

Cardiogenesis Corp /CA  
Form 10-Q  
November 10, 2009

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

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

**For the quarterly period ended September 30, 2009.**

**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 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 30, 2009, there were 46,856,849 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/>2009<br/>(unaudited)</b> | <b>December<br/>31,<br/>2008<br/>(audited)</b> |
|---|---|--|
| <b>ASSETS</b>   |   |  |
| Current assets:   |   |  |
| Cash and cash equivalents   | \$ 2,517  | \$ 2,907                                       |
| Accounts receivable, net of allowance for doubtful accounts of \$7 and \$20, respectively             | 941   | 1,330  |
| Inventories   | 984   | 1,164  |
| Investments in marketable securities  |   | 75   |
| Prepays and other current assets  | 356   | 395  |
| Total current assets  | 4,798   | 5,871  |
| Property and equipment, net   | 350   | 382  |
| Other assets, net   | 18  | 18   |
| Total assets  | \$ 5,166  | \$ 6,271                                       |
| <b>LIABILITIES AND SHAREHOLDERS EQUITY</b>  |   |  |
| Current liabilities:  |   |  |
| Accounts payable  | \$ 338  | \$ 200   |
| Accrued liabilities   | 1,020   | 1,103  |
| Deferred revenue  | 971   | 800  |
| Note payable  | 140   |  |
| Current portion of capital lease obligations  | 9   | 6  |
| Total current liabilities   | 2,478   | 2,109  |
| Capital lease obligations, less current portion   | 16  | 13   |
| Total liabilities   | 2,494   | 2,122  |
| 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; 45,549 and 45,487 shares issued and outstanding, respectively | 174,165   | 173,999  |

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|  |           |           |
|--|-----------|-----------|
| Accumulated deficit                        | (171,493) | (169,850) |
| Total shareholders' equity                 | 2,672     | 4,149     |
| Total liabilities and shareholders' equity | \$ 5,166  | \$ 6,271  |

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</b> |             | <b>Nine months ended</b> |             |
|--------------------------------------|---------------------------|-------------|--------------------------|-------------|
|                                      | <b>September 30,</b>      |             | <b>September 30,</b>     |             |
|                                      | <b>2009</b>               | <b>2008</b> | <b>2009</b>              | <b>2008</b> |
| Net revenues                         | \$ 2,134                  | \$ 2,618    | \$ 7,222                 | \$ 9,719    |
| Cost of revenues                     | 380                       | 474         | 1,307                    | 1,589       |
| Gross profit                         | 1,754                     | 2,144       | 5,915                    | 8,130       |
| Operating expenses:                  |                           |             |                          |             |
| Research and development             | 379                       | 165         | 1,013                    | 633         |
| Sales and marketing                  | 1,363                     | 1,536       | 4,104                    | 4,858       |
| General and administrative           | 730                       | 753         | 2,375                    | 2,404       |
| Total operating expenses             | 2,472                     | 2,454       | 7,492                    | 7,895       |
| Operating income (loss)              | (718)                     | (310)       | (1,577)                  | 235         |
| Other income (expense):              |                           |             |                          |             |
| Interest expense                     | (4)                       | (1)         | (35)                     | (22)        |
| Interest income                      | 1                         | 13          | 3                        | 55          |
| Other non-operating expense          | (20)                      |             | (20)                     |             |
| Total other income (expense), net    | (23)                      | 12          | (52)                     | 33          |
| Income (loss) before income taxes    | (741)                     | (298)       | (1,629)                  | 268         |
| Provision (benefit) for income taxes | (2)                       | 10          | 14                       | 10          |
| Net income (loss)                    | \$ (739)                  | \$ (308)    | \$ (1,643)               | \$ 258      |
| Net earnings (loss) per share:       |                           |             |                          |             |
| Basic                                | \$ (0.02)                 | \$ (0.01)   | \$ (0.04)                | \$ 0.01     |
| Diluted                              | \$ (0.02)                 | \$ (0.01)   | \$ (0.04)                | \$ 0.01     |
| Weighted average shares outstanding: |                           |             |                          |             |
| Basic                                | 45,549                    | 45,292      | 45,519                   | 45,292      |
| Diluted                              | 45,549                    | 45,292      | 45,519                   | 45,328      |

See accompanying notes.

