

CARDIOGENESIS CORP /CA

Form 10-Q

November 13, 2008

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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, 2008**  
**Commission file number 0-28288**

**CARDIOGENESIS CORPORATION**  
*(Exact name of small business issuer 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)*

Check whether the issuer (1) filed all reports required to be filed by Section 13 or 15(d) of the Securities Exchange Act during the past 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 is a large accelerated filer, an accelerated filer, a non-accelerated filer, or a smaller reporting company. See definition of "accelerated filer," "large accelerated filer" and "smaller reporting company" in Rule 12b-2 of the Exchange Act. (Check one):

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

State the number of shares outstanding of each of the issuer's classes of common equity as of the latest practicable date:

45,314,389 shares of Common Stock, no par value, as of October 31, 2008.

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

|   | <b>September<br/>30,<br/>2008<br/>(unaudited)</b> | <b>December<br/>31,<br/>2007<br/>(audited)</b> |
|---|---|--|
| <b>ASSETS</b>   |   |  |
| Current assets:   |   |  |
| Cash and cash equivalents   | \$ 3,439  | \$ 2,824                                       |
| Accounts receivable, net of allowance for doubtful accounts of \$49 and \$28, respectively            | 1,319   | 1,763  |
| Inventories   | 1,380   | 1,602  |
| Prepays and other current assets  | 466   | 486  |
| Total current assets  | 6,604   | 6,675  |
| Long-term investments in marketable securities  | 75  |  |
| Property and equipment, net   | 341   | 457  |
| Other assets, net   | 27  | 27   |
| Total assets  | \$ 7,047  | \$ 7,159                                       |
| <b>LIABILITIES AND SHAREHOLDERS EQUITY</b>  |   |  |
| Current liabilities:  |   |  |
| Accounts payable  | \$ 338  | \$ 169   |
| Accrued liabilities   | 1,124   | 1,458  |
| Deferred revenue  | 902   | 1,210  |
| Current portion of capital lease obligation   | 8   | 12   |
| Total current liabilities   | 2,372   | 2,849  |
| Capital lease obligation, less current portion  | 14  | 19   |
| Total liabilities   | 2,386   | 2,868  |
| 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; 45,314 and 45,274 shares issued and outstanding, respectively |   |  |
|   | 173,938   | 173,826  |
| Accumulated deficit   | (169,277)   | (169,535)                                      |
| Total shareholders equity   | 4,661   | 4,291  |

|   |    |       |    |       |
|---|----|-------|----|-------|
| Total liabilities and shareholders equity | \$ | 7,047 | \$ | 7,159 |
|---|----|-------|----|-------|

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>2008</b>               | <b>2007</b> | <b>2008</b>              | <b>2007</b> |
| Net revenues                         | \$ 2,618                  | \$ 3,486    | \$ 9,719                 | \$ 9,292    |
| Cost of revenues                     | 474                       | 739         | 1,589                    | 1,913       |
| Gross profit                         | 2,144                     | 2,747       | 8,130                    | 7,379       |
| Operating expenses:                  |                           |             |                          |             |
| Research and development             | 165                       | 103         | 633                      | 612         |
| Sales and marketing                  | 1,536                     | 1,246       | 4,858                    | 3,268       |
| General and administrative           | 753                       | 719         | 2,404                    | 2,611       |
| Total operating expenses             | 2,454                     | 2,068       | 7,895                    | 6,491       |
| Operating (loss) income              | (310)                     | 679         | 235                      | 888         |
| Other income (expense):              |                           |             |                          |             |
| Interest expense                     | (1)                       | (10)        | (22)                     | (59)        |
| Interest income                      | 13                        | 29          | 55                       | 94          |
| Non-cash interest expense            |                           | (13)        |                          | (89)        |
| Change in fair value of derivatives  |                           | (133)       |                          | (323)       |
| Other non-cash income, net           |                           | 38          |                          | 151         |
| Total other income (expense), net    | 12                        | (89)        | 33                       | (226)       |
| (Loss) income before income taxes    | (298)                     | 590         | 268                      | 662         |
| Tax provision                        | 10                        |             | 10                       |             |
| Net (loss) income                    | \$ (308)                  | \$ 590      | \$ 258                   | \$ 662      |
| Net (loss) earnings per share:       |                           |             |                          |             |
| Basic                                | \$ (0.01)                 | \$ 0.01     | \$ 0.01                  | \$ 0.01     |
| Diluted                              | \$ (0.01)                 | \$ 0.01     | \$ 0.01                  | \$ 0.01     |
| Weighted average shares outstanding: |                           |             |                          |             |
| Basic                                | 45,292                    | 45,274      | 45,292                   | 45,274      |
| Diluted                              | 45,292                    | 45,274      | 45,328                   | 45,274      |

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>2008</b>              | <b>2007</b> |
| Cash flows from operating activities:   |                          |             |
| Net income  | \$ 258                   | \$ 662      |
| Adjustments to reconcile net income to net cash provided by operating activities:   |                          |             |
| Derivative and warrant fair value adjustments   |                          | 172         |
| Amortization of discount on note payable  |                          | 72          |
| Depreciation and amortization   | 219                      | 366         |
| Bad debt expense  | 21                       | 62          |
| Amortization of debt issuance costs   |                          | 17          |
| Stock-based compensation expense  | 102                      | 62          |
| Changes in operating assets and liabilities:  |                          |             |
| Accounts receivable   | 423                      | 240         |
| Inventories   | 237                      | (329)       |
| Prepays and other current assets  | 20                       | 79          |
| Other assets  |                          | 10          |
| Accounts payable  | 169                      | 187         |
| Accrued liabilities   | (334)                    | (156)       |
| Deferred revenue  | (308)                    | (65)        |
| Net cash provided by operating activities   | 807                      | 1,379       |
| Cash flows from investing activities:   |                          |             |
| Acquisition of property and equipment   | (118)                    | (45)        |
| Purchase of investments in marketable securities  | (150)                    |             |
| Proceeds from the sale of marketable securities   | 75                       |             |
| Net cash used in investing activities   | (193)                    | (45)        |
| 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                       |             |
| Payments on secured convertible term note   |                          | (937)       |
| Payments on capital lease obligation and short term note payable  | (9)                      | (98)        |
| Net cash provided by (used in) financing activities   | 1                        | (1,035)     |
| Net increase in cash and cash equivalents   | 615                      | 299         |
| Cash and cash equivalents at beginning of period  | 2,824                    | 2,118       |
| Cash and cash equivalents at end of period  | \$ 3,439                 | \$ 2,417    |
| Supplemental schedule of cash flow information:   |                          |             |



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|   |       |        |
|---|-------|--------|
| Interest paid   | \$ 3  | \$ 55  |
| Taxes paid  | \$ 14 | \$ 67  |
| Supplemental schedule of non-cash investing activities: |       |        |
| Reclassification of fixed assets to inventories         | \$ 15 | \$ 296 |

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 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 accounting principles generally accepted in the United States of America 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. These financial statements should be read in conjunction with the Company s audited consolidated financial statements and notes thereto for the year ended December 31, 2007, contained in the Company s Annual Report on Form 10-KSB, 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. Although Cardiogenesis achieved operating income for the year ended December 31, 2007 and for the nine months ended September 30, 2008, it does not have a history of operating income. Management believes its cash balance as of September 30, 2008 and expected results of operations are sufficient to meet the Company s capital and operating requirements for the next 12 months.

The Company may require additional financing in the future. 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 stockholders, 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 and convertible notes payable using the if-converted 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 months ended September 30, 2008, there were approximately 23,000 potentially dilutive shares that were related to stock options. For the three and nine months ended September 30, 2007, there were approximately 208,000 potentially dilutive shares related to the potential conversion of convertible debt. For the three and nine

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months ended September 30, 2007 and the three months ended September 30, 2008, the potentially diluted shares were excluded from the diluted income (loss) per share as their effect would be anti-dilutive.

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 accounting principles generally accepted in the United States of America requires management to make estimates and assumptions that affect the reported amounts of assets and liabilities and disclosure of contingent assets and liabilities at the date of the financial statements and the reported amounts of revenues and expenses during the reporting period. Actual results could differ from those estimates. Significant estimates made in preparing the unaudited condensed consolidated financial statements include (but are not limited to) the realizability of accounts receivable and inventories, recoverability of long-lived assets, and the valuation of warranty obligations, embedded derivatives, deferred tax assets, stock options and warrants.

*Reclassifications:*

Certain reclassifications have been made to prior period amounts to conform to the current period presentation.

*Investments in Marketable Securities:*

Effective January 1, 2008, the Company adopted Statement of Financial Accounting Standards ( SFAS ) No. 157, *Fair Value Measurements* ( SFAS No. 157 ), except as it applies to the nonfinancial assets and nonfinancial liabilities subject to FSP SFAS No. 157-2, *Effective Date of FASB Statement No. 157*. SFAS No. 157 clarifies that fair value is an exit price, representing the amount that would be received to sell an asset or paid to transfer a liability in an orderly transaction between market participants. As such, fair value is a market-based measurement that should be determined based on assumptions that market participants would use in pricing an asset or liability. As a basis for considering such assumptions, SFAS No. 157 establishes a three-tier value hierarchy, which prioritizes the inputs used in the valuation methodologies in measuring fair value:

- Level 1 Observable inputs that reflect quoted prices (unadjusted) for identical assets or liabilities in active markets.
- Level 2 Include other inputs that are directly or indirectly observable in the marketplace.
- Level 3 Unobservable inputs which are supported by little or no market activity.

The fair value hierarchy also requires an entity to maximize the use of observable inputs and minimize the use of unobservable inputs when measuring fair value.

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In accordance with SFAS No. 157, the Company measures its cash and cash equivalents and marketable securities at fair value. The Company's investments in auction rate securities are classified within level 3 due to a lack of a liquid market for such securities. The Company has formed its own opinion on the condition of the securities based on information regarding the quality of the security and the quality of the collateral, among other things.

In accordance with the fair value hierarchy described above, the following table shows the fair value of the Company's financial assets that are required to be measured at fair value on a recurring basis at September 30, 2008 (in thousands):

| Description             | Fair Value<br>at<br>September<br>30,<br>2008 | Quoted<br>Market<br>Prices<br>in Active<br>Markets<br>for | Significant<br>Other              | Significant                         |
|-------------------------|--|---|-----------------------------------|-------------------------------------|
|                         |  | Identical<br>Assets<br>(Level 1)                          | Observable<br>Inputs<br>(Level 2) | Unobservable<br>Inputs<br>(Level 3) |
| Marketable Securities:  |  |   |                                   |                                     |
| Auction Rate Securities | \$ 75  | \$  | \$                                | \$ 75                               |

The following table provides a reconciliation of the beginning and ending balances for the Company's assets measured at fair value using significant unobservable inputs (Level 3) as defined in SFAS No. 157 at September 30, 2008 (in thousands):

| Description                   |       |
|-------------------------------|-------|
| Balance at December 31, 2007  | \$    |
| Transfers into Level 3        | 750   |
| Transfers out of Level 3      | (675) |
| Total unrealized losses       |       |
| Total realized gains/(losses) |       |
| Balance at September 30, 2008 | \$ 75 |

Marketable securities measured at fair value using Level 3 inputs are comprised entirely of auction rate securities. Although auction rate securities would typically be measured using Level 2 inputs, the recent failure of auctions (beginning in February 2008) and the lack of market activity and liquidity required that these securities be measured using Level 3 inputs. The underlying assets of the Company's auction rate securities are collateralized primarily by the underlying assets of certain AAA rated funds.

**Derivative Financial Instruments:**

In October 2004, the Company completed a financing transaction with Laurus Master Fund, Ltd., a Cayman Islands corporation (Laurus), pursuant to which the Company issued a Secured convertible term note (the Note). Prior to the repayment of the Note in October 2007, the Company's derivative financial instruments consisted of embedded derivatives related to the Note. These embedded derivatives included certain conversion features and variable interest features. The accounting treatment of derivatives required that the Company record the derivatives at their fair values as of the inception date of the agreement, and at fair value as of each subsequent balance sheet date until the Note was paid off. Any change in fair value was recorded as non-operating, non-cash income or expense at each reporting date. If the fair value of the derivatives was higher at the subsequent balance sheet date, the Company recorded a

non-operating, non-cash charge. If the fair value of the derivatives was lower at the subsequent balance sheet date, the Company recorded non-operating, non-cash income. As a result of the repayment of the Note in October 2007, the Company does not have any derivative financial instruments as of September 30, 2008.

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In connection with the Note, the Company recorded the following items of other income (expense) during the three and nine months ended September 30, 2007, respectively:

\$11,000 and \$72,000 of interest expense related to the accretion of the debt discount,

\$2,000 and \$17,000 of interest expense related to the amortization of debt issuance costs,

\$133,000 and \$323,000 of other expense related to the change in fair value of certain derivatives,

\$38,000 and \$151,000 of other income related to the change in fair value of certain warrants.

