

Cardiogenesis Corp /CA  
Form 10-Q  
May 16, 2011

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

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

**For the quarterly period ended March 31, 2011.**

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

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

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

**California**

**77-0223740**

(State of incorporation or organization)

(I.R.S. Employer  
Identification Number)

**11 Musick**

**Irvine, California 92618**

(Address of principal executive offices)

**(949) 420-1800**

(Issuer's telephone number)

Indicate by check mark whether the registrant (1) has filed all reports required to be filed by Section 13 or 15(d) of the Securities Exchange Act of 1934 during the preceding 12 months (or for such shorter period that the registrant was required to file such reports), and (2) has been subject to such filing requirements for the past 90 days.

Yes ☒ No ☐

Indicate by check mark whether the registrant has submitted electronically and posted on its corporate Web site, if any, every Interactive Data File required to be submitted and posted pursuant to Rule 405 of Regulation S-T (§232.405 of this chapter) during the preceding 12 months (or for such shorter period that the registrant was required to submit and post such files). Yes ☐ No ☐

Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, a non-accelerated filer or a smaller reporting company. See the definitions of large accelerated filer, accelerated filer and smaller reporting company in Rule 12b-2 of the Exchange Act:

Large accelerated filer <input type="checkbox"/>	Accelerated filer <input type="checkbox"/>	Non-accelerated filer <input type="checkbox"/> (Do not check if a smaller reporting company)	Smaller reporting company <input checked="" type="checkbox"/>
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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 April 29, 2011, there were 46,564,910 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>March 31, 2011 (unaudited)</b>	<b>December 31, 2010 (audited)</b>
<b>ASSETS</b>		
Current assets:		
Cash and cash equivalents	\$ 1,147	\$ 1,810
Accounts receivable, net of allowance for doubtful accounts of \$1 and \$11, respectively	1,520	1,375
Inventories	616	627
Prepays and other current assets	287	412
Total current assets	3,570	4,224
Property and equipment, net	236	275
Total assets	\$ 3,806	\$ 4,499
<b>LIABILITIES AND SHAREHOLDERS' EQUITY</b>		
Current liabilities:		
Accounts payable	\$ 189	\$ 359
Accrued salaries and related	739	723
Accrued liabilities	602	531
Deferred revenue	540	684
Note payable	47	111
Current portion of capital lease obligations	7	8
Total current liabilities	2,124	2,416
Capital lease obligations, less current portion	5	5
Total liabