operations was significantly impacted by increases in revenue and gross margin, partially offset by an increase in operating expenses, as discussed above.

# 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. A form of Adjusted EBITDA is also used to measure performance in our financial covenants as required by Silicon Valley Bank and Partners for Growth.

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 measures 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 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 measures 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.

## LIQUIDITY AND CAPITAL RESOURCES

We had cash and cash equivalents of \$22.0 million and \$23.7 million at September 30, 2010 and June 30, 2010, respectively. During the three months ended September 30, 2010, net cash used in operations amounted to \$1.4 million. As of September 30, 2010, we had an accumulated deficit of \$155.6 million. We have historically funded our operating losses primarily from the issuance of common and preferred stock, convertible promissory notes, and debt.

### Loan and Security Agreement with Silicon Valley Bank

On March 29, 2010, we entered into an amended and restated loan and security agreement with Silicon Valley Bank. The agreement includes a \$10.0 million term loan and a \$15.0 million line of credit. The terms of each of these loans are as follows:

The \$10.0 million term loan has a fixed interest rate of 9.0% and a final payment amount equal to 1.0% of the loan amount due at maturity. This term loan has a 36 month maturity, with repayment terms that include interest only payments during the first six months followed by 30 equal principal

# and interest payments. This term loan also includes

an acceleration provision that requires us to pay the entire outstanding balance, plus a penalty ranging from 1.0% to 3.0% of the principal amount, upon prepayment or the occurrence and continuance of an event of default. In connection with entering into the agreement, the Company amended a warrant previously granted to Silicon Valley Bank. The warrant provides an option to purchase 8,493 shares of common stock at an exercise price of \$5.48 per share. This warrant is immediately exercisable and expires ten years after the date of the amendment. The balance outstanding on the term loan at September 30, 2010 was \$9.6 million, net of the unamortized discount associated with the warrants.

The \$15.0 million line of credit has a two year maturity and a floating interest rate equal to Silicon Valley Bank s prime rate, plus 2.0%, with an interest rate floor of 6.0%. Interest on borrowings is due monthly and the principal balance is due at maturity. Borrowings on the line of credit are based on (a) 80% of eligible domestic receivables, plus (b) the lesser of 40% of eligible inventory or 25% of eligible domestic receivables or \$2.5 million, minus (c) to the extent in effect, certain loan reserves as defined in the agreement. Accounts receivable receipts are deposited into a lockbox account in the name of Silicon Valley Bank. The accounts receivable line of credit is subject to non-use fees, annual fees, and cancellation fees. The agreement provides that initially 50% of the outstanding principal balance of the \$10.0 million term loan reduces available borrowings under the line of credit. Upon the achievement of certain financial covenants, the amount reducing available borrowings will be reduced to zero. There was not an outstanding balance on the line of credit at September 30, 2010.

Borrowings from Silicon Valley Bank are secured by all of our assets. The borrowings are subject to prepayment penalties and financial covenants, including maintaining certain liquidity and fixed charge coverage ratios and certain three-month EBITDA targets. We were in compliance with all financial covenants as of September 30, 2010. The agreement also includes subjective acceleration clauses which permit Silicon Valley Bank to accelerate the due date under certain circumstances, including, but not limited to, material adverse effects on our financial status or otherwise. Any non-compliance by us under the terms of our debt arrangements could result in an event of default under the Silicon Valley Bank loan, which, if not cured, could result in the acceleration of this debt.

Loan and Security Agreement with Partners for Growth

On April 14, 2010, we entered into a loan and security agreement with Partners for Growth III, L.P. (PFG). The agreement provides that PFG will make loans to us up to \$4.0 million. The agreement has a maturity date of April 14, 2015. The loans bear interest at a floating per annum rate equal to 2.75% above Silicon Valley Bank s prime rate, and such interest is payable monthly. The principal balance of and any accrued and unpaid interest on any notes are due on the maturity date and may not be prepaid by us at any time in whole or in part.