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

|   | <b>Nine months ended</b> |             |
|---|--------------------------|-------------|
|   | <b>September 30,</b>     |             |
|   | <b>2009</b>              | <b>2008</b> |
| Cash flows from operating activities:   |                          |             |
| Net income (loss)   | \$ (1,643)               | \$ 258      |
| Adjustments to reconcile net income (loss) to net cash (used in) provided by operating activities:                                  |                          |             |
| Depreciation and amortization   | 233                      | 219         |
| Provision for doubtful accounts   | 10                       | 21          |
| Stock-based compensation expense  | 156                      | 102         |
| Changes in operating assets and liabilities:  |                          |             |
| Accounts receivable   | 379                      | 423         |
| Inventories   | 15                       | 237         |
| Prepays and other current assets  | 197                      | 20          |
| Accounts payable  | 138                      | 169         |
| Accrued liabilities   | (83)                     | (334)       |
| Deferred revenue  | 171                      | (308)       |
| Net cash (used in) provided by operating activities   | (427)                    | 807         |
| Cash flows from investing activities:   |                          |             |
| Acquisition of property and equipment   | (24)                     | (118)       |
| Purchase of investments in marketable securities  |                          | (150)       |
| Proceeds from the sale of marketable securities   | 75                       | 75          |
| Net cash provided by (used in) investing activities   | 51                       | (193)       |
| Cash flows from financing activities:   |                          |             |
| Net proceeds from issuance of common stock from exercise of options and from stock purchased under the Employee Stock Purchase Plan | 10                       | 10          |
| Payments on note payable  | (18)                     |             |
| Payments on capital lease obligation  | (6)                      | (9)         |
| Net cash (used in) provided by financing activities   | (14)                     | 1           |
| Net (decrease) increase in cash and cash equivalents  | (390)                    | 615         |
| Cash and cash equivalents at beginning of period  | 2,907                    | 2,824       |
| Cash and cash equivalents at end of period  | \$ 2,517                 | \$ 3,439    |
| Supplemental schedule of cash flow information:   |                          |             |
| Interest paid   | \$ 2                     | \$ 3        |
| Taxes paid  | \$ 6                     | \$ 14       |



Supplemental schedule of non-cash financing activities:

|   |        |    |    |
|---|--------|----|----|
| Financing of insurance premiums under note payable        | \$ 158 | \$ |    |
| Financing of property and equipment                       | \$ 12  | \$ |    |
| Reclassification of inventories to property and equipment | \$ 165 | \$ | 15 |

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. Currently, Cardiogenesis emphasis is on the development of products for transmyocardial revascularization ( TMR ), a treatment for cardiac ischemia in patients with severe angina.

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 November 10, 2009, 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, 2008, 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, 2009 it had an accumulated deficit of \$171.5 million. Management believes its cash balance as of September 30, 2009 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. 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.

For the three and nine months ended September 30, 2009, there were approximately 716,000 and 418,000 potentially dilutive shares, respectively. For the three months ended September 30, 2008, there were approximately 23,000 potentially dilutive shares that were related to stock options.

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The following table reconciles BEPS and DEPS and the related weighted average number of shares outstanding for the nine months ended September 30, 2008 (in thousands, except per share amounts):

|  | Numerator<br>(Income) | Denominator<br>(Shares) | Per<br>Share<br>Amount |
|--|-----------------------|-------------------------|------------------------|
| Basic EPS:   |                       |                         |                        |
| Net income   | \$ 258                |                         | \$                     |
| Income available to common shareholders                        | 258                   | 45,292                  | 0.01                   |
| Effect of dilutive securities:                                 |                       |                         |                        |
| Options  |                       | 36                      |                        |
| Diluted EPS:   |                       |                         |                        |
| Income available to common shareholders plus assumed exercises | \$ 258                | 45,328                  | \$ 0.01                |

*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 period. 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, valuation of inventories, 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 primarily to hospitals and other healthcare providers in North America, Europe and Asia. 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, 2009, no customer individually accounted for more than 10% of gross accounts receivable. At December 31, 2008, one customer individually accounted for 21% of gross accounts receivable. For the three and nine month periods ended September 30, 2009 and for the three and nine month periods ended September 30, 2008, no customer individually accounted for more than 10% of net revenues.

As of September 30, 2009, approximately \$969,000 of the Company's cash and cash equivalents were maintained in mutual funds, and approximately \$1,574,000 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 on such deposits. Generally, these deposits may be redeemed upon demand and, therefore, are believed to bear low risk. Effective October 3, 2008, the Emergency Economic Stabilization Act of 2008 raised the Federal Deposit Insurance Corporation (the "FDIC") deposit coverage limits to \$250,000 per owner from \$100,000 per owner. This program is currently available through December 31, 2009.

After giving effect to the increased FDIC insurance, at September 30, 2009, the Company's uninsured cash totaled approximately \$2,293,000.

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

Certain components of laser units 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



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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.

The Company at times will loan lasers 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. In accordance with the accounting standards for leases, these arrangements are recorded as leases as they convey the right to use the lasers over the period of time the customers are purchasing handpieces. The loaned lasers are classified as operating leases and are transferred from inventory to fixed assets upon commencement of the loaned laser program. In addition, the Premium is considered contingent rent, and therefore, such amounts allocated to the lease of the laser should be excluded from minimum lease payments and should be 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 lasers and handpieces, by allocating revenue for each respective element based on its relative fair value 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, Canada and Asia and amounted to approximately \$4,000 and \$96,000 for the three and nine months ended September 30, 2009, respectively. For the three and nine months ended September 30, 2008, the Company's international sales were \$4,000 and \$96,000, respectively. International sales represent approximately 1% of total sales for the three and nine months ended September 30, 2009, respectively, and approximately 1% for the three and nine months ended September 30, 2008, 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 June 2009, the Financial Accounting Standards Board (FASB) issued a pronouncement which establishes the FASB Accounting Standards Codification<sup>TM</sup> as the source of authoritative accounting guidance under GAAP. The rules and interpretive releases of the SEC under authority of federal securities laws are also sources of authoritative GAAP for SEC registrants. This pronouncement is effective for periods ending after September 15,

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2009. The Company has concluded that the application of this pronouncement did not have a material impact on its consolidated financial position and results of operations as of and for the period ended September 30, 2009.

In December 2007, the FASB issued a pronouncement, which establishes principles and requirements for how the acquirer of a business recognizes and measures in its financial statements the identifiable assets acquired, the liabilities assumed, and any noncontrolling interest in the acquiree. This pronouncement also provides guidance for recognizing and measuring the goodwill acquired in the business combination and determines what information to disclose to enable users of the financial statement to evaluate the nature and financial effects of the business combination. This pronouncement is effective for financial statements issued for fiscal years beginning after December 15, 2008. The Company has concluded that the application of this pronouncement did not have a material impact on its consolidated financial position and results of operations as of and for the period ended September 30, 2009.

In June 2008, the Emerging Issues Task Force of the FASB published a pronouncement to address concerns regarding the meaning of "indexed to an entity's own stock" contained in a FASB accounting statement. This accounting statement related to the determination of whether a free-standing equity-linked instrument should be classified as equity or debt. If an instrument is classified as debt, it is valued at fair value, and this value is re-measured on an ongoing basis, with changes recorded in earnings in each reporting period. This pronouncement is effective for years beginning after December 15, 2008 and earlier adoption is not permitted. Although this pronouncement is effective for fiscal years beginning after December 15, 2008, any outstanding instrument at the date of adoption will require a retrospective application of the accounting through a cumulative effect adjustment to retained earnings upon adoption. The Company has concluded that the application of this pronouncement did not have a material impact on its consolidated financial position and results of operations as of and for the period ended September 30, 2009.

In April 2009, the FASB issued pronouncements to require disclosures about fair value of financial instruments in interim and annual reporting periods. The pronouncements are effective for interim reporting periods ending after June 15, 2009, which for the Company was the second quarter of fiscal 2009. The Company has concluded that the application of the pronouncements did not have a material impact on its consolidated financial position and results of operations as of and for the period ended September 30, 2009.

In April 2009, the FASB issued a pronouncement which provides additional guidance for estimating fair value when the volume and level of activity for the asset or liability have significantly decreased. This pronouncement also includes guidance on identifying circumstances that indicate a transaction is not orderly. This pronouncement is effective for periods ending after June 15, 2009. The Company has concluded that the application of this pronouncement did not have a material impact on its consolidated financial position and results of operations as of and for the period ended September 30, 2009.

In June 2008, the FASB issued a pronouncement which clarifies that share-based payment awards that entitle their holders to receive nonforfeitable dividends before vesting should be considered participating securities. As participating securities, these instruments should be included in the calculation of basic earnings per share. This pronouncement is effective for financial statements issued for fiscal years beginning after December 15, 2008, as well as interim periods in those years. Once effective, all prior period earnings per share data presented must be adjusted retrospectively and early application is not permitted. The Company has concluded that the application of this pronouncement did not have a material impact on its consolidated financial position and results of operations as of and for the period ended September 30, 2009.

In September 2009, the FASB ratified a pronouncement which requires companies to allocate revenue in arrangements involving multiple deliverables based on the estimated selling price of each deliverable, even though such deliverables are not sold separately either by the company itself or other vendors. This pronouncement eliminates the requirement that all undelivered elements must have objective and reliable evidence of fair value before a company can recognize the portion of the overall arrangement fee that is attributable to items that already have been delivered. As a result, the new guidance may allow some companies to recognize revenue on transactions that involve multiple deliverables earlier than under current requirements. This pronouncement is effective for revenue arrangements entered into or materially modified in fiscal years beginning on or after December 15, 2009. Early adoption is permitted at the beginning of a company's fiscal year. The Company expects to adopt this



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pronouncement on January 1, 2010 and does not expect this pronouncement to have a material impact on its consolidated financial position and results of operations.

Other recent accounting pronouncements issued by the FASB (including the 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):

|                 | <b>September<br/>30,<br/>2009<br/>(unaudited)</b> | <b>December<br/>31,<br/>2008<br/>(audited)</b> |
|-----------------|---|--|
| Raw materials   | \$ 141  | \$ 139   |
| Work-in-process | 70  | 70   |
| Finished goods  | 773   | 955  |
| Total           | \$ 984  | \$ 1,164                                       |

**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 Plan and Director Stock Option Plan 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 on the trading day immediately prior thereto). 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, 2009, 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 15, 2008 offering period.

The Company has treated the ESPP as a compensatory plan. During the three and nine month periods ended September 30, 2009, there were zero and 62,496 shares purchased under the ESPP, respectively. For the three and nine month periods ended September 30, 2009, the Company recognized zero and \$12,000, respectively, of share-based compensation expense in relation to the ESPP as compared to approximately \$7,000 and \$13,000, respectively, recognized in the prior year comparative periods.



**Table of Contents****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.

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, 2009 and 2008 were based on the following assumptions:

|                         | <b>Nine Months Ended</b>          |                                   |       |
|-------------------------|-----------------------------------|-----------------------------------|-------|
|                         | <b>September<br/>30,<br/>2009</b> | <b>September<br/>30,<br/>2008</b> |       |
| Expected term           | 6.27<br>6.35<br>years             | 4 years                           |       |
| Expected volatility     | 97.6<br>105.51%                   | 91.5                              | 92.9% |
| Risk-free interest rate | 1.63<br>2.84%                     | 2.24                              | 3.53% |
| Expected dividend yield |                                   |                                   |       |

Compensation expense under the ESPP is measured as the fair value of the employees' purchase rights during the look-back option period as calculated under the Black-Scholes option pricing model. The weighted average assumptions used in the model are outlined in the following table:

|                         | <b>Nine Months Ended</b>          |                                   |       |
|-------------------------|-----------------------------------|-----------------------------------|-------|
|                         | <b>September<br/>30,<br/>2009</b> | <b>September<br/>30,<br/>2008</b> |       |
| Expected term           | 0.50<br>years                     | 0.50 years                        |       |
| Expected volatility     | 104.82<br>105.51%                 | 91.5                              | 92.9% |
| Risk-free interest rate | 1.63<br>2.03%                     | 2.24                              | 3.53% |
| Expected dividends      |                                   |                                   |       |

A summary of option activity as of September 30, 2009 and changes during the nine months then ended, is presented below (in thousands except per share data):

**Weighted**

|   | <b>Shares</b> | <b>Weighted<br/>Average<br/>Exercise<br/>Price</b> | <b>Average<br/>Remaining<br/>Contractual<br/>Term<br/>(Years)</b> | <b>Aggregate<br/>Intrinsic<br/>Value</b> |
|---|---------------|--|---|--|
| Options outstanding at January 1, 2009                            | 3,295         | \$0.66   | 5.7   | \$                                       |
| Options granted   | 942           | \$0.17   |   | \$                                       |
| Options exercised   |               | \$   |   | \$                                       |
| Options forfeited/canceled  | (243)         | \$1.06   |   | \$                                       |
| Options outstanding and expected to vest at<br>September 30, 2009 | 3,994         | \$0.52   | 5.8   | \$ 56                                    |
| Options exercisable at September 30, 2009                         | 2,489         | \$0.71   | 3.8   | \$                                       |

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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. At September 30, 2009, there were no exercisable stock options that were in-the-money. During the nine months ended September 30, 2009, there were no options exercised and therefore, the aggregate intrinsic value of options exercised was zero.

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. The weighted average grant date fair value of options granted during the three and nine months ended September 30, 2008 was \$0.25 and \$0.23 per option, respectively.

As of September 30, 2009, there was approximately \$183,000 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 1.8 years. For the three and nine month periods ended September 30, 2009, the amount of stock-based compensation expense related to stock options was approximately \$31,000 and \$95,000, respectively, as compared to \$33,000 and \$89,000, respectively, recognized in the prior year comparative periods.

On March 31, 2009, the Company granted awards of restricted stock to each of its employees totaling approximately 1,208,000 shares. 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 under the Company's Stock Option Plan. See Note 6. 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.

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 cliff vesting and none have vested as of September 30, 2009, all shares have been excluded from the issued and outstanding shares and basic earnings per share computations. As of September 30, 2009, there was approximately \$260,000 of total unrecognized compensation cost related to restricted stock that is expected to be recognized over the weighted average remaining vesting period of 2.3 years.

The following table summarizes the restricted stock activity for the nine months ended September 30, 2009 (in thousands):

|   | <b>September<br/>30,<br/>2009</b> |
|---|-----------------------------------|
| Unvested Restricted Stock Outstanding at January 1, 2009    |                                   |
| Granted   | 1,508                             |
| Forfeited   | (200)                             |
| Vested  |                                   |
| Unvested Restricted Stock Outstanding at September 30, 2009 | 1,308                             |

The following table summarizes stock-based compensation expense related to stock options, restricted stock and ESPP purchases under SFAS No. 123R for the three and nine months ended September 30, 2009 and 2008 which was allocated as follows (in thousands):

| <b>Three Months Ended</b>                     |                                   | <b>Nine Months Ended</b>          |                                   |
|---|-----------------------------------|-----------------------------------|-----------------------------------|
| <b>September<br/>30,<br/>2009</b>             | <b>September<br/>30,<br/>2008</b> | <b>September<br/>30,<br/>2009</b> | <b>September<br/>30,<br/>2008</b> |
| Stock-based compensation expense included in: |                                   |                                   |                                   |

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|                            |       |       |        |        |
|----------------------------|-------|-------|--------|--------|
| Research and development   | \$ 4  | \$ 1  | \$ 10  | \$ 3   |
| Sales and marketing        | 24    | 24    | 72     | 59     |
| General and administrative | 28    | 15    | 74     | 40     |
|                            | \$ 56 | \$ 40 | \$ 156 | \$ 102 |

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**Table of Contents****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. In the complaint, Cardiofocus alleges that Cardiogenesis and the other defendants had previously violated patent rights of three (3) patents 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 U.S. Patent and Trademark Office 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 U.S. Patent and Trademark Office granted Cardiogenesis reexamination requests. Reexamination requests filed by other named defendants were also granted.

Because the reexamination requests were granted and substantial new issues of patentability raised, Cardiogenesis, along with other named defendants, moved to stay the litigation until the reexamination of Cardiofocus asserted patents is completed. On October 14, 2008, an order was issued by the court staying the present litigation for one year or until the reexamination is completed, whichever occurs sooner. So far, the USPTO has concluded that: (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) all asserted claims of U.S. Patent No. 5,843,073 (the 073 Patent ) are unpatentable. Because of the progress made thus far via reexamination, Cardiogenesis and the other defendants have jointly filed a motion with the court for a further extension of the stay, for a period not to exceed one additional year, based upon good cause shown by the defendants.

