

Cardiogenesis Corp /CA  
Form 10-Q  
November 05, 2010

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**UNITED STATES SECURITIES AND EXCHANGE COMMISSION**  
**Washington, D.C. 20549**  
**FORM 10-Q**

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

**For the quarterly period ended September 30, 2010.**

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

**For the transition period from \_\_\_\_\_ to \_\_\_\_\_**  
**Commission file number 0-28288**

**CARDIOGENESIS CORPORATION**  
(Exact name of registrant as specified in its charter)

**California**

**77-0223740**

(State of incorporation or organization)

(I.R.S. Employer  
Identification Number)

**11 Musick**

**Irvine, California 92618**

(Address of principal executive offices)

**(949) 420-1800**

(Issuer's telephone number)

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:

Large accelerated filer ☐ Accelerated filer ☐ Non-accelerated filer ☐ Smaller reporting  
o company ☒

(Do not check if a 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 ☒

As of October 31, 2010, there were 46,691,249 shares of the registrant's common stock, no par value, outstanding.



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**PART I**  
**FINANCIAL INFORMATION**

**Item 1. Financial Statements**

**CARDIOGENESIS CORPORATION**  
**CONDENSED CONSOLIDATED BALANCE SHEETS**  
**(in thousands)**

|                                                                                                       | <b>September<br/>30,<br/>2010<br/>(unaudited)</b> | <b>December<br/>31,<br/>2009<br/>(audited)</b> |
|-------------------------------------------------------------------------------------------------------|---------------------------------------------------|------------------------------------------------|
| <b>ASSETS</b>                                                                                         |                                                   |                                                |
| Current assets:                                                                                       |                                                   |                                                |
| Cash and cash equivalents                                                                             | \$ 2,139                                          | \$ 2,568                                       |
| Accounts receivable, net of allowance for doubtful accounts of \$10 and \$6, respectively             | 1,137                                             | 933                                            |
| Inventories                                                                                           | 768                                               | 914                                            |
| Prepays and other current assets                                                                      | 462                                               | 253                                            |
| Total current assets                                                                                  | 4,506                                             | 4,668                                          |
| Property and equipment, net                                                                           | 248                                               | 341                                            |
| Other assets, net                                                                                     | 9                                                 | 9                                              |
| Total assets                                                                                          | \$ 4,763                                          | \$ 5,018                                       |
| <b>LIABILITIES AND SHAREHOLDERS' EQUITY</b>                                                           |                                                   |                                                |
| Current liabilities:                                                                                  |                                                   |                                                |
| Accounts payable                                                                                      | \$ 382                                            | \$ 127                                         |
| Accrued salaries and related                                                                          | 559                                               | 604                                            |
| Accrued liabilities                                                                                   | 362                                               | 299                                            |
| Deferred revenue                                                                                      | 704                                               | 744                                            |
| Note payable                                                                                          | 177                                               | 88                                             |
| Current portion of capital lease obligations                                                          | 10                                                | 9                                              |
| Total current liabilities                                                                             | 2,194                                             | 1,871                                          |
| Capital lease obligations, less current portion                                                       | 5                                                 | 14                                             |
| Total liabilities                                                                                     | 2,199                                             | 1,885                                          |
| Commitments and contingencies                                                                         |                                                   |                                                |
| Shareholders' equity:                                                                                 |                                                   |                                                |
| Preferred stock:                                                                                      |                                                   |                                                |
| no par value; 5,000 shares authorized; none issued and outstanding                                    |                                                   |                                                |
| Common stock:                                                                                         |                                                   |                                                |
| no par value; 75,000 shares authorized; 45,888 and 45,549 shares issued and outstanding, respectively | 174,387                                           | 174,217                                        |
| Accumulated deficit                                                                                   | (171,823)                                         | (171,084)                                      |

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|                                            |    |       |    |       |
|--------------------------------------------|----|-------|----|-------|
| Total shareholders' equity                 |    | 2,564 |    | 3,133 |
| Total liabilities and shareholders' equity | \$ | 4,763 | \$ | 5,018 |

See accompanying notes.

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**CARDIOGENESIS CORPORATION**  
**CONDENSED CONSOLIDATED STATEMENTS OF**  
**OPERATIONS**  
(in thousands, except per share amounts)  
(unaudited)

|                                        | <b>Three months ended<br/>September 30,</b> |             | <b>Nine months ended<br/>September 30,</b> |             |
|----------------------------------------|---------------------------------------------|-------------|--------------------------------------------|-------------|
|                                        | <b>2010</b>                                 | <b>2009</b> | <b>2010</b>                                | <b>2009</b> |
| Net revenues                           | \$ 2,764                                    | \$ 2,134    | \$ 8,426                                   | \$ 7,222    |
| Cost of revenues                       | 454                                         | 380         | 1,363                                      | 1,307       |
| Gross profit                           | 2,310                                       | 1,754       | 7,063                                      | 5,915       |
| Operating expenses:                    |                                             |             |                                            |             |
| Research and development               | 272                                         | 379         | 830                                        | 1,013       |
| Sales and marketing                    | 1,443                                       | 1,363       | 4,728                                      | 4,104       |
| General and administrative             | 740                                         | 730         | 2,211                                      | 2,375       |
| Total operating expenses               | 2,455                                       | 2,472       | 7,769                                      | 7,492       |
| Operating loss                         | (145)                                       | (718)       | (706)                                      | (1,577)     |
| Other income (expense):                |                                             |             |                                            |             |
| Interest expense                       |                                             | (4)         | (3)                                        | (35)        |
| Interest income                        |                                             | 1           | 1                                          | 3           |
| Other non-operating expense            | (2)                                         | (20)        | (2)                                        | (20)        |
| Total other expense, net               | (2)                                         | (23)        | (4)                                        | (52)        |
| Loss before provision for income taxes | (147)                                       | (741)       | (710)                                      | (1,629)     |
| Provision for income taxes             | 7                                           | (2)         | 14                                         | 14          |
| Net loss                               | \$ (154)                                    | \$ (739)    | \$ (724)                                   | \$ (1,643)  |
| Net loss per share:                    |                                             |             |                                            |             |
| Basic                                  | \$ (0.00)                                   | \$ (0.02)   | \$ (0.02)                                  | \$ (0.04)   |
| Diluted                                | \$ (0.00)                                   | \$ (0.02)   | \$ (0.02)                                  | \$ (0.04)   |
| Weighted average shares outstanding:   |                                             |             |                                            |             |
| Basic                                  | 45,928                                      | 45,549      | 45,727                                     | 45,519      |
| Diluted                                | 45,928                                      | 45,549      | 45,727                                     | 45,519      |

See accompanying notes.