Under the agreement, PFG provided us with an initial loan of \$1.5 million on April 15, 2010. In addition, for a period of one year until April 14, 2011, we may request up to \$2.5 million of additional proceeds from time to time, in minimum increments of \$250,000. After this period, we may only request additional proceeds (in increments of not less than \$250,000) equal to the aggregate principal amount converted into our common stock through an optional conversion or mandatory conversion. At any time prior to the maturity date, PFG may at its option convert any amount into our common stock at the conversion price set forth in each note, which conversion price will be subject to adjustment upon certain events as provided in such note. The initial agreement has a conversion price of \$5.43, which equaled the ten-day volume weighted average price per share of our common stock prior to the date of the agreement. We may also effect at any time a mandatory conversion of amounts, subject to certain terms, conditions and limitations provided in the agreement, including a requirement that the ten-day volume weighted average price of our common stock prior to the date of conversion is at least 15% greater than the conversion price. We also may reduce the conversion price to a price that represents a 15% discount to the ten-day volume weighted average price of our common stock to satisfy this condition and effect a mandatory conversion.

The loans are secured by certain of our assets, and the agreement contains customary covenants limiting our ability to, among other things, incur debt or liens, make certain investments and loans, effect certain redemptions of and declare and pay certain dividends on our stock, permit or suffer certain change of control transactions, dispose of

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collateral, or change the nature of our business. In addition, the PFG loan and security agreement contains financial covenants requiring us to maintain certain liquidity and fixed charge coverage ratios, and certain three-month EBITDA targets. We were in compliance with all financial covenants as of September 30, 2010. If we do not comply with the various covenants, PFG may, subject to various customary cure rights, decline to provide additional loans, require amortization of the loan over its remaining term, or require the immediate payment of all amounts outstanding under the loan and foreclose on any or all collateral, depending on which financial covenants are not maintained.

In connection with the execution of the PFG loan and security agreement, we issued a warrant to PFG on April 14, 2010, which allows PFG to purchase 147,330 shares of our common stock at a price per share of \$5.43, which price was based on the ten-day volume weighted average price per share of our common stock prior to the date of the agreement. The warrant vests with respect to 50% on the issue date, and thereafter, vests pro rata from time to time according to a percentage equal to (a) the additional loans actually drawn until April 14, 2011, divided by (b) \$2.5 million. The warrant expires on the fifth anniversary of the issue date, subject to earlier expiration in accordance with the terms. The balance outstanding on the convertible loan at September 30, 2010 was \$1.3 million, net of the unamortized discount associated with the warrants.

*Cash and Cash Equivalents.* Cash and cash equivalents was \$22.0 million at September 30, 2010 and \$23.7 million at June 30, 2010. The decrease is primarily attributable to net cash used in operating activities during the three months ended September 30, 2010.

*Operating Activities.* Net cash used in operating activities improved 30% to \$1.4 million from \$2.0 million for the three months ended September 30, 2010 and, 2009, respectively. For the three months ended September 30, 2010 and 2009, we had a net loss of \$4.3 million and \$6.2 million, respectively. Changes in working capital accounts had a favorable effect on the net cash used in both periods. Significant changes in working capital during these periods included:

Cash (used in) provided by accounts receivable of \$(1.2) million and \$293,000 during the three months ended September 30, 2010 and 2009, respectively. For the three months ended September 30, 2010, cash (used in) accounts receivable was primarily due to timing and growth of revenue, a receivable for estimated insurance proceeds associated with the ev3 lawsuit settlement of \$500,000, and a receivable of \$510,000 representing additional grants for the Texas facility. For the three months ended September 30, 2009, cash provided by accounts receivable was due to lower revenues.

Cash (used in) inventories of \$(137,000) and \$(713,000) during the three months ended September 30, 2010 and 2009, respectively. For both periods, cash (used in) inventories was primarily due to the timing of inventory purchases and sales.

Cash (used in) prepaid expenses and other current assets of \$(326,000) and \$(394,000) during the three months ended September 30, 2010 and 2009, respectively. For both periods, cash provided by prepaid expenses and other current assets was primarily due to payment timing of vendor deposits and other expenditures.