Cardiogenesis intends to continue to vigorously defend itself. However, any litigation involves risks and uncertainties and the likely outcome of the case cannot be determined at this time.

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

**6. Related Party Transactions:**

The Company provided unrestricted educational grants of \$40,000 in February 2008 and \$40,000 in June 2008 to the University of Arizona Sarver Heart Center (the Sarver Heart Center ) to support the research of cardiovascular disease and stroke. Dr. Marvin Slepian, a member of the Company s Board of Directors, is Director of Interventional Cardiology at Sarver Heart Center. The Company is not legally bound to provide any additional funding for such research but may choose to do so in the future.

The Company entered into a consulting agreement with Paul McCormick, the Company s Chairman of the Board of Directors, 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 is 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 will be 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 will also be reimbursed for all reasonable expenses incurred by him in respect of his services to the Company under the employment agreement. The employment agreement has an initial term of one year, which term will be 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

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stock 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.

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 February 27, 2009 and effective as of January 1, 2009. Pursuant to the agreement, Dr. Slepian will provide consulting services 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 \$50,000 for the year ended December 31, 2009. The agreement expires December 31, 2009, but may be terminated by either party upon ten days written notice.

**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, 2008. 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.

**Overview**

We are a California corporation, incorporated in 1989, and we primarily design, develop and distribute laser-based surgical products and disposable fiber-optic accessories for the treatment of cardiac ischemia associated with advanced cardiovascular disease through laser myocardial revascularization. This therapeutic procedure can be performed surgically as transmyocardial revascularization, or TMR. TMR is a procedure used to relieve severe angina, or chest pain, in very ill patients who are not candidates for bypass surgery or percutaneous coronary intervention. TMR is a laser-based heart treatment in which transmural channels are made in the heart muscle. Many scientific experts believe these procedures encourage new vessel formation, or angiogenesis. Typically, TMR is performed by a cardiac surgeon while the patient is under general anesthesia as an adjunctive procedure to coronary bypass, or may be performed on a stand-alone basis through a small left anterior thoracotomy incision in the chest.

In May 1997, we received CE Mark approval for our TMR System. We have also received CE Mark approval for our minimally invasive Port Enabled Angina Relief with Laser, or PEARL, handpieces and our PHOENIX handpieces, in November 2005 and October 2006, respectively. The CE Mark allows us to commercially distribute these products within the European Union and is an international symbol of adherence to quality assurance standards

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and compliance with applicable European medical device directives. In February 1999, we received approval from the U.S. Food and Drug Administration, or FDA, for the marketing of our TMR products for treatment of patients suffering from chronic, severe angina. Effective July 1999, the Centers for Medicare and Medicaid Services implemented a national coverage decision for Medicare coverage for any TMR procedure as a primary and secondary procedure. As a result, hospitals and physicians are eligible to receive Medicare reimbursement for TMR equipment and procedures on indicated Medicare patients.

In December 2004, we received FDA approval for the Solargen 2100s laser system, the advanced laser console for TMR. In addition, in November 2007 we received FDA approval for the PEARL 5.0 robotic handpiece delivery system, which is designed for delivering TMR therapy with surgical robotic systems. We have submitted the Pre-Market Approval (PMA) Supplement for the PEARL 8.0 thoracoscopic handpiece delivery system and have submitted a pre-Investigational Device Exemption (IDE) for the PHOENIX handpiece.

As of September 30, 2009, we had an accumulated deficit of \$171.5 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 TMR System laser base units, related handpieces and related services. The handpieces are a single-use product and disposable. At times we will loan lasers to hospitals and charge an additional amount over the stated list price on our handpieces in exchange for the use of the laser.

Net revenues of \$2,134,000 for the three months ended September 30, 2009 decreased \$484,000, or 18%, when compared to net revenues of \$2,618,000 for the three months ended September 30, 2008. The decrease in sales was primarily attributed to the absence of laser sales during the three month period ended September 30, 2009 as compared to laser sales of \$373,000 for the three months ended September 30, 2008.

For the three months ended September 30, 2009, domestic handpiece revenue decreased by \$151,000, or 8%, and domestic laser revenue decreased by \$373,000, or 100%, when compared to the three months ended September 30, 2008. In the third quarter of 2009, domestic handpiece revenue included \$126,000 in sales of product to customers operating under our loaned laser program. Sales of handpieces to customers not operating under the loaned laser program were \$1,701,000. In the third quarter of 2008, domestic handpiece revenue included \$154,000 in sales of product to customers operating under our loaned laser program. Sales of handpieces to customers not operating under the loaned laser program were \$1,824,000.