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**CARDIOGENESIS CORPORATION**  
**CONDENSED CONSOLIDATED STATEMENTS OF CASH FLOWS**  
(in thousands)  
(unaudited)

|                                                                                                                                     | <b>Nine months ended<br/>September 30,</b> |             |
|-------------------------------------------------------------------------------------------------------------------------------------|--------------------------------------------|-------------|
|                                                                                                                                     | <b>2010</b>                                | <b>2009</b> |
| Cash flows from operating activities:                                                                                               |                                            |             |
| Net loss                                                                                                                            | \$ (724)                                   | \$ (1,643)  |
| Adjustments to reconcile net loss to net cash used in operating activities:                                                         |                                            |             |
| Depreciation                                                                                                                        | 193                                        | 233         |
| Provision for doubtful accounts                                                                                                     | 4                                          | 10          |
| Stock-based compensation expense                                                                                                    | 203                                        | 156         |
| Changes in operating assets and liabilities:                                                                                        |                                            |             |
| Accounts receivable                                                                                                                 | (208)                                      | 379         |
| Inventories                                                                                                                         | 81                                         | 15          |
| Prepays and other current assets                                                                                                    | (10)                                       | 197         |
| Accounts payable                                                                                                                    | 255                                        | 138         |
| Accrued liabilities                                                                                                                 | 18                                         | (83)        |
| Deferred revenue                                                                                                                    | (40)                                       | 171         |
| Net cash used in operating activities                                                                                               | (228)                                      | (427)       |
| Cash flows from investing activities:                                                                                               |                                            |             |
| Acquisition of property and equipment                                                                                               | (35)                                       | (24)        |
| Proceeds from the sale of marketable securities                                                                                     |                                            | 75          |
| Net cash (used in) provided by investing activities                                                                                 | (35)                                       | 51          |
| Cash flows from financing activities:                                                                                               |                                            |             |
| Shares withheld to satisfy income tax withholding obligations                                                                       | (48)                                       |             |
| Payments on note payable                                                                                                            | (110)                                      | (18)        |
| Net proceeds from issuance of common stock from exercise of options and from stock purchased under the Employee Stock Purchase Plan |                                            | 10          |
| Payments on capital lease obligations                                                                                               | (8)                                        | (6)         |
| Net cash (used in) provided by in financing activities                                                                              | (166)                                      | (14)        |
| Net decrease in cash and cash equivalents                                                                                           | (429)                                      | (390)       |
| Cash and cash equivalents at beginning of period                                                                                    | 2,568                                      | 2,907       |
| Cash and cash equivalents at end of period                                                                                          | \$ 2,139                                   | \$ 2,517    |
| Supplemental schedule of cash flow information:                                                                                     |                                            |             |
| Interest paid                                                                                                                       | \$ 2                                       | \$ 2        |
| Taxes paid                                                                                                                          | \$ 12                                      | \$ 6        |

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Supplemental schedule of non-cash investing and financing activities:

|                                                           |        |        |
|-----------------------------------------------------------|--------|--------|
| Financing of insurance premiums under note payable        | \$ 199 | \$ 158 |
| Financing of property and equipment                       | \$     | \$ 12  |
| Reclassification of inventories to property and equipment | \$ 65  | \$ 165 |

See accompanying notes.

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**CARDIOGENESIS CORPORATION**

**NOTES TO UNAUDITED CONDENSED CONSOLIDATED FINANCIAL STATEMENTS**

**1. Nature of Operations:**

Cardiogenesis Corporation ( Cardiogenesis or the Company ) was founded in 1989 to design, develop, and distribute surgical lasers and single-use fiber optic laser delivery systems ( handpieces ) for the treatment of cardiovascular disease.

Cardiogenesis markets its products for sale primarily in the United States and operates in a single segment.

**2. Summary of Significant Accounting Policies:**

*Interim Financial Information:*

The accompanying unaudited condensed consolidated financial statements have been prepared by the Company in accordance with accounting principles generally accepted in the United States of America ( GAAP ) for interim financial information, and pursuant to the instructions to Form 10-Q and Article 8 of Regulation S-X promulgated by the Securities and Exchange Commission ( SEC ). Accordingly, they do not include all of the information and footnotes required by GAAP for complete financial statement presentation. In the opinion of management, all adjustments (consisting primarily of normal recurring accruals) considered necessary for a fair presentation have been included. The Company has evaluated subsequent events through the filing date of this Form 10-Q, and determined that no subsequent events have occurred that would require recognition in the condensed consolidated financial statements or disclosure in the notes thereto other than as disclosed in the accompanying notes. These unaudited condensed consolidated financial statements should be read in conjunction with the Company s audited consolidated financial statements and notes thereto for the year ended December 31, 2009, contained in the Company s Annual Report on Form 10-K, as filed with the SEC.

These unaudited condensed consolidated financial statements contemplate the realization of assets and the satisfaction of liabilities in the normal course of business. Cardiogenesis has incurred significant losses and as of September 30, 2010 it had an accumulated deficit of \$171.8 million. Management believes its cash balance as of September 30, 2010 and expected results of operations are sufficient to meet the Company s capital and operating requirements for the next 12 months.

However, the Company may require additional financing in the future if revenues are not as expected or the Company s costs exceed its estimates. In particular, the Company expects to incur significant costs in connection with its planned clinical trials for the PHOENIX handpiece and if the Company is not able to significantly increase its revenues, it will have to obtain additional financing to fund the clinical trials or abandon the clinical trials. There can be no assurance that the Company will be able to obtain additional debt or equity financing if and when needed or on terms acceptable to the Company. Any additional debt or equity financing may involve substantial dilution to the Company s shareholders, restrictive covenants or high interest costs. The failure to raise needed funds on sufficiently favorable terms could have a material adverse effect on the Company s business, operating results and financial condition. The Company s long term liquidity also depends upon its ability to increase revenues from the sale of its products and achieve consistent profitability. The failure to achieve these goals could have a material adverse effect on the business, operating results and financial condition.

*Net Earnings (Loss) Per Share:*

Basic earnings (loss) per share ( BEPS ) is computed by dividing the net income (loss) by the weighted average number of common shares outstanding for the period. Diluted earnings (loss) per share ( DEPS ) is computed giving effect to all dilutive potential common shares that were outstanding during the period. Dilutive potential common shares consist of incremental shares issuable upon the exercise of stock options and warrants using the treasury stock method. The computation of DEPS does not assume conversion, exercise or contingent exercise of securities that would have an anti-dilutive effect on earnings.

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For the three and nine months ended September 30, 2010, there were approximately 673,000 and 704,000 potentially dilutive shares, respectively, that were excluded from diluted loss per share as their effect would have been anti-dilutive for the periods then ended. For the three and nine months ended September 30, 2009, there were approximately 716,000 and 418,000 potentially dilutive shares, respectively.

### *Use of Estimates:*

The preparation of 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 periods. Actual results could differ from those estimates. Significant estimates made in preparing the consolidated financial statements include (but are not limited to) the determination of the allowance for bad debt, inventory reserves, valuation allowance relating to deferred tax assets, warranty reserve, the assessment of future cash flows in evaluating long-lived assets for impairment and assumptions used in fair value determination of stock-based compensation.

### *Risks and Concentrations:*

Cardiogenesis sells its products to hospitals and other healthcare providers primarily in the United States. Cardiogenesis performs ongoing credit evaluations of its customers and generally does not require collateral. Although Cardiogenesis maintains allowances for potential credit losses that it believes to be adequate, a payment default on a significant sale could materially and adversely affect its operating results and financial condition. At September 30, 2010 and December 31, 2009, no customer individually accounted for more than 10% of gross accounts receivable. For the three and nine month periods ended September 30, 2010 and September 30, 2009, no customer individually accounted for more than 10% of net revenues.