*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 frequently loans lasers to hospitals in accordance with its loaned laser programs. Under certain loaned laser programs the Company charges the customer an additional amount (the Premium) over the stated list price on its handpieces in exchange for the use of the laser or collects an upfront deposit that can be applied towards the purchase of a laser. These arrangements meet the definition of a lease and are recorded in accordance with SFAS No. 13 *Accounting for Leases* ( SFAS No. 13 ) as they convey the right to use the lasers over the period of time the customers are purchasing handpieces. Based on the provisions of SFAS No. 13, 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 under SFAS No. 29 *Determining Contingent Rentals* ( SFAS No. 29 ) 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 such multiple element arrangements in accordance with Emerging Issues Task Force Issue ( EITF ) No. 00-21, *Revenue Arrangements with Multiple Deliverables*. For arrangements that involve multiple elements, such as sales of lasers and handpieces, revenue is allocated to each respective element based on its relative fair value and recognized when revenue recognition criteria for each element have been met.

*Segment Disclosures:*

The Company operates in one segment. The principal markets for the Company's products are in the United States, but the Company does have sales to customers in Europe, Canada, Mexico, Asia and Egypt. For the three and nine months ended September 30, 2008, the Company's international sales were \$4,000 and \$96,000, respectively. For the three and nine months ended September 30, 2007, the Company's international sales were \$163,000 and \$243,000, respectively. International sales represent approximately 1% of total sales for the three and nine months ended September 30, 2008, respectively, and 5% and 3% of total sales for the three and nine months ended September 30, 2007, respectively. The majority of international sales are denominated in U.S. Dollars.

*Recent Accounting Pronouncements:*

In September 2006 the Financial Accounting Standards Board (the FASB) issued SFAS No. 157, *Fair Value Measurements*, ( SFAS No. 157 ), which defines fair value, establishes a framework for measuring fair value in



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accordance with generally accepted accounting principles, and expands disclosures about fair value measurements. SFAS No. 157 is effective for financial statements issued for fiscal years beginning after November 15, 2007. In February 2008, the FASB issued FSP 157-2, *Effective Date of FASB Statement No. 157*, which delays the effective date of SFAS No. 157 for non-financial assets and liabilities to fiscal years beginning after November 15, 2008. The adoption of SFAS No. 157 related to financial assets and liabilities did not have a material impact on the Company's consolidated financial statements. The Company is currently evaluating the impact, if any, that SFAS No. 157 may have on its future consolidated financial statements related to non-financial assets and liabilities.

In October 2008, the FASB issued FASB Staff Position No. 157-3, *Determining the Fair Value of a Financial Asset When the Market for That Asset is Not Active* ( FSP 157-3 ). FSP 157-3 clarifies the application of SFAS 157 in a market that is not active, and provides an illustrative example intended to address certain key application issues. FSP 157-3 is effective immediately, and applies to the Company's September 30, 2008 financial statements. The Company has concluded that the application of FSP 157-3 did not have a material impact on its consolidated financial position and results of operations as of and for the periods ended September 30, 2008.

In December 2007 the FASB issued SFAS No. 141R, *Business Combinations*, 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. SFAS No. 141R 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. SFAS No. 141R is effective for financial statements issued for fiscal years beginning after December 15, 2008. Accordingly, any business combinations the Company engages in will be recorded and disclosed according to SFAS No. 141, *Business Combinations*, until January 1, 2009. The Company is currently evaluating the impact, if any, that SFAS No. 141R may have on its 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/>2008<br/>(unaudited)</b> | <b>December<br/>31,<br/>2007<br/>(audited)</b> |
|-----------------|---|--|
| Raw materials   | \$ 253  | \$ 295   |
| Work-in-process | 72  | 96   |
| Finished goods  | 1,055   | 1,211  |
| Total           | \$ 1,380  | \$ 1,602                                       |

**4. Stock-Based Compensation:**

On January 1, 2006, the Company adopted SFAS No. 123R, *Share-Based Payment*, ( SFAS No. 123R ) which establishes standards for the accounting of transactions in which an entity exchanges its equity instruments for goods or services, primarily focusing on accounting for transactions where an entity obtains employee services in share-based payment transactions. SFAS No. 123R requires a public entity to measure the cost of employee services received in exchange for an award of equity instruments, including stock options, based on the grant-date fair value of the award and to recognize it as compensation expense over the period the employee is required to provide service in exchange for the award, usually the vesting period. SFAS No. 123R supersedes the Company's previous accounting under Accounting Principles Board Opinion No. 25, *Accounting for Stock Issued to Employees* ( APB 25 ) for periods beginning in fiscal 2006. In March 2005, the SEC issued Staff Accounting Bulletin No. 107 ( SAB 107 ) relating to SFAS No. 123R. The Company has applied the provisions of SAB 107 in its adoption of SFAS No. 123R.

The Company adopted SFAS No. 123R using the modified prospective transition method, which requires the application of the accounting standard as of January 1, 2006, the first day of the Company's fiscal year 2006. The Company's consolidated financial statements for the three and nine month periods ended September 30, 2008 and





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2007 reflect the impact of SFAS No. 123R.

SFAS No. 123R requires companies to estimate the fair value of share-based payment awards on the date of grant using an option-pricing model. The value of the portion of the award that is ultimately expected to vest is recognized as expense over the requisite service periods in the Company's unaudited consolidated statements of operations. Prior to the adoption of SFAS No. 123R, the Company accounted for stock-based awards to employees and directors using the intrinsic value method in accordance with APB 25 as allowed under SFAS No. 123, *Accounting for Stock-Based Compensation* (SFAS No. 123). Under the intrinsic value method, stock-based compensation expense was recognized in the Company's condensed consolidated statements of operations for option grants to employees and directors below the fair market value of the underlying stock at the date of grant.

Stock-based compensation expense recognized during the period is based on the value of the portion of share-based payment awards that is ultimately expected to vest during the period. Stock-based compensation expense recognized in the Company's unaudited consolidated statements of operations for the three and nine month periods ended September 30, 2008 and 2007 included compensation expense for share-based payment awards granted prior to, but not yet vested, as of December 31, 2005 based on the grant date fair value estimated in accordance with the pro forma provisions of SFAS No. 123 and compensation expense for the share-based payment awards granted subsequent to December 31, 2005 based on the grant date fair value estimated in accordance with the provisions of SFAS No. 123R. As stock-based compensation expense recognized in the unaudited condensed consolidated statements of operations for the three and nine month periods ended September 30, 2008 and 2007 is based on awards ultimately expected to vest, it has been reduced for estimated forfeitures. SFAS No. 123R requires forfeitures to be estimated at the time of grant and revised, if necessary, in subsequent periods if actual forfeitures differ from those estimates. The estimated average forfeiture rate for the three and nine month periods ended September 30, 2008 and 2007 was based on historical forfeiture experience and expected future employee forfeitures.

SFAS No. 123R requires the cash flows resulting from the tax benefits resulting from tax deductions in excess of the compensation cost recognized for those options to be classified as financing cash flows. There were no such tax benefits during the three and nine month periods ended September 30, 2008 and 2007. Prior to the adoption of SFAS No. 123R those benefits would have been reported as operating cash flows had the Company received any tax benefits related to stock option exercises.