Cash provided by (used in) accounts payable of \$1.7 million and \$(383,000) during the three months ended September 30, 2010 and 2009, respectively. For the three months ended September 30, 2010, cash provided by accounts payable was due to timing of purchases, vendor payments, and \$750,000 payable to ev3 as part of the lawsuit settlement. For the three months ended September 30, 2010, cash (used in) accounts payable was due to timing of purchases.

Cash provided by accrued expenses and other liabilities of \$370,000 and \$3.0 million during the three months ended September 30, 2010 and 2009, respectively. For the three months ended September 30, 2010, cash provided by accrued expenses and other liabilities was primarily due to timing of payments. For the three months ended September 30, 2009, cash provided by accrued expenses and other liabilities was primarily due to receipt of \$3.5 million in net cash incentives under the agreement to establish a manufacturing facility in Texas.

*Investing Activities.* Net cash (used in) investing activities was \$(320,000) and \$(80,000) for the three months ended September 30, 2010 and 2009, respectively. For the three months ended September 30, 2009, we sold investments in the amount of \$100,000. The balance of cash (used in) investing activities related to the purchase of property and equipment and patents. Purchases of property and equipment and patents used cash of \$(320,000) and \$(180,000) for the three months ended September 30, 2010 and 2009, respectively.

*Financing Activities*. Net cash (used in) financing activities was \$(590,000) in the three months ended September 30, 2009. Cash provided by financing activities during this period included:

exercise of stock options and warrants of \$285,000.

Cash used in financing activities in these periods included:

payment of long-term debt of \$875,000.

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, and market and regulatory developments. As of September 30, 2010, we believe our current cash and cash equivalents and available debt will be sufficient to fund working capital requirements, capital expenditures and operations for at least the next 12 months. 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.

# INFLATION

We do not believe that inflation has 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.

## **RECENT ACCOUNTING PRONOUNCEMENTS**

In January 2010, the FASB issued further guidance regarding additional disclosures relating to fair value of transfers in and out of input Levels 1 and 2 and for activity in Level 3 and clarifies certain other existing disclosure requirements. This guidance had no impact on our consolidated financial position, results of operations or cash flows for the three months ended September 30, 2010.

In October 2009, the FASB issued guidance providing principles for allocation of consideration among multiple-elements, and accounting for separate deliverables under such an arrangement. The guidance introduces an estimated selling price method for valuing the elements of a bundled arrangement if vendor-specific objective evidence or third-party evidence of selling price is not available, and significantly expands related disclosure requirements. This standard is effective on a prospective basis for revenue arrangements entered into or materially modified in fiscal years beginning on or after June 15, 2010. Alternatively, adoption may be on a retrospective basis, and early application is permitted. We adopted this guidance on July 1, 2010, and it had no impact on our consolidated financial position, results of operations or cash flows for the three months ended September 30, 2010.

# 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 approval of our product for coronary use; our expectation that our losses will continue but generally decline; our plans to continue to expand our sales and marketing efforts; our expectation of increased revenue, and selling, general and administrative expenses; the possibility of selling our products internationally in the future; our expectation that research and development expenses for the remainder of the fiscal year will be incurred at a similar rate than for the three months ended September 30, 2010; our expectation that gross margin will stay fairly consistent; the sufficiency of our current and anticipated financial resources; and our belief that our current cash and cash equivalents and available debt will be sufficient to fund working capital requirements, capital expenditures and operations for the foreseeable future.

In some cases, you can identify forward-looking statements by the following words: anticipate, believe. continue. estimate, may, could, expect, intend, ongoing, plan, potential, predict, project, should, will. 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; the experience of physicians regarding the effectiveness and reliability of the Diamondback 360°; success of our clinical trials; competition from other devices; unanticipated developments affecting our estimates regarding expenses, future revenues and capital requirements; our inability to expand our sales and marketing organization; 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 general economic conditions. These and additional risks and uncertainties are described more fully in our Form 10-K filed with the SEC on September 28, 2010. Copies of filings made with the SEC are available through the SEC s electronic data gathering analysis and retrieval system (EDGAR) at <u>www.sec.gov</u>.