As of September 30, 2010, approximately \$969,000 of the Company's cash and cash equivalents were maintained in money market mutual funds, and approximately \$1,170,000 of the Company's cash and cash equivalents were maintained at a major financial institution in the United States. At times, deposits held with the financial institution may exceed the amount of insurance provided by the Federal Deposit Insurance Corporation (the "FDIC"), which provides deposit coverage with limits up to \$250,000 per owner through December 31, 2013. Generally, these deposits may be redeemed upon demand and, therefore, are believed to bear low risk.

After giving effect to the increased FDIC insurance, at September 30, 2010, the Company's uninsured cash totaled approximately \$1,985,000.

The Company outsources the manufacturing and assembly of its handpieces to a single contract manufacturer. The Company also outsources the manufacturing of its laser consoles to a different single contract manufacturer.

Certain components of laser consoles and fiber-optic handpieces are generally acquired from multiple sources. Other laser and fiber-optic components and subassemblies are purchased from single sources. Although the Company has identified alternative vendors, the qualification of additional or replacement vendors for certain components or services is a lengthy process. Any significant supply interruption would have a material adverse effect on the Company's ability to manufacture its products and, therefore, would harm its business. The Company intends to continue to qualify multiple sources for components that are presently single sourced.

### *Revenue Recognition:*

Cardiogenesis recognizes revenue on product sales upon shipment of the products when the price is fixed or determinable and when collection of sales proceeds is reasonably assured. Where purchase orders allow customers an acceptance period or other contingencies, revenue is recognized upon the earlier of acceptance or removal of the contingency.

Revenues from sales to distributors and agents are recognized upon shipment when there is evidence of an arrangement, delivery has occurred, the sales price is fixed or determinable and collection of the sales proceeds is reasonably assured. The contracts regarding these sales do not include any rights of return or price protection clauses.

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The Company, at times, will loan laser consoles to hospitals and charge an additional amount (the Premium) over the stated list price on its handpieces in exchange for the use of the laser console. In accordance with the accounting standards for leases, these arrangements are recorded as leases as they convey the right to use the laser console over the period of time the customers are purchasing handpieces. The loaned laser consoles are classified as operating leases and are transferred from inventory to property and equipment upon commencement of the loan. In addition, the Premium is considered contingent rent, and therefore, such amounts allocated to the lease of the laser console are recognized as revenue when the contingency is resolved. In these instances, the contingency is resolved upon the sale of the handpiece.

Cardiogenesis enters into contracts to sell its products and services and, while the majority of its sales agreements contain standard terms and conditions, there are agreements that contain multiple elements or non-standard terms and conditions. As a result, significant contract interpretation is sometimes required to determine the appropriate accounting, including whether the deliverables specified in a multiple element arrangement should be treated as separate units of accounting for revenue recognition purposes and, if so, how the contract value should be allocated among the deliverable elements and when to recognize revenue for each element. The Company recognizes revenue for multiple element arrangements, such as sales of laser consoles and handpieces, by allocating revenue for each respective element based on its selling price and when revenue recognition criteria for each element have been met.

In addition to the standard product warranty, the Company periodically offers extended warranties to its customers in the form of product maintenance services. Service agreements on its equipment are typically sold separately from the sale of the equipment. In accordance with the accounting standards for warranties, revenues on these service agreements are recognized ratably over the life of the agreement, typically one to three years.

*Segment Disclosures:*

The Company operates in one segment. The principal market for the Company's products is in the United States. International sales occur primarily in Europe, Mexico and Asia and amounted to approximately \$7,000 and \$47,000 for the three and nine months ended September 30, 2010, respectively. For the three and nine months ended September 30, 2009, the Company's international sales were \$4,000 and \$96,000, respectively. International sales represented less than 1% of total net revenues for both the three and nine months ended September 30, 2010 and less than 1% and approximately 1% of total net revenues for the three and nine months ended September 30, 2009, respectively. The majority of international sales are denominated in U.S. Dollars. All of the Company's long-lived assets are located in the United States.

*Recent Accounting Pronouncements:*

In September 2009, the Financial Accounting Standards Board (FASB) issued an update to its accounting guidance regarding multiple-deliverable revenue arrangements. The guidance addresses how to measure and allocate consideration to one or more units of accounting. Specifically, the guidance requires that consideration be allocated among multiple deliverables based on relative selling prices. The guidance establishes a selling price hierarchy of (1) vendor-specific objective evidence, (2) third-party evidence and (3) estimated selling price. This guidance is effective for annual periods beginning on or after June 15, 2010 but may be early adopted as of the beginning of an annual period. The Company adopted this guidance on January 1, 2010 and it did not have a material impact on its consolidated financial statements.

In January 2010, the FASB issued an update to its accounting guidance regarding fair value measurement and disclosure. The guidance affects the disclosures made about recurring and non-recurring fair value measurements. This guidance is effective for annual reporting periods beginning after December 15, 2009, except for the disclosures about purchases, sales, issuances and settlements in the roll forward of activity in Level 3 fair value measurements. Those disclosures are effective for fiscal years beginning after December 15, 2010. Early adoption is permitted. The Company is currently evaluating the impact that this guidance will have on its consolidated financial statements.

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Other recent accounting pronouncements issued by the FASB (including the Emerging Issues Task Force ( EITF )) and the American Institute of Certified Public Accountants did not, or are not believed by management to, have a material impact on the Company's present or future consolidated financial statements.

**3. Inventories:**

Inventories are stated at the lower of cost (first-in, first-out) or market and consist of the following (in thousands):

|                 | September<br>30,<br>2010<br>(unaudited) | December<br>31,<br>2009<br>(audited) |
|-----------------|-----------------------------------------|--------------------------------------|
| Raw materials   | \$ 115                                  | \$ 141                               |
| Work-in-process | 174                                     | 192                                  |
| Finished goods  | 479                                     | 581                                  |
| Total           | \$ 768                                  | \$ 914                               |

**4. Stock-Based Compensation:**

In accordance with the accounting standards for stock-based compensation, the Company recognizes all share-based payments to employees, including grants of employee stock options and restricted stock grants, based upon their fair values. The Company uses the Black-Scholes option pricing model to estimate the grant-date fair value of share-based awards with the fair value determined at the date of grant. The financial statement effect of forfeitures is estimated at the time of grant and revised, if necessary, if the actual effect differs from those estimates.

***Description of Plans***

The Company's stock option plans provide for grants of options to employees and directors of the Company to purchase the Company's shares at the fair value of such shares on the grant date (based on the closing price of the Company's common stock). The options vest immediately or up to four years beginning on the grant date and have a 10-year term. The terms of the option grants are determined by the Company's Board of Directors. As of September 30, 2010, the Company is authorized to issue up to an aggregate of 12,125,000 shares under these plans.