***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, 2008, the Company is authorized to issue up to 12,125,000 shares under these plans.

The Company's 1996 Employee Stock Purchase Plan (the ESPP) was adopted in April 1996. As of September 30, 2008, a total of 1,500,000 common shares are authorized and reserved for issuance under this plan, as amended and 230,804 shares remain available for issuance. This plan 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 has treated the ESPP as a compensatory plan and has recorded compensation expense of approximately \$7,000 and \$13,000 during the three and nine month periods ended September 30, 2008, respectively, and zero during the three and nine month periods ended September 30, 2007 in accordance with SFAS No. 123R.

From November 15, 2006 to November 15, 2007, the Company suspended the ESPP. As of November 16, 2007, the ESPP has been reinstated. During the three and nine month periods ended September 30, 2008, there were zero and 36,939 shares purchased under the ESPP, respectively. During the three and nine month periods ended September 30, 2007, there were no shares purchased under the ESPP.

**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, if any, 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, 2008 and 2007 were based on the following assumptions:

|                         | <b>Nine Months Ended</b> |       |                  |
|-------------------------|--------------------------|-------|------------------|
|                         | <b>September</b>         |       | <b>September</b> |
|                         | <b>30,</b>               |       | <b>30,</b>       |
|                         | <b>2008</b>              |       | <b>2007</b>      |
| Expected term           | 4 years                  |       | 4 years          |
| Expected volatility     | 91.5                     | 92.9% | 96.19%           |
| Risk-free interest rate | 2.29                     | 3.53% | 4.75%            |
| 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 30,</b>     |       | <b>September</b> |
|                         | <b>2008</b>              |       | <b>30,</b>       |
|                         | <b>2008</b>              |       | <b>2007</b>      |
| Expected term           | 0.50 years               |       | 0.50 years       |
| Expected volatility     | 91.5                     | 92.9% | 96.19%           |
| Risk-free interest rate | 2.29                     | 3.53% | 4.75%            |
| Expected dividends      |                          |       |                  |

A summary of option activity as of September 30, 2008 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, 2008 | 3,076         | \$ 0.81  | 5.8  | \$                                       |
| Options granted                        | 760           | \$ 0.34  |  |  |
| Options exercised                      | (3)           | \$ 0.27  |  |  |

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|   |       |    |      |     |       |
|---|-------|----|------|-----|-------|
| Options forfeited/canceled  | (391) | \$ | 1.17 |     |       |
| Options outstanding and expected to vest at<br>September 30, 2008 | 3,442 | \$ | 0.67 | 5.9 | \$ 11 |
| Options exercisable at September 30, 2008                         | 2,300 | \$ | 0.83 | 4.3 | \$ 4  |

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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 for the 362,000 outstanding and 121,000 exercisable stock options that were in-the-money at September 30, 2008.

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. The weighted average grant date fair value of options granted during the nine months ended September 30, 2007 was \$0.22 per option. There were no options granted or exercised during the three months ended September 30, 2007.

As of September 30, 2008, there was approximately \$219,000 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 vesting period of 2.2 years.

The following table summarizes stock-based compensation expense related to stock options and ESPP purchases under SFAS No. 123R for the three and nine months ended September 30, 2008 and 2007 which was allocated as follows (in thousands):

|   | <b>Three Months Ended</b> |                  | <b>Nine Months Ended</b> |                  |
|---|---------------------------|------------------|--------------------------|------------------|
|   | <b>September</b>          | <b>September</b> | <b>September</b>         | <b>September</b> |
|   | <b>30,</b>                | <b>30,</b>       | <b>30,</b>               | <b>30,</b>       |
|   | <b>2008</b>               | <b>2007</b>      | <b>2008</b>              | <b>2007</b>      |
| Stock-based compensation expense included in: |                           |                  |                          |                  |
| Research and development                      | \$ 1                      | \$ 2             | \$ 3                     | \$ 8             |
| Sales and marketing                           | 24                        | 5                | 59                       | 25               |
| General and administrative                    | 15                        | 10               | 40                       | 29               |
| Total   | \$ 40                     | \$ 17            | \$ 102                   | \$ 62            |

**5. Legal Matters:**

Previously, 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 have violated patent rights allegedly held by Cardiofocus.

On June 13, 2008, Cardiogenesis filed requests for reexamination of the patents being asserted against Cardiogenesis with the United States 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 United States 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 (1) year or until the reexamination is completed, whichever ever occurs sooner. After one year, if the reexamination continues, the Court will consider further extensions of the stay, for a period not to exceed one additional year, 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 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



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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.

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

This Management's Discussion and Analysis contains descriptions of our expectations regarding future trends affecting our business. These forward-looking statements and other forward-looking statements made elsewhere in this document are made in reliance upon the safe harbor provisions of the Private Securities Litigation Reform Act of 1995. Forward-looking statements are identified by words such as believes, anticipates, expects, intends, plans, may 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. Please read the section titled Risk Factors contained in Part I, Item 1 of our Annual Report on Form 10-KSB for the year ended December 31, 2007 for a discussion of certain risk factors and other conditions which we believe could cause actual results to differ materially from those contemplated by the forward-looking statements. Such factors include, among others, (i) the effects of any inability of us to obtain financing if and when needed to fund operations and the effect on recent uncertainty in global credit markets and the economy in general, (ii) the effect of any failure of our technology or products to be accepted in the marketplace, (iii) the effect of Medicare and other insurance reimbursement policies and rates, (iv) the effect of FDA and other regulations on our business and product development, as well as other factors, many of which are outside of our control. 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**

Cardiogenesis Corporation, incorporated in California in 1989, designs, develops and distributes surgical lasers and single-use fiber optic laser delivery systems ( handpieces ) for the treatment of cardiac ischemia in patients with severe angina. This therapy is a surgical laser-based heart treatment in which transmural channels are made in the heart muscle to improve cardiac perfusion and is referred to as Transmyocardial Revascularization or TMR. It is performed by a cardiac surgeon through a surgical incision while the patient is under general anesthesia. The procedure can be performed adjunctively with coronary bypass or as a sole therapy. Prospective, randomized, multi-center controlled clinical trials have demonstrated a significant reduction in angina and increase in exercise duration in patients treated with the Cardiogenesis TMR technology, when compared with patients who received medications alone. Many scientific experts believe these procedures encourage new vessel formation, or angiogenesis.