International sales, accounting for less than 1% of net revenues for the three months ended September 30, 2009, were consistent with the prior year period. In addition, service and other revenue of \$303,000 increased \$40,000 for the three months ended September 30, 2009, when compared to \$263,000 for the three months ended September 30, 2008.

Net revenues of \$7,222,000 for the nine months ended September 30, 2009 decreased \$2,497,000, or 26%, when compared to net revenues of \$9,719,000 for the nine months ended September 30, 2008. The decrease was primarily attributed to a decrease in laser sales of \$1,832,000 and a decrease in handpiece sales of \$786,000 as compared to the prior year period.

For the nine months ended September 30, 2009, domestic disposable handpiece revenue decreased by \$811,000 and domestic laser revenue decreased by \$1,809,000 compared to the nine months ended September 30, 2008. Included in the domestic disposable handpiece revenue for the nine months ended September 30, 2008, was \$234,000 related to revenue which had been previously deferred in accordance with revenue recognition accounting standards and was recognized during the period. For the nine months ended September 30, 2009, domestic handpiece revenue included \$361,000 in sales of product to customers operating under our loaned laser program. Sales of handpieces to customers not operating under the loaned laser program were \$5,067,000. For the nine

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months ended September 30, 2008, domestic handpiece revenue included \$625,000 in sales of product to customers operating under our loaned laser program. Sales of handpieces to customers not operating under the loaned laser program were \$5,614,000.

International sales, accounting for approximately 1% of net revenues for the nine months ended September 30, 2009, were consistent with the prior year period. In addition, service and other revenue of \$933,000 increased \$121,000 for the nine months ended September 30, 2009, when compared to \$812,000 for the nine months ended September 30, 2008.

*Gross Margin*

For the three months ended September 30, 2009, the gross margin percentage of 82% of net revenues was consistent with the prior year period. Gross profit in absolute dollars decreased by \$390,000 to \$1,754,000 for the current year third quarter as compared with \$2,144,000 for the 2008 third quarter. For the nine months ended September 30, 2009, the gross margin percentage decreased to 82% of net revenues as compared to 84% of net revenues for the nine months ended September 30, 2008. Gross profit in absolute dollars decreased by \$2,215,000 to \$5,915,000 for the nine months ended September 30, 2009, as compared to \$8,130,000 for the nine months ended September 30, 2008. The decrease in the gross margin percentage for the three months and nine month periods was primarily attributed to a decrease in laser sales.

*Research and Development*

Research and development expense represents 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, 2009, research and development expenditures of \$379,000 increased \$214,000, or 130%, when compared to \$165,000 for the three months ended September 30, 2008. As a percentage of revenues, research and development expenditures were 18% during the three months ended September 30, 2009 as compared to 6% for the prior year period. For the nine months ended September 30, 2009, research and development expenditures of \$1,013,000 increased \$380,000 or 60%, when compared to \$633,000 for the nine months ended September 30, 2008. As a percentage of revenues, research and development expenditures were 14% for the nine months ended September 30, 2009 as compared to 7% for the prior year period. The dollar increase for the nine months ended September 30, 2009 was primarily attributed to the recent submissions and follow-up to the Food and Drug Administration related to the PMA Application for the PEARL 8.0 handpiece and the pre-IDE to initiate a feasibility trial for the PHOENIX handpiece. The dollar increase for the three months ended September 30, 2009 was primarily attributed to the submission and follow-up related to the pre-IDE for the PHOENIX handpiece

*Sales and Marketing*

Sales and marketing expense represents expenses incurred in connection with the 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.

For the three months ended September 30, 2009, sales and marketing expenditures of \$1,363,000 decreased \$173,000, or 11%, when compared to \$1,536,000 for the three months ended September 30, 2008. As a percentage of revenues, sales and marketing expenditures were 64% during the three months ended September 30, 2009 as compared to 59% for the prior year period. The decrease in sales and marketing expenditures for the quarter ended September 30, 2009 as compared to the prior year period was primarily due to a \$132,000 decrease in salary and other employee related expenses as a result of lower commissions. In addition, there was a \$41,000 decrease in travel expenses for the three month period ended September 30, 2009 as compared to the prior year period. The increase as a percentage of revenues in sales and marketing expenditures for the three month period was primarily a result of a lower revenue base in the current period.