The Company's 1996 Employee Stock Purchase Plan (the ESPP) was adopted in April 1996 and amended in July 2005. A total of 1,500,000 common shares are reserved for issuance under the ESPP, as amended. The ESPP permits employees to purchase common shares at a price equal to the lower of 85% of the fair market value of the common stock at the beginning of each offering period or the end of each offering period. The ESPP has two offering periods, the first one from May 16 through November 15 and the second one from November 16 through May 15. Employee purchases are nonetheless limited to 15% of eligible cash compensation, and other restrictions regarding the amount of annual purchases also apply. The Company suspended the ESPP effective at the end of the November 16, 2008 offering period.

The Company has treated the ESPP as a compensatory plan.

***Summary of Assumptions and Activity***

The fair value of stock-based awards to employees and directors is calculated using the Black-Scholes option pricing model, even though the model was developed to estimate the fair value of freely tradable, fully transferable options without vesting restrictions, which differ significantly from the Company's stock options. The Black-Scholes model also requires subjective assumptions, including future stock price volatility and expected time to exercise, which greatly affect the calculated values. The expected term of options granted is derived from historical data on employee exercises and post-vesting employment termination behavior. The risk-free rate selected to value any particular grant is based on the U.S. Treasury rate that corresponds to the term of the grant effective as of the date of the grant. The expected volatility is based on the historical volatility of the Company's stock price. These factors could change in the future, affecting the determination of stock-based compensation expense in future periods.

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The weighted-average fair value of stock-based compensation is based on the single option valuation approach. Forfeitures are estimated and it is assumed no dividends will be declared. The estimated fair value of stock-based compensation awards to employees is amortized using the straight-line method over the vesting period of the options.

The Company's fair value calculations for stock-based compensation awards to employees under its stock option plans for the nine months ended September 30, 2010 and 2009 were based on the following assumptions:

|                         | <b>Nine Months Ended</b> |            |                  |            |
|-------------------------|--------------------------|------------|------------------|------------|
|                         | <b>September</b>         |            | <b>September</b> |            |
|                         | <b>30,</b>               |            | <b>30,</b>       |            |
|                         | <b>2010</b>              |            | <b>2009</b>      |            |
| Expected term           | 5.36                     | 5.56 years | 6.27             | 6.35 years |
| Expected volatility     | 96.05                    | 97.59%     | 97.6             | 105.51%    |
| Risk-free interest rate | 1.80                     | 2.53%      | 1.63             | 2.84%      |
| Expected dividend yield |                          |            |                  |            |

A summary of option activity as of September 30, 2010 and changes during the nine months then ended, is presented below (in thousands except per share data):

|                                                                | <b>Shares</b> | <b>Weighted<br/>Average<br/>Exercise<br/>Price</b> | <b>Weighted<br/>Average<br/>Remaining<br/>Contractual<br/>Term<br/>(Years)</b> | <b>Aggregate<br/>Intrinsic<br/>Value</b> |
|----------------------------------------------------------------|---------------|----------------------------------------------------|--------------------------------------------------------------------------------|------------------------------------------|
| Options outstanding at January 1, 2010                         | 3,223         | \$0.49                                             |                                                                                |                                          |
| Options granted                                                | 420           | \$0.37                                             |                                                                                |                                          |
| Options exercised                                              |               | \$                                                 |                                                                                |                                          |
| Options forfeited/canceled                                     | (425)         | \$0.80                                             |                                                                                |                                          |
| Options outstanding and expected to vest at September 30, 2010 | 3,218         | \$0.43                                             | 5.95                                                                           | \$ 42                                    |
| Options exercisable at September 30, 2010                      | 2,299         | \$0.50                                             | 5.10                                                                           | \$ 26                                    |

The aggregate intrinsic value is calculated as the difference between the exercise price of the stock options and the quoted price of the Company's common stock at period end. There were no stock options exercised during the nine months ended September 30, 2010. There were 1,165,000 options outstanding and 742,846 exercisable options as of September 30, 2010, that were in-the-money. At September 30, 2009, there were no exercisable stock options that were in-the-money.

The weighted average grant date fair value of options was \$0.26 and \$0.28 for the three and nine months ended September 30, 2010, respectively. The weighted average grant date fair value of options granted during the three and nine months ended September 30, 2009 was \$0.18 and 0.14 per option, respectively.

As of September 30, 2010, there was approximately \$132,000, net of forfeitures, of total unrecognized compensation cost related to employee and director stock option compensation arrangements. That cost is expected to be recognized over the weighted average remaining vesting period of approximately 1.1 years. For the three and nine months ended September 30, 2010, the amount of stock-based compensation expense related to stock options was approximately \$41,000 and \$114,000, respectively as compared to \$31,000 and \$95,000, respectively recognized in the prior year comparative periods. There was no stock-based compensation expense related to ESPP contributions

during the three and nine months ended September 30, 2010. For the three and nine months ended September 30, 2009, the amount of stock-based compensation expense related to ESPP contributions was approximately \$0 and \$12,000, respectively.

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On March 31, 2009, the Company granted awards of restricted stock to each of its employees totaling approximately 1,208,000 shares with a grant date fair value of approximately \$302,000. The shares vest as to 33% of the shares on the first anniversary of the grant date, 33% of the shares on the second anniversary of the grant date and 34% of the shares on the third anniversary of the grant date. In addition, in connection with Paul McCormick's appointment to Executive Chairman on July 1, 2009, Mr. McCormick was granted 300,000 shares of restricted stock, with a grant date fair value of \$57,000, under the Company's Stock Option Plan. The restrictions on Mr. McCormick's shares of restricted stock will lapse in equal installments upon the first and second anniversaries of the date of grant. On May 17, 2010, in connection with his amended employment agreement, Mr. McCormick was granted an additional 100,000 shares of restricted stock under the Company's Stock Option Plan. The restrictions of these shares of restricted stock will lapse on the one year anniversary of the grant date. The grant date fair value of these shares of restricted stock was \$38,000.

During the nine month period ended September 30, 2010, the Company withheld 125,983 shares of its common stock upon the vesting of 315,324 shares of restricted stock to satisfy its income tax withholding obligations. The value of the shares withheld was approximately \$48,000, based on the closing market price on the measurement date. Accordingly, the Company recorded the aggregate original issue price of approximately \$33,000 to equity and the difference of the fair value at vesting and the original issue price of approximately \$15,000 to accumulated deficit.

For the three and nine months ended September 30, 2010, the stock based compensation related to the amortization of the related compensation cost of the restricted stock was approximately \$33,000 and \$89,000, respectively. For the three and nine months ended September 30, 2009, the stock compensation related to the amortization of the related compensation cost of the restricted stock was approximately \$25,000 and \$49,000, respectively. Since shares of restricted stock are subject to vesting, the unvested shares as of September 30, 2010 have been excluded from the issued and outstanding shares and basic loss per share computations. As of September 30, 2010, there was approximately \$150,000 of total unrecognized compensation cost related to restricted stock that is expected to be recognized over the weighted average remaining vesting period of approximately 1.2 years.