In May 1997, we received CE Mark approval for our TMR 2000 laser system and Sologrip® handpieces. We received CE Mark for our minimally invasive PEARL® (Port Enabled Angina Relief with Laser) handpieces (PEARL 5.0 Robotic delivery system ( PEARL 5.0 ) and PEARL 8.0 Thoracoscopic delivery system ( PEARL 8.0 )) and our PHOENIX Combination delivery system ( PHOENIX ) in November 2005 and October 2006, respectively. The less-invasive PEARL 5.0 handpiece is compatible for use with surgical robotic systems, including Intuitive Surgical, Inc.'s da Vinci Surgical System®, while the PHOENIX handpiece combines the delivery of laser energy and precise injection of a biologic substance through the same handpiece. The CE Mark allows us to commercially distribute these products within the European Community. The CE Marking is an international symbol of adherence to quality assurance standards and compliance with applicable European medical device directives.

In February 1999, we received approval from the Food and Drug Administration ( FDA ) for the marketing of our TMR 2000 Laser and Sologrip handpieces for treatment of severe angina. Effective July 1999, the Centers for Medicare and Medicaid Services ( CMS ), formerly known as the Health Care Financial Administration ( HCFA ) implemented a national coverage decision for Medicare coverage for TMR as a primary and secondary procedure.

In December 2004, we received FDA approval for the Solargen® 2100s Laser Console, our second generation TMR laser system. In addition, in November 2007 we received FDA approval for the PEARL 5.0 handpiece designed for delivering TMR therapy with surgical robotic systems. We are in the process of completing the Investigational Device Exemption ( IDE ) trial for the PEARL 8.0 handpiece, and we are developing our FDA

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regulatory strategy for the PHOENIX handpiece.

As of September 30, 2008, we had an accumulated deficit of \$169,277,000. We may incur operating losses in the future. 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 laser systems, handpieces, and related services. Net revenues of \$2,618,000 for the quarter ended September 30, 2008 decreased \$868,000, or 25%, when compared to net revenues of \$3,486,000 for the quarter ended September 30, 2007. We attribute the decrease in sales for the three months ended September 30, 2008 primarily to the decrease in the number of lasers and disposable handpieces sold.

For the quarter ended September 30, 2008, domestic handpiece revenue decreased by \$238,000, or 11%, and domestic laser revenue decreased by \$464,000, or 55%, when compared to the quarter ended September 30, 2007. 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. In the third quarter of 2007, domestic handpiece revenue included \$150,000 in sales of product to customers operating under the loaned laser program and sales of handpieces to customers not operating under the loaned laser program were \$2,066,000.

International sales, accounting for less than 1% of net revenues for the quarter ended September 30, 2008 decreased \$158,000 from the prior year period. We define international sales as sales to customers located outside of the United States. In addition, service and other revenue of \$263,000 decreased \$8,000 for the quarter ended September 30, 2008, when compared to \$271,000 for the quarter ended September 30, 2007.

Net revenues of \$9,719,000 for the nine months ended September 30, 2008 increased \$427,000, or 5%, when compared to net revenues of \$9,292,000 for the nine months ended September 30, 2007. We attribute the increase in sales for the nine months ended September 30, 2008 primarily to the increase in the number of laser units sold.

For the nine months ended September 30, 2008, domestic disposable handpiece revenue decreased by \$153,000, or 2%, and domestic laser revenue increased by \$759,000, or 42%, compared to the nine months ended September 30, 2007. Included in the domestic disposable handpiece revenue, was \$234,000 related to revenue which had been previously deferred and became recognizable during the second quarter of 2008. For the nine 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. For the nine months ended September 30, 2007, domestic handpiece revenue included \$648,000 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 \$5,745,000.

International sales, accounting for approximately 1% of net revenues for the nine months ended September 30, 2008, decreased \$147,000 from the prior year period. In addition, service and other revenue of \$812,000 decreased \$30,000 for the nine months ended September 30, 2008, when compared to \$842,000 for the nine months ended September 30, 2007.

*Gross Profit*

For the quarter ended September 30, 2008, gross margin increased to 82% of net revenues as compared to 79% of net revenues for the quarter ended September 30, 2007. The increase in gross margin for the three month period is primarily attributable to an increase in the average selling price of disposable handpieces.

For the nine months ended September 30, 2008, gross margin increased to 84% of net revenues as compared to



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79% of net revenues for the nine months ended September 30, 2007. The increase in gross margin for the nine month period is primarily attributed to higher average selling prices for both laser and disposable handpiece units. In addition, during the second quarter of 2008, we recognized \$234,000 of deferred revenue for which there is no associated cost of goods sold.

*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 quarter ended September 30, 2008, research and development expenditures of \$165,000 increased \$62,000, or 60%, when compared to \$103,000 for the quarter ended September 30, 2007. As a percentage of revenues, research and development expenditures were 6% during the quarter ended September 30, 2008 as compared to 3% for the prior year period. For the nine months ended September 30, 2008, research and development expenditures of \$633,000 increased \$21,000, or 3%, when compared to \$612,000 for the nine months ended September 30, 2007. As a percentage of revenues, research and development expenditures were 7% for the nine months ended September 30, 2008 and 2007, respectively. The dollar increase for both the three months and nine months ended September 30, 2008 was attributed primarily to an increase in the use of outside services. The increase of research and development expenditures as a percentage of revenues in the quarter ended September 30, 2008 was primarily due to an increase in the use of outside services combined with decreased revenues in the most recent quarter as compared to the prior year period.

*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 quarter ended September 30, 2008, sales and marketing expenditures of \$1,536,000 increased \$290,000, or 23%, when compared to \$1,246,000 for the quarter ended September 30, 2007. As a percentage of revenues, sales and marketing expenditures were 59% during the quarter ended September 30, 2008 as compared to 36% for the prior year period. The dollar and percentage increase in sales and marketing expenditures for the three month period was primarily due to higher compensation expenses related to investments made to strengthen the sales and marketing organization. The percentage increase in sales and marketing expenditures for the three month period was also a result of a lower revenue base in the current period.

For the nine months ended September 30, 2008, sales and marketing expenditures of \$4,858,000 increased \$1,590,000, or 49%, when compared to \$3,268,000 for the nine months ended September 30, 2007. As a percentage of revenues, sales and marketing expenditures were 50% during the quarter ended September 30, 2008 as compared to 35% for the prior year period. The dollar and percentage increase in sales and marketing expenditures for the nine month period was primarily due to higher compensation expenses related to investments made to strengthen the sales and marketing organization.

*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 quarter ended September 30, 2008, general and administrative expenditures ( G&A ) totaled \$753,000, or 29% of net revenues, as compared to \$719,000, or 21% of net revenues during the quarter ended September 30, 2007. This represents an increase of \$34,000, or 5%. The increase as a percentage of revenues was due to expenditures being incurred over a smaller revenue base. For the nine months ended September 30, 2008, G&A totaled \$2,404,000, or 25% of net revenues, as compared to \$2,611,000, or 28% of net revenues, for the nine months ended September 30, 2007. This reduction of \$207,000, or 8%, was primarily attributable to lower insurance expense in the current year.