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 activities 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 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, 2010 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.

## **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, 2010. 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 in ensuring that information relating to the Company required to be disclosed in the reports that the Company files or submits under the Exchange Commission's rules and forms, including ensuring that such information is accumulated and communicated to the Company's management, including the Chief Executive Officer and the Chief Financial Officer, as appropriate to allow timely decisions regarding required disclosure.

## **Changes in Internal Control Over Financial Reporting**

There were no changes in our internal controls 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, 2010 that have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

# PART II. OTHER INFORMATION ITEM 1. LEGAL PROCEEDINGS

Refer to Part I, Item 3 (Legal Proceedings) of the Company s Annual Report on Form 10-K for the year ended June 30, 2010.

On October 27, 2010, we entered into a settlement agreement with ev3, Inc., ev3 Endovascular, Inc., FoxHollow Technologies, Inc., Tyco Healthcare Group LP d/b/a Covidien. The agreement dismisses all claims and counterclaims in the legal proceeding between the two parties, with neither party admitting any liability or wrongdoing. Pursuant to the agreement, we paid ev3 \$1,000,000, in the form of \$750,000 cash and a \$250,000 promissory note. The promissory note bears interest at 3.5% per annum, with principal and cumulative interest due and payable on or before January 1, 2014. We received insurance proceeds of \$500,000 related to the settlement, and recorded a net expense of \$500,000 in selling, general, and administrative expenses related to the settlement during the three months ended September 30, 2010.

# **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, 2010 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. Although we are not aware of any other factors that we currently anticipate will cause our forward-looking statements to differ materially from our future actual results, or materially affect the Company s 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 5. OTHER INFORMATION None.
 ITEM 6. EXHIBITS

 (a) Exhibits See Exhibit Index on page following signatures

## SIGNATURES

Pursuant to the requirements of Section 13 or 15(d) of the Securities Exchange Act of 1934, the Company has duly caused this Report to be signed on its behalf by the undersigned, thereunto duly authorized.

Dated: November 12, 2010

CARDIOVASCULAR SYSTEMS, INC.

By /s/ David L. Martin David L. Martin President and Chief Executive Officer (Principal Executive Officer)

By /s/ Laurence L. Betterley Laurence L. Betterley Chief Financial Officer (Principal Financial and Accounting Officer) 21

## EXHIBIT INDEX CARDIOVASCULAR SYSTEMS, INC. FORM 10-Q

#### Exhibit No. Description 10.1 Summary of Fiscal Year 2011 Executive Officer Base Salaries. (1) 10.2 \* Summary of Fiscal Year 2011 Executive Officer Annual Cash Incentive Compensation Plan. 10.3\* Settlement Agreement among ev3, Inc., ev3 Endovascular, Inc., FoxHollow Technologies, Inc., Tyco Healthcare Group LP d/b/a Covidien, Cardiovascular Systems, Inc., Aaron Lew, Paul Tyska, Sean Collins, David Gardner, Michael Micheli, Kevin Moore, Steve Pringle, Jason Proffitt, Thadd Taylor and Ren Treanor-Sarria, dated October 29, 2010. Certification of President and Chief Executive Officer Pursuant to Section 302 of the Sarbanes-Oxley 31.1\* Act of 2002. 31.2\* Certification of Chief Financial Officer Pursuant to Section 302 of the Sarbanes-Oxley Act of 2002. Certification of President and Chief Executive Officer Pursuant to Section 906 of the Sarbanes-Oxley 32.1\* Act of 2002. 32.2\* Certification of Chief Financial Officer Pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.

\* Filed herewith.

Compensatory plan or agreement.

(1) Previously filed with the SEC as an Exhibit to and incorporated herein by reference from the Company s Annual Report on Form 10-K filed on September 28, 2010.