The following table summarizes the restricted stock activity for the nine months ended September 30, 2010 (in thousands):

|                                                             | <b>September<br/>30,<br/>2010</b> |
|-------------------------------------------------------------|-----------------------------------|
| Unvested Restricted Stock Outstanding at January 1, 2010    | 1,256                             |
| Granted                                                     | 100                               |
| Forfeited                                                   | (88)                              |
| Vested                                                      | (465)                             |
| Unvested Restricted Stock Outstanding at September 30, 2010 | 803                               |

The following table summarizes stock-based compensation expense related to stock options, restricted stock and ESPP purchases for the three and nine months ended September 30, 2010 and 2009 which was allocated as follows (in thousands):

|                                               | <b>Three Months Ended<br/>September<br/>30,<br/>2010</b> | <b>September<br/>30,<br/>2009</b> | <b>Nine Months Ended<br/>September<br/>30,<br/>2010</b> | <b>September<br/>30,<br/>2009</b> |
|-----------------------------------------------|----------------------------------------------------------|-----------------------------------|---------------------------------------------------------|-----------------------------------|
| Stock-based compensation expense included in: |                                                          |                                   |                                                         |                                   |
| Research and development                      | \$ 6                                                     | \$ 4                              | \$ 14                                                   | \$ 10                             |
| Sales and marketing                           | 20                                                       | 24                                | 76                                                      | 72                                |
| General and administrative                    | 48                                                       | 28                                | 113                                                     | 74                                |

\$ 74 \$ 56 \$ 203 \$ 156

**5. Legal Matters:**

As previously reported, CardioFocus, Inc. ( CardioFocus ) filed a complaint in the United States District Court for the District of Massachusetts (Case No. 1.08-cv-10285) against the Company and a number of other companies.

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In the complaint, CardioFocus alleges that Cardiogenesis and the other defendants had previously violated patent rights allegedly held by CardioFocus. All of the asserted patents have now expired.

On June 13, 2008, Cardiogenesis filed requests for reexamination of the patents being asserted against Cardiogenesis with the United States Patent and Trademark Office ( USPTO ) and asserted that prior art had been identified that raised substantial new issues of patentability with respect to the inventions claimed by CardioFocus patents. In August 2008, the USPTO granted Cardiogenesis reexamination requests. Reexamination requests filed by other named defendants were also granted. The USPTO finally concluded and CardioFocus is not appealing the following determinations made in reexamination: (a) all asserted claims of CardioFocus U.S. Patent No. 6,159,203 (the 203 Patent ) are unpatentable; (b) 11 of 14 claims of U.S. Patent No. 6,547,780 (the 780 Patent ) are unpatentable; and (c) 8 of 13 claims of U.S. Patent No. 5,843,073 (the 073 Patent ) are unpatentable. Three claims being asserted by CardioFocus against the Company, namely, Claim 2 of the 780 Patent and Claims 2 and 7 of the 073 Patent have been confirmed by the USPTO.

In view of the reexamination having been completed, the Court, at a status conference held on April 22, 2010, issued a scheduling order scheduling dates in connection with the litigation regarding discovery, law and motion practice, a briefing schedule and hearing for patent claim interpretation proceedings, and other key events. A settlement conference has been scheduled for November 9, 2010 and trial is set to commence on November 7, 2011.

Since the Court s issuance of the scheduling order, the parties have engaged and continue to engage in discovery. The parties are further exchanging infringement and non-infringement contentions, as well as claim term constrictions. Cardiogenesis has further filed four further reexamination requests seeking to invalidate the remaining claims of the 780 Patent and 073 Patent being asserted against Cardiogenesis. Two of the reexamination requests were filed on June 30, 2010, and two others were filed on October 15, 2010. These further reexamination requests are based, in part, on newly identified prior art not previously considered by the USPTO.

The Company intends to defend itself vigorously in this action. At this time, the Company is unable to predict the outcome of this matter. At this time, the Company believes that the outcome of this matter will not have a material adverse effect on the Company s financial position, results of operations, or cash flow. However, as this matter is ongoing, there is no assurance that this matter will be resolved favorably by the Company or will not result in a material liability.

Except as described above, the Company is not a party to any material legal proceeding.

### **6. Related Party Transactions:**

The Company entered into a consulting agreement with Mr. McCormick, the Company s Chairman of the Board, effective January 15, 2009. Pursuant to the consulting agreement, Mr. McCormick provided consulting services relating to corporate strategy development and execution, financing and investor relations up to 16 hours per week. In consideration for such services, the Company paid Mr. McCormick \$8,000 per month and reimbursed Mr. McCormick for healthcare insurance coverage up to \$15,600 per year. The consulting agreement had a term of 18 months, but was mutually terminated as of June 30, 2009.

Effective July 1, 2009, the Company entered into an employment agreement with Mr. McCormick whereby he agreed to serve as the Executive Chairman of the Board of Directors and principal executive officer of the Company. Under the terms of the employment agreement, Mr. McCormick was entitled to an annual base salary of \$250,000, provided that he devotes at least 75% of his time to his duties and responsibilities as Executive Chairman under the employment agreement. Mr. McCormick is entitled to receive certain benefits which will include, at a minimum, medical insurance for Mr. McCormick and his spouse, as well as no less than three weeks paid vacation per year. In addition, Mr. McCormick is entitled to be reimbursed for all reasonable expenses incurred by him in respect of his services to the Company under the employment agreement. The employment agreement had an initial term of one year, which term is automatically renewed for successive additional one year periods, unless terminated upon 30 days written notice by either Mr. McCormick or the Company. In connection with Mr. McCormick s appointment to Executive Chairman, the Board of Directors granted him 300,000 shares of restricted stock under the Company s Stock Option Plan. The restrictions on Mr. McCormick s shares of restricted stock lapse in equal installments upon the first and second anniversaries of the date of grant.



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Effective July 1, 2010, the Company entered into an amendment to the employment agreement dated as of July 1, 2009 by and between the Company and Mr. McCormick, pursuant to which the Company and Mr. McCormick agreed to the following changes to his employment agreement: (i) Mr. McCormick will receive an annual base salary of \$200,000, which represents a decrease of \$50,000 per year. In conjunction with the amended agreement, on May 17, 2010, the Board of Directors approved a grant of 100,000 shares of restricted stock under the Company's Stock Option Plan, with such restrictions lapsing after one year from the date of grant, and an option to purchase 100,000 shares of common stock, which would vest in full on the first anniversary of the date of grant.

Effective July 1, 2009, the Company entered into an amendment to the employment agreement dated as of July 30, 2007 by and between the Company and Richard P. Lanigan, pursuant to which the Company and Mr. Lanigan agreed to the following changes to his employment agreement: (i) Mr. Lanigan's title will be Executive Vice President, Marketing of the Company, (ii) Mr. Lanigan will receive an annual base salary of \$225,000, which represents a decrease of \$22,500 per year, and (iii) Mr. Lanigan will report directly to the Executive Chairman of the Company.

The Company entered into a consulting agreement with Dr. Marvin Slepian, a member of the Company's Board of Directors, dated April 1, 2010 and effective March 24, 2010. Pursuant to the agreement, Dr. Slepian will provide consulting services at the Company's direction relating to basic and clinical scientific initiatives as well as development of certain scientific and educational materials. In consideration for such services, the Company will pay Dr. Slepian \$400 per hour up to a maximum of \$2,500 per day. The agreement may be terminated by either party upon thirty days written notice. For both the three and nine months ended September 30, 2010, the Company paid Dr. Slepian a total of \$0 and \$2,500, respectively, for consulting services half of which is included in research and development expenses and the other half is included in sales and marketing expenses in the accompanying consolidated statements of operations.