**Table of Contents***Other Income (Expense)*

The following table reflects the components of other income (expense):

|  | Three months ended<br>September 30, |         | Nine months ended<br>September 30, |          |
|--|-------------------------------------|---------|------------------------------------|----------|
|  | 2008                                | 2007    | 2008                               | 2007     |
|  | (\$ In thousands)                   |         |                                    |          |
| Interest expense Secured Convertible Term Note                                     | \$                                  | \$      | \$                                 | \$       |
| Interest expense other   | (1)                                 | (1)     | (22)                               | (9)      |
| Interest income  | 13                                  | 29      | 55                                 | 94       |
| Non-cash interest expense Accretion of discount on Note                            |                                     | (11)    |                                    | (72)     |
| Non-cash interest expense Amortization of debt issuance costs relating to the Note |                                     | (2)     |                                    | (17)     |
| Change in fair value of derivative   |                                     | (133)   |                                    | (323)    |
| Other non-cash income (expense) Change in fair value of warrants                   |                                     | 38      |                                    | 151      |
| Total other income (expense), net.   | \$ 12                               | \$ (89) | \$ 33                              | \$ (226) |

Net other income for the three months ended September 30, 2008 was \$12,000 as compared to net other expense for the three months ended September 30, 2007 of \$89,000. For the nine months ended September 30, 2008 net other income was \$33,000 as compared to net other expense of \$226,000 for the nine months ended September 30, 2007. For both the three and nine month periods, the changes in the components of other income and expense were primarily due to the fact that at September 30, 2007 we incurred expenses and income associated with certain outstanding debt obligations. However, since such debt was paid in full in October 2007, for the three and nine months ended September 30, 2008, there was no associated expense or income in those periods.

**Liquidity and Capital Resources**

At September 30, 2008, we had cash and cash equivalents of \$3,439,000 compared to \$2,824,000 at December 31, 2007, an increase of \$615,000. During the nine months ended September 30, 2008, we had net income of \$258,000 and net cash provided by operating activities of \$807,000 primarily from a decrease in accounts receivable, inventories, and prepaid expenses in addition to an increase in accounts payable. These changes were offset by a decrease in accrued liabilities and deferred revenue. The decrease in deferred revenue primarily relates to the recognition of \$234,000 of previously deferred revenue in accordance with EITF No. 00-21 which became recognizable during the second quarter of 2008.

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

Prior to 2007, we had incurred significant operating losses for several years and at September 30, 2008 we had an accumulated deficit of \$169,277,000. 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 drive growth in our core products and continue to pursue regulatory approval for our PEARL 8.0 and PHOENIX handpieces, while achieving consistent profitability at the operating level. Our actions have been guided by this initiative, and the resulting cost containment measures have helped to conserve our cash. Our focus is upon core and critical activities, thus operating expenses that are nonessential to our core operations have been eliminated.

We believe our cash balance as of September 30, 2008, 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 12 months. We believe that if revenues from sales or new funds from debt or equity



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instruments are insufficient to maintain the current expenditure rate, it will be necessary to significantly reduce our operations until an appropriate solution is implemented.

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. As a result, we may be required to seek additional sources of financing, which could include short-term debt, long-term debt or equity. We believe that if we are unable to generate sufficient funds from sales or from debt or equity issuances to maintain our current expenditure rate, it will be necessary to significantly reduce our operations as we would not have sufficient cash to fund our operations.

**Related Party Transactions**

We provided unrestricted educational grants of \$40,000 in February 2008 and \$40,000 in June 2008 to the University of Arizona Sarver Heart Center to support the research of cardiovascular disease and stroke. Dr. Marvin Slepian, a member of our board of directors, is Director of Interventional Cardiology of the Sarver Heart Center. While we are not legally bound to provide any additional funding for such research, we may elect to do so in the future. We believe the research will lead to a better understanding of the mechanisms of action for TMR which could ultimately assist us in product development efforts.

**Critical Accounting Policies and Estimates**

The preparation of financial statements in conformity with generally accepted accounting principles requires our 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.

The following presents a summary of our critical accounting policies and estimates, defined as those policies and estimates we believe are: (i) the most important to the portrayal of our financial condition and results of operations, and (ii) that require our most difficult, subjective or complex judgments, often as a result of the need to make estimates about the effects of matters that are inherently uncertain. Our most significant estimates relate 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 options.

**Revenue Recognition:**

We recognize 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.

We frequently loan lasers to hospitals in accordance with our loaned laser programs. Under certain loaned laser programs we charge the customer an additional amount (the Premium) over the stated list price on our handpieces in exchange for the use of the laser or we collect an upfront deposit that can be applied towards the purchase of a laser.

These arrangements meet the definition of a lease and are recorded in accordance with Statement of Financial Accounting Standards (SFAS) No. 13 *Accounting for Leases* (SFAS No. 13) as they convey the right to use the lasers over the period of time the customers are purchasing handpieces. Based on the provisions of SFAS No. 13, 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 under SFAS

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No. 29 *Determining Contingent Rentals* ( SFAS No. 29 ) 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.

We enter into contracts to sell our products and services and, while the majority of our 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. We recognize revenue for such multiple element arrangements in accordance with Emerging Issues Task Force Issue ( EITF ) No. 00-21, *Revenue Arrangements with Multiple Deliverables*. For arrangements that involve multiple elements, such as sales of lasers and handpieces, revenue is allocated to each respective element based on its relative fair value and recognized when revenue recognition criteria for each element have been met.

**Stock Based Compensation:**

We account for equity issuances to non-employees in accordance with SFAS No. 123, *Accounting for Stock Based Compensation*, and EITF Issue No. 96-18, *Accounting for Equity Instruments that are Issued to Other Than Employees for Acquiring, or in Conjunction with Selling, Goods and Services*. All transactions in which goods or services are the consideration received for the issuance of equity instruments are accounted for based on the fair value of the consideration received or the fair value of the equity instrument issued, whichever is more reliably measurable. The measurement date used to determine the fair value of the equity instrument issued is the earlier of the date on which the third-party performance is complete or the date on which it is probable that performance will occur.

On January 1, 2006, we adopted SFAS No. 123R, *Share-Based Payment*, which requires the measurement and recognition of compensation expense for all share-based payment awards made to our employees and directors related to our Amended and Restated 2000 Equity Incentive Plan based on estimated fair values. We adopted SFAS No. 123R using the modified prospective transition method, which requires the application of the accounting standard as of January 1, 2006, the first day of our fiscal year 2006. Our unaudited condensed consolidated financial statements for the three and nine months ended September 30, 2008 and 2007 reflect the impact of adopting SFAS No. 123R. The value of the portion of the award that is ultimately expected to vest is recognized as expense over the requisite service periods in our condensed consolidated statement of operations. As stock-based compensation expense recognized in the unaudited condensed consolidated statement of operations for the three and nine months ended September 30, 2008 and 2007 is based on awards ultimately expected to vest, it has been reduced for any estimated forfeitures if applicable. SFAS No. 123R requires forfeitures to be estimated at the time of grant and revised, if necessary, in subsequent periods if actual forfeitures differ from those estimates. The estimated forfeiture rate was based on historical forfeiture experience and estimated future employee forfeitures.