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For the nine months ended September 30, 2009, sales and marketing expenditures of \$4,104,000 decreased \$754,000, or 16%, when compared to \$4,858,000 for the nine months ended September 30, 2008. As a percentage of revenues, sales and marketing expenditures were 57% during the nine months ended September 30, 2009 as compared to 50% for the prior year period. The dollar and percentage decrease in sales and marketing expenditures for the nine month period results primarily from a \$550,000 decrease in salary and other employee related expenses as a result of lower commissions. In addition, there was a \$151,000 decrease in travel expenses for the first nine months of 2009 as compared to the prior year period.

### *General and Administrative*

General and administrative expenditures represent all other operating expenses not included in research and development or sales and marketing expenses. For the three months ended September 30, 2009, general and administrative expenditures totaled \$730,000, or 34% of net revenues, as compared to \$753,000, or 29% of net revenues during the three months ended September 30, 2008. This represents a decrease of \$23,000, or 3%. The increase as a percentage of revenues in general and administrative expenditures was primarily a result of a smaller revenue base in the current period. For the nine months ended September 30, 2009, general and administrative expenditures totaled \$2,375,000, or 33% of net revenues, as compared to \$2,404,000, or 25% of net revenues, for the nine months ended September 30, 2008. This represents a \$29,000 decrease, or approximately 1%.

### **Liquidity and Capital Resources**

At September 30, 2009, we had cash and cash equivalents of \$2,517,000 compared to \$2,907,000 at December 31, 2008, a decrease of \$390,000. During the nine months ended September 30, 2009, we had a net loss of \$1,643,000 and net cash used in operating activities of \$427,000 primarily from a decrease in accounts receivable as a result of the decrease in revenues and an increase in accounts payable.

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 investing activities during the nine months ended September 30, 2008 was \$193,000 due to the purchase of marketable securities and property and equipment purchases.

We have incurred significant operating losses and as of September 30, 2009 we had an accumulated deficit of \$171.5 million. Our ability to maintain current operations is dependent upon maintaining our sales at least at the same levels achieved in the prior year. Currently, our primary goal is to achieve and sustain profitability at the operating level and our actions have been guided by this initiative. Our focus is upon core and critical activities, thus operating expenses that are nonessential to our core operations have been reduced or eliminated.

We believe our cash balance as of September 30, 2009, our projected cash flows from operations and actions we have taken to reduce 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;

- 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.

We believe that if revenues from sales or new funds from debt or equity instruments are insufficient to maintain the current expenditure rate, it will be necessary to significantly reduce our operations until an appropriate solution is implemented.

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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 increased direct sales and marketing efforts on existing products and achieving regulatory approval for other products. If our direct sales and marketing efforts are unsuccessful or we are unable to achieve regulatory approval for our products, 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 recent global economic crisis, it has become very difficult for companies to obtain debt or equity financing on reasonable terms, if at all. 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, 2008. 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, 2008.

**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, 2009. 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 30, 2009 were effective in timely alerting them to the material information relating to us (or to our consolidated subsidiaries) 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.

**Inherent Limitations on Effectiveness of Controls**

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 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, 2009 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 6. Exhibits**

The exhibits below are filed or incorporated herein by reference.

**Exhibit No. Description**

- |          |  |
|----------|--|
| 31.1 (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 (1) | Certification of the Chief Financial Officer pursuant to Rule 13a-14(a)/15d-14(a) of the Securities Exchange Act of 1934.                                |
| 32.1 (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 (1) | 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.     |

(1) Filed herewith.

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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 10, 2009

/s/ Paul J. McCormick  
Paul J. McCormick  
Executive Chairman  
(Principal Executive Officer)

Date: November 10, 2009

/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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**Exhibit Index**

**Exhibit No. Description**

- 31.1 (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 (1) Certification of the Chief Financial Officer pursuant to Rule 13a-14(a)/15d-14(a) of the Securities Exchange Act of 1934.
- 32.1 (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 (1) 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.
- (1) Filed herewith.