### **7. Commitments:**

Effective September 15, 2010, the Company entered into an agreement with the Texas Heart Institute (THI), whereby the Company will sponsor biocompatibility and animal safety studies to support the PHOENIX Investigational Device Exemption to the Food and Drug Administration. In consideration for such services, the Company will pay THI total project funds not to exceed \$651,000. The agreement will terminate on June 30, 2011, but may be extended for an additional term by the mutual written consent of both parties. The agreement may be terminated by either party upon thirty days written notice.

### **8. Subsequent Event:**

On November 2, 2010, the Company was awarded a research grant of approximately \$244,500 from the Qualifying Therapeutic Discovery Project (QTDP) Program.

## **Item 2. Management's Discussion and Analysis of Financial Condition and Results of Operations**

Management's Discussion and Analysis of Financial Condition and Results of Operations contains certain statements relating to future results, which are forward-looking statements within the meaning of Section 27A of the Securities Act of 1933, as amended and Section 21E of the Securities Exchange Act of 1934, as amended. Forward-looking statements are identified by words such as believes, anticipates, expects, intends, plans, will, and similar expressions. In addition, any statements that refer to our plans, expectations, strategies or other characterizations of future events or circumstances are forward-looking statements. These forward-looking statements are based on the beliefs of management, as well as assumptions and estimates based on information available to us as of the dates such assumptions and estimates are made, and are subject to certain risks and uncertainties that could cause actual results to differ materially from historical results or those anticipated, depending on a variety of factors, including those factors discussed in the section titled Risk Factors contained in Part I, Item 1A of our Annual Report on Form 10-K for the year ended December 31, 2009. Should one or more of those risks or uncertainties materialize adversely, or should underlying assumptions or estimates prove incorrect, actual results may vary materially from those described. Those events and uncertainties are difficult or impossible to predict accurately and many are beyond our control. Except as may be required by applicable law, we assume no obligation to publicly release the result of any revisions that may be made to any forward-looking statements to reflect events or circumstances after the date of such statements or to reflect the occurrence of anticipated or unanticipated events. Our business may have changed since the date hereof and we undertake no obligation to update these forward looking statements. The following

discussion should be read in conjunction with the unaudited condensed consolidated financial statements and notes thereto included in this Quarterly Report on Form 10-Q.

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### **Overview**

We design, develop and distribute laser-based surgical products and disposable fiber-optic delivery systems (handpieces) for the treatment of diffuse coronary artery disease. Transmyocardial revascularization, or TMR, is a surgical procedure, in which transmural channels are made in heart muscle that cannot be treated by conventional methods and has been proven to reduce angina in selected patients.

We have received both FDA approval and a CE mark for our products. Hospitals and physicians are eligible to receive Medicare reimbursement for TMR equipment and procedures on indicated Medicare patients.

We generate the majority of our revenue from sales of our laser consoles and our disposable handpiece units. In 2009, we refocused our sales strategy in 2009 to emphasize sales of our handpieces, particularly to focus on increasing penetration of accounts with previously installed laser consoles. In combination with the emphasis on sales of handpieces, we have also become more active in conducting and sponsoring professional seminars to educate cardiac surgeons, as well as cardiologists that refer patients to the cardiac surgeon for treatment. Cardiologists are the gatekeepers for patients with cardiac disease and must be updated on the data and clinical benefits of TMR. We believe this refocused strategy will be effective in growing our revenue over the long term.

In addition, we continue our research and development activities in an effort to develop new technologies for the treatment of cardiac ischemia. We submitted an IDE application in December 2009, to begin a U.S. clinical trial for the PHOENIX handpiece; a product that combines TMR as tissue stimulation with the intramyocardial delivery of biologics or stem cells. We are currently investing resources to support our domestic strategy. We believe that if the PHOENIX handpiece can ultimately obtain FDA marketing approval it will be the core product to enable us to achieve our desired future growth.

As of September 30, 2010, we had an accumulated deficit of \$171.8 million. We may continue to incur operating losses. The timing and amounts of our expenditures will depend upon a number of factors, including the efforts required to develop our sales and marketing organization, the timing of market acceptance of our products and the status and timing of regulatory approvals.

### **Results of Operations**

#### *Net Revenues*

We generate our revenues primarily through the sale of our laser consoles and handpieces, which are the components of our TMR System, and related services. In addition, we loan our laser consoles to hospitals in accordance with our loaned laser programs. Under certain loaned laser programs we charge the customer an additional amount over the stated list price on our handpieces in exchange for the use of the laser console or we collect an upfront deposit that can be applied towards the purchase of a laser console.

Net revenues of \$2,764,000 for the three months ended September 30, 2010 increased \$630,000, or 30%, when compared to net revenues of \$2,134,000 for the three months ended September 30, 2009. The increase in sales was attributed to both an increase in handpiece revenue for the three month period ended September 30, 2010, as compared to the prior year as well as absence of laser sales in the prior year period. We refocused our sales strategy in 2009 to emphasize sales of our handpieces, particularly to focus on increasing penetration of accounts with previously installed laser consoles. Going forward we anticipate continued growth in handpiece sales, however we expect net revenue to fluctuate quarter to quarter depending on quarterly capital equipment sales.

For the three months ended September 30, 2010, domestic handpiece revenue increased by \$319,000, or 17%, compared to the prior year period. In the third quarter of 2010, domestic handpiece revenue was \$2,147,000, inclusive of \$271,000 in sales of product to customers operating under our loaned laser program. In the third quarter of 2009, domestic handpiece revenue was \$1,828,000, inclusive of \$126,000 in sales of product to customers operating under our loaned laser program. For the three months ended September 30, 2010 sales of our laser consoles were \$295,000 as compared to no sales of laser consoles in the three months ended September 30, 2009.

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International sales, which accounted for less than 1% of net revenues for the three months ended September 30, 2010, were consistent with the prior year period. In addition, service and other revenue of \$315,000 increased \$12,000 for the three months ended September 30, 2010, when compared to \$303,000 for the quarter ended September 30, 2009.

Net revenues of \$8,426,000 for the nine months ended September 30, 2010 increased \$1,204,000, or 17%, when compared to net revenues of \$7,222,000 for the nine months ended September 30, 2009. This increase can be attributed to an increases in both domestic handpiece and sales of our laser consoles.

For the nine months ended September 30, 2010, domestic handpiece revenue increased by \$989,000 or 18% and domestic laser revenue increased by \$302,000 compared to the nine months ended September 30, 2009. In the first nine months of 2010, domestic handpiece revenue was \$6,417,000, inclusive of \$644,000 in sales of product to customers operating under our loaned laser program. In the first nine months of 2009, domestic handpiece revenue was \$5,428,000, inclusive of \$361,000 in sales of product to customers operating under our loaned laser program.

International sales, which accounted for less than 1% of net revenues for the nine months ended September 30, 2010, decreased \$48,000, or 51%, as compared to the prior year period. In addition, service and other revenue of \$893,000 decreased \$40,000 for the nine months ended September 30, 2010 when compared to \$933,000 for the nine months ended September 30, 2009.