Employee stock-based compensation expense recognized under SFAS No. 123R for the three and nine months ended September 30, 2008 was \$40,000 and \$102,000, respectively, and for the three and nine months ended September 30, 2007 was \$17,000 and \$62,000, respectively, and was determined by the Black-Scholes valuation model. As of September 30, 2008, total unrecognized compensation cost, adjusted for estimated forfeitures, related to unvested stock options was \$219,000, which is expected to be recognized as an expense over a weighted-average period of approximately 2.2 years. See Note 4 to our unaudited condensed consolidated financial statements for additional information.

**Investments in Marketable Securities:**

Effective January 1, 2008, we adopted SFAS No. 157, except as it applies to the nonfinancial assets and nonfinancial liabilities subject to FSP SFAS No. 157-2. SFAS No. 157 clarifies that fair value is an exit price, representing the amount that would be received to sell an asset or paid to transfer a liability in an orderly transaction between market participants. As such, fair value is a market-based measurement that should be determined based on assumptions that market participants would use in pricing an asset or liability. As a basis for considering such

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assumptions, SFAS No. 157 establishes a three-tier value hierarchy, which prioritizes the inputs used in the valuation methodologies in measuring fair value:

Level 1 Observable inputs that reflect quoted prices (unadjusted) for identical assets or liabilities in active markets.

Level 2 Include other inputs that are directly or indirectly observable in the marketplace.

Level 3 Unobservable inputs which are supported by little or no market activity.

The fair value hierarchy also requires an entity to maximize the use of observable inputs and minimize the use of unobservable inputs when measuring fair value.

In accordance with SFAS No. 157, we measure our cash and cash equivalents and marketable securities at fair value. Our investments in auction rate securities are classified within level 3 due to a lack of a liquid market for such securities. We have formed our own opinion on the condition of the securities based on information regarding the quality of the security and the quality of the collateral, among other things.

In accordance with the fair value hierarchy described above, the following table shows the fair value of our financial assets that are required to be measured at fair value on a recurring basis at September 30, 2008 (in thousands):

| Description             | Fair Value<br>at<br>September<br>30,<br>2008 | Quoted<br>Market<br>Prices<br>in Active<br>Markets<br>for | Significant<br>Other              | Significant                         |
|-------------------------|--|---|-----------------------------------|-------------------------------------|
|                         |  | Identical<br>Assets<br>(Level 1)                          | Observable<br>Inputs<br>(Level 2) | Unobservable<br>Inputs<br>(Level 3) |
| Marketable Securities:  |  |   |                                   |                                     |
| Auction Rate Securities | \$ 75  | \$  | \$                                | \$ 75                               |

The following table provides a reconciliation of the beginning and ending balances for our assets measured at fair value using significant unobservable inputs (Level 3) as defined in SFAS No. 157 at September 30, 2008 (in thousands):

| Description                   |       |
|-------------------------------|-------|
| Balance at December 31, 2007  | \$    |
| Transfers into Level 3        | 750   |
| Transfers out of Level 3      | (675) |
| Total unrealized losses       |       |
| Total realized gains/(losses) |       |
| Balance at September 30, 2008 | \$ 75 |

Marketable securities measured at fair value using Level 3 inputs are comprised entirely of auction rate securities. Although auction rate securities would typically be measured using Level 2 inputs, the recent failure of auctions (beginning in February 2008) and the lack of market activity and liquidity required that these securities be measured using Level 3 inputs. The underlying assets of our auction rate securities are collateralized primarily by the underlying assets of certain AAA rated funds.

**Accounts Receivable:**

Accounts receivable consist of trade receivables recorded upon recognition of revenue for product sales, reduced



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by reserves for the estimated amount deemed uncollectible due to bad debt. The allowance for doubtful accounts is our best estimate of the amount of probable credit losses in our existing accounts receivable. We review the allowance for doubtful accounts quarterly with the corresponding provision included in general and administrative expenses. Past due balances over 90 days and over a specified amount are reviewed individually for collectability. All other balances are reviewed on a pooled basis by type of receivable. Account balances are charged off against the allowance when we feel it is probable the receivable will not be recovered. We do not have any off-balance-sheet credit exposure related to our customers.

***Inventories:***

Inventories are stated at the lower of cost (principally at actual cost on a first-in, first-out basis) or market value. We regularly monitor potential excess or obsolete inventory by analyzing the usage for parts on hand and comparing the market value to cost. When necessary, we reduce the carrying amount of inventory to its market value.

***Accounting for the Impairment or Disposal of Long-Lived Assets:***

We assess potential impairment of our long-lived assets when there is evidence that recent events or changes in circumstances indicate that their carrying value may not be recoverable. Reviews are performed to determine whether the carrying value of assets is impaired based on comparison to the undiscounted estimated future cash flows. If the comparison indicates that there is impairment, the impaired asset is written down to fair value, which is typically calculated using estimated discounted future cash flows. The amount of impairment would be recognized as the excess of the asset's carrying value over its fair value. Events or changes in circumstances which may cause impairment include: significant changes in the manner of use of the acquired asset, negative industry or economic trends, and underperformance relative to historic or projected future operating results.

***Income Taxes:***

We account for income taxes using the asset and liability method under which deferred tax assets or liabilities are calculated at the balance sheet date using current tax laws and rates in effect for the year in which the differences are expected to affect taxable income. Valuation allowances are established, when necessary, to reduce deferred tax assets to the amounts expected to be realized.

**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 the Company's management, including our President and our Chief 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, 2008. Based upon that evaluation, the President and the Chief Financial Officer concluded that the design and operation of these disclosure controls and procedures at September 30, 2008 were effective in timely alerting them to the material information relating to the Company (or the Company's consolidated subsidiaries) required to be included in the Company's periodic filings with the SEC, such that the information relating to the Company, 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 the Company's management, including our President and CFO, 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.



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**Changes in internal control over financial reporting**

There were no changes in the Company's internal control over financial reporting that occurred during the quarter ended September 30, 2008 that has materially affected, or are reasonably likely to materially affect, the Company's internal control over financial reporting.

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**Part II Other Information**

**Item 1. Legal Proceedings**

Previously, 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 have violated patent rights allegedly held by Cardiofocus.

On June 13, 2008, we filed requests for reexamination of the patents being asserted against us with the United States 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 United States Patent and Trademark Office granted our 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, we, 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 (1) year or until the reexamination is completed, which ever occurs sooner. After one year, if the reexamination continues, the Court will consider further extensions of the stay, for a period not to exceed one additional year, upon good cause shown by the defendants.

We intend to continue to vigorously defend ourselves. However, any litigation involves risks and uncertainties and the likely outcome of the case cannot be determined at this time. In addition, litigation involves significant expenses and distraction of management resources which may have an adverse effect on our results of operations.

Except as described above, we are not a party to any material legal proceeding.

**Item 6. Exhibits**

The exhibits below are filed or incorporated herein by reference.

| <b>Exhibit No.</b> | <b>Description</b>   |
|--------------------|--|
| 3.1.1 (1)          | Restated Articles of Incorporation, as filed with the California Secretary of State on May 1, 1996   |
| 3.1.2 (2)          | Certificate of Amendment of Restated Articles of Incorporation, as filed with California Secretary of State on July 18, 2001                             |
| 3.1.3 (3)          | Certificate of Determination of Preferences of Series A Preferred Stock, as filed with the California Secretary of State on August 23, 2001              |
| 3.1.4 (4)          | Certificate of Amendment of Restated Articles of Incorporation, as filed with the California Secretary of State on January 23, 2004                      |
| 3.2 (5)            | Amended and Restated Bylaws  |
| 4.1 (6)            | Third Amendment to Rights Agreement, dated October 26, 2004, between the Company and EquiServe Trust Company N.A   |
| 4.2 (7)            | Second Amendment to Rights Agreement, dated as of January 21, 2004, between Cardiogenesis Corporation and EquiServe Trust Company, N.A., as Rights Agent |
| 4.3 (8)            | First Amendment to Rights Agreement, dated as of January 17, 2002, between Cardiogenesis Corporation and EquiServe Trust Company, N.A., as Rights Agent  |
| 4.4 (9)            | Rights Agreement, dated as of August 17, 2001, between Cardiogenesis Corporation and EquiServe Trust Company, N.A., as Rights Agent                      |



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| <b>Exhibit No.</b> | <b>Description</b>   |
|--------------------|--|
| 4.5 (10)           | Registration Rights Agreement, dated as of January 21, 2004, by and among Cardiogenesis Corporation and the investors identified therein   |
| 4.6 (11)           | Form of Common Stock Purchase Warrant, dated January 21, 2004, having an exercise price of \$1.37 per share  |
| 4.7 (12)           | Registration Rights Agreement, dated October 26, 2004, between the Company and Laurus Master Fund, Ltd.  |
| 4.8 (13)           | Common Stock Purchase Warrant, dated October 26, 2004, in favor of Laurus Master Fund, Ltd.  |
| 31.1 (14)          | Certification of the Chief Executive Officer pursuant to Rule 13a-14(a) of Securities Exchange Act of 1934, as adopted pursuant to Section 302 of the Sarbanes-Oxley Act of 2002   |
| 31.2 (14)          | Certification of the Chief Financial Officer pursuant to Rule 13a-14(a) of Securities Exchange Act of 1934, as adopted pursuant to Section 302 of the Sarbanes-Oxley Act of 2002   |
| 32.1 (14)          | Certifications of the Chief Executive Officer and Chief Financial Officer pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002 |
| (1)                | Incorporated by reference to Exhibit 3.1 to the Registrant's Registration Statement on Form S-1/A (File No. 33-03770), filed on May 21, 1996                                       |
| (2)                | Incorporated by reference to Exhibit 3.2 to the Registrant's Quarterly Report on Form 10-Q filed on August 14, 2001  |
| (3)                | Incorporated by reference to Exhibit 4.2 to the Registrant's Current Report on Form 8-K  |

filed on  
August 20, 2001

(4) Incorporated by  
reference to  
Exhibit 3.1.4 to  
the Registrant's  
Annual Report  
on Form 10-K  
filed on  
March 10, 2004

(5) Incorporated by  
reference to  
Exhibit 3.2 to  
the Registrant's  
Annual Report  
on Form 10-K  
filed on  
March 10, 2004

(6) Incorporated by  
reference to  
Exhibit 4.1 to  
the Registrant's  
Current Report  
on Form 8-K  
filed  
October 28,  
2004

(7) Incorporated by  
reference to  
Exhibit 4.1 to  
the Registrant's  
Current Report  
on Form 8-K  
filed January 22,  
2004

(8) Incorporated by  
reference to  
Exhibit 4.1 to  
the Registrant's  
Current Report  
on Form 8-K  
filed January 18,  
2002

(9) Incorporated by  
reference to

Exhibit 4.1 to  
the Registrant's  
Current Report  
on Form 8-K  
filed August 20,  
2001

(10) Incorporated by  
reference to  
Exhibit 4.5 to  
the Registrant's  
Current Report  
on Form 8-K  
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2004

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reference to  
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the Registrant's  
Current Report  
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2004

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the Registrant's  
Current Report  
on Form 8-K  
filed  
October 28,  
2004

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reference to  
Exhibit 4.5 to  
the Registrant's  
Current Report  
on Form 8-K  
filed  
October 28,  
2004

(14) 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 13, 2008

/s/ Richard P. Lanigan

Richard P. Lanigan  
President  
(Principal Executive  
Officer)

Date: November 13, 2008

/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**

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| 32.1 (14)          | Certifications of the Chief Executive Officer and Chief Financial Officer pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002 |
| (1)                |  |



Incorporated by  
reference to  
Exhibit 3.1 to  
the Registrant's  
Registration  
Statement on  
Form S-1/A  
(File  
No. 33-03770),  
filed on May 21,  
1996

(2) Incorporated by  
reference to  
Exhibit 3.2 to  
the Registrant's  
Quarterly  
Report on Form  
10-Q filed on  
August 14, 2001

(3) Incorporated by  
reference to  
Exhibit 4.2 to  
the Registrant's  
Current Report  
on Form 8-K  
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August 20, 2001

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- (4) Incorporated by reference to Exhibit 3.1.4 to the Registrant's Annual Report on Form 10-K filed on March 10, 2004
- (5) Incorporated by reference to Exhibit 3.2 to the Registrant's Annual Report on Form 10-K filed on March 10, 2004
- (6) Incorporated by reference to Exhibit 4.1 to the Registrant's Current Report on Form 8-K filed October 28, 2004
- (7) Incorporated by reference to Exhibit 4.1 to the Registrant's Current Report on Form 8-K filed January 22, 2004
- (8) Incorporated by reference to Exhibit 4.1 to the Registrant's Current Report on Form 8-K filed January 18, 2002
- (9) Incorporated by reference to Exhibit 4.1 to

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