### *Gross Margin*

Gross margin, which was of 84% of net revenues for the three months ended September 30, 2010, was higher than our gross margin of 82% of net revenues for the three months ended September 30, 2009. Gross profit in absolute dollars increased by \$556,000 to \$2,310,000 for the current year third quarter as compared with \$1,754,000 for the 2009 third quarter. For the nine months ended September 30, 2010, the gross margin percentage increased to 84% of net revenues as compared to 82% of net revenues for the nine months ended September 30, 2009. Gross profit in absolute dollars increased by \$1,148,000 to \$7,063,000 for the nine months ended September 30, 2010, as compared to \$5,915,000 for the nine months ended September 30, 2009. The increase in the gross margin percentage for the third quarter was primarily attributed to a higher average selling price on handpieces. We anticipate gross margins to remain constant going forward.

### *Research and Development*

Research and development expense consists of expenses incurred in connection with the development of technologies and products including the costs of third party studies, salaries and stock-based compensation associated with research and development personnel.

For the three months ended September 30, 2010, research and development expenses of \$272,000 decreased \$107,000, or 28%, when compared to \$379,000 for the three months ended September 30, 2009. As a percentage of revenues, research and development expenses were 10% during the three months ended September 30, 2010 as compared to 18% for the prior year period. For the nine months ended September 30, 2010, research and development expenses of \$830,000 decreased \$183,000 or 18% when compared to \$1,013,000 for the nine months ended September 30, 2009. As a percentage of revenues, research and development expenses were 10% for the nine months ended September 30, 2010 as compared to 14% for the prior year period. The dollar decrease for the three and nine months ended September 30, 2010 was primarily attributed to prior year submissions to the Food and Drug Administration related to the Premarket Approval Application for the PEARL 8.0 handpiece and the pre-Investigational Device Exemption to initiate a feasibility trial for the PHOENIX handpiece. As we start the PHOENIX feasibility trial in Europe and the biocompatibility and animal safety studies at the Texas Heart Institute, we anticipate an increase in research and development expense over the next several quarters.

### *Sales and Marketing*

Sales and marketing expense consists of salaries, stock-based compensation, commissions, taxes and benefits for sales, marketing, and service employees and other sales, general and administrative expenses directly associated with the sales, marketing, and service departments.

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For the three months ended September 30, 2010, sales and marketing expenses of \$1,443,000 increased \$80,000, or 6%, when compared to \$1,363,000 for the three months ended September 30, 2009. As a percentage of revenues, sales and marketing expenses were 52% during the three months ended September 30, 2010 as compared to 64% for the prior year period. The increase in sales and marketing expenses for the three months ended September 30, 2010 as compared to the prior year period was primarily due to a \$142,000 increase in salary and other employee related expenses as a result of increased headcount as well as higher commissions expense related to the increase in net revenues and partially offset by a \$59,000 decrease in advertising and marketing expenses.

For the nine months ended September 30, 2010, sales and marketing expenses of \$4,728,000 increased \$624,000, or 15%, when compared to \$4,104,000 for the nine months ended September 30, 2009. As a percentage of revenues, sales and marketing expenses were 56% as compared to 57% for the prior year period. The dollar and percentage increase in sales and marketing expenses for the nine month periods was also a result of increased headcount which led to higher salaries and wage expense as well as higher travel and entertainment expense. Salaries and wage expense was also higher for the nine months ended September 30, 2010, due to higher commission expense as a result of the increase in net revenues. As a large portion of sales and marketing expenses are directly related to revenue, we anticipate expenses to fluctuate with revenues but trend downward as a percent of net revenues as sales increase.

*General and Administrative*

General and administrative expenses represent all other operating expenses not included in research and development or sales and marketing expenses. For the three months ended September 30, 2010, general and administrative expenses totaled \$740,000, or 27% of net revenues, as compared to \$730,000, or 34% of net revenues, during the three months ended September 30, 2009. This represents an increase of \$10,000, or 1%. For the nine months ended September 30, 2010, general and administrative expenses totaled \$2,211,000 or 26% of net revenues as compared to \$2,375,000, or 33% of net revenues, for the nine months ended September 30, 2009. The decrease for the nine month period was primarily a result of a reduced headcount which led to lower salaries and wages expense. We anticipate general and administrative expenses in absolute dollars to remain relatively constant going forward.

**Liquidity and Capital Resources**

At September 30, 2010, we had cash and cash equivalents of \$2,139,000 compared to \$2,568,000 at December 31, 2009, a decrease of \$429,000. During the nine months ended September 30, 2010, cash used in operating activities totaled \$228,000, which primarily resulted from a net loss of \$724,000 and an increase in accounts receivable, partially offset by an increase in accounts payable and a reduction in inventory levels. During the nine months ended September 30, 2009 cash used in operating activities totaled \$427,000, which primarily resulted from a net loss of \$1,643,000 partially offset by decreases in accounts receivable, inventory, and prepaids and other current assets and increases in accounts payable and deferred revenue.

Cash used in investing activities during the nine months ended September 30, 2010 was \$35,000 due to property and equipment purchases. Cash provided by investing activities during the nine months ended September 30, 2009 was \$51,000 primarily due to the redemption of investments in marketable securities.

Cash used in financing activities during the nine months ended September 30, 2010 was \$166,000, which primarily consisted of repayment of \$110,000 related to the short term note payable and \$48,000 related to the withholding of 125,983 shares of our common stock for the payment of income tax withholdings due upon the vesting of restricted stock issued to employees. Cash used by financing activities during the nine months ended September 30, 2009 was \$14,000 which consisted of payments on the short term note payable and capital lease obligations partially offset by proceeds from purchases of common stock under the Employee Stock Purchase Plan.

We have incurred significant operating losses and as of September 30, 2010 we had an accumulated deficit of \$171.8 million. Our ability to maintain current operations is dependent upon increasing our sales from current levels. Our focus is executing upon our core and critical activities, thus operating expenses that are nonessential to our core operations have been reduced or eliminated.

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We believe our cash balance as of September 30, 2010, cash receipts from sales of our products, and actions we have taken to manage sales and marketing and general and administrative expenses will be sufficient to meet our capital, debt and operating requirements through the next twelve months. However, our actual future capital requirements will depend on many factors, including the following:

the success of the commercialization of our products and our refocused sales strategy;

sales and marketing activities, and expansion of our commercial infrastructure, related to our approved products and product candidates;

the results of our clinical trials and requirements to conduct additional clinical trials;

the rate of progress of our research and development programs;

the time and expense necessary to obtain regulatory approvals;

activities and payments in connection with potential acquisitions of companies, products or technology; and

competitive, technological, market and other developments.

In particular, we anticipate that we will have to incur significant expenses to complete the clinical trials required to obtain FDA approval of our PHOENIX handpiece. If revenues from sales of our products are not sufficient to continue our current operations and fund these clinical trials, we will need to obtain debt or equity financing, significantly reduce our operations, or abandon clinical trials for the PHOENIX handpiece.

We will have a continuing need for new infusions of cash if we incur losses or are otherwise unable to generate positive cash flow from operations in the future. We plan to increase our sales through successful execution of our refocused sales strategy and achieving regulatory approval for the PHOENIX handpiece. If these efforts are unsuccessful, we will be unable to significantly increase our revenues and may have to obtain additional financing to continue our operations or scale back our operations. Due to the current economic conditions, it has become very difficult for companies to obtain debt financing on reasonable terms, if at all. In addition, it may be difficult for us to obtain significant equity financing as a result of our low trading price and trading volume combined with our stock not being listed on a national securities exchange, such as NYSE, Amex, or NASDAQ. As a result, we may not be able to obtain additional financing if required, or even if we were to obtain any financing, it may contain burdensome restrictions on our business, in the case of debt financing, or result in significant dilution, in the case of equity financing.

### **Critical Accounting Policies and Estimates**

The preparation of our financial statements requires that we make estimates and assumptions that affect the reported amounts of assets and liabilities and related disclosure of contingent assets and liabilities at the date of the financial statements and the reported amounts of revenues and expenses during the reporting periods. On an ongoing basis, we evaluate these estimates and assumptions, which are based on historical experience and on other assumptions that we believe to be reasonable. In the event that any of our estimates and assumptions are inaccurate in any material respect, it could have a material adverse effect on our reported amounts of assets and liabilities at the date of the financial statements and the reported amounts of revenues and expenses during the reporting periods. A summary of our critical accounting policies is included in Item 7 (Management's Discussion and Analysis of Financial Condition and Results of Operations) of Part II, of our Annual Report on Form 10-K for the fiscal year ended December 31, 2009. There have been no material changes to the critical accounting policies disclosed in our Annual Report on Form 10-K for the fiscal year ended December 31, 2009.

### **Item 4(T). Controls and Procedures**

#### **Evaluation of Disclosure Controls and Procedures**

An evaluation was carried out under the supervision and with the participation of our management, including our principal executive officer and our principal financial officer, of the effectiveness of the design and operation of our

disclosure controls and procedures (as defined in Rule 13a-15(e) and 15d-15(e) under the Securities Exchange Act of 1934) as of September 30, 2010. Based upon that evaluation, our principal executive officer and our principal financial officer concluded that the design and operation of these disclosure controls and procedures at September

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30, 2010 were effective in timely alerting them to the material information relating to us required to be included in our periodic filings with the SEC, such that the information relating to us, required to be disclosed in SEC reports (i) is recorded, processed, summarized and reported within the time periods specified in SEC rules and forms, and (ii) is accumulated and communicated to our management, including our principal executive officer and principal financial officer, as appropriate to allow timely decisions regarding required disclosure.

All internal control systems, no matter how well designed, have inherent limitations. Therefore, even those systems determined to be effective may not prevent or detect all misstatements and can provide only reasonable assurance with respect to financial statement preparation and presentation. Also, projections of any evaluation of effectiveness to future periods are subject to the risk that controls may become inadequate because of changes in conditions, or that the degree of compliance with the policies or procedures may deteriorate.

**Changes in internal control over financial reporting**

There were no changes in our internal control over financial reporting that occurred during the quarter ended September 30, 2010 that have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

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**PART II**  
**OTHER INFORMATION**

**Item 1. Legal Proceedings**

As previously reported, CardioFocus, Inc. ( CardioFocus ) filed a complaint in the United States District Court for the District of Massachusetts (Case No. 1.08-cv-10285) against us and a number of other companies. In the complaint, CardioFocus alleges that we and the other defendants had previously violated patent rights allegedly held by CardioFocus. All of the asserted patents have now expired.

On June 13, 2008, we filed requests for re-examination of the patents being asserted against us with the United States Patent and Trademark Office, or USPTO, and asserted that prior art had been identified that raised substantial new issues of patentability with respect to the inventions claimed by CardioFocus patents. In August 2008, the USPTO granted our reexamination requests. Reexamination requests filed by other named defendants were also granted. The USPTO has now finally concluded, and CardioFocus is not appealing, the following determinations made in reexamination: (a) all asserted claims of CardioFocus U.S. Patent No. 6,159,203 are unpatentable; (b) 11 of 14 claims of U.S. Patent No. 6,547,780 are unpatentable; and (c) 8 of 13 claims of U.S. Patent No. 5,843,073 are unpatentable. However, three claims being asserted by CardioFocus against us, namely, Claim 2 of the 780 patent and Claims 2 and 7 of the 073 patent have been confirmed by the USPTO.

In view of the re-examination having been completed, the Court, at a status conference held on April 22, 2010, issued a scheduling order scheduling dates in connection with the litigation regarding discovery, law and motion practice, a briefing schedule and hearing for patent claim interpretation proceedings, and other key events. A settlement conference has been scheduled for November 9, 2010 and trial is set to commence on November 7, 2011.

Since the Court's issuance of the scheduling order, the parties have engaged and continue to engage in discovery. The parties are further exchanging infringement and non-infringement contentions, as well as claim term constructions. We have further filed four further reexamination requests seeking to invalidate the remaining claims of the 780 Patent and 073 Patent being asserted against us. Two of the reexamination requests were filed on June 30, 2010, and two others were filed on October 15, 2010. These further reexamination requests are based, in part, on newly identified prior art not previously considered by the USPTO.

We intend to defend ourselves vigorously in this action. At this time, we are unable to predict the outcome of this matter. At this time, we believe that the outcome of this matter will not have a material adverse effect on our financial position, results of operations, or cash flow. However, as this matter is ongoing, there is no assurance that this matter will be resolved favorably by us or will not result in a material liability.

**Item 6. Exhibits**

The exhibits below are filed or incorporated herein by reference.

| <b>Exhibit No.</b> | <b>Description</b>                                                                                                                                       |
|--------------------|----------------------------------------------------------------------------------------------------------------------------------------------------------|
| 31.1               | Certification of the Principal Executive Officer pursuant to Rule 13a-14(a)/15d-14(a) of the Securities Exchange Act of 1934.                            |
| 31.2               | Certification of the Chief Financial Officer pursuant to Rule 13a-14(a)/15d-14(a) of the Securities Exchange Act of 1934.                                |
| 32.1               | Certification of the Principal Executive Officer pursuant to Rule 13a-14(b)/15d-14(b) of the Securities Exchange Act of 1934 and 18 U.S.C. Section 1350. |
| 32.2               | Certification of the Chief Financial Officer pursuant to Rule 13a-14(b)/15d-14(b) of the Securities Exchange Act of 1934 and 18 U.S.C. Section 1350.     |

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**SIGNATURES**

Pursuant to the requirements of the Securities Exchange Act of 1934, the Registrant has duly caused this report to be signed on its behalf by the undersigned thereunto duly authorized.

**CARDIOGENESIS CORPORATION**

Registrant

Date: November 5, 2010

/s/ Paul J. McCormick

Paul J. McCormick

Executive Chairman

(Principal Executive Officer)

Date: November 5, 2010

/s/ William R. Abbott

William R. Abbott

Senior Vice President, Chief Financial

Officer, Secretary and Treasurer

(Principal Financial and Accounting

Officer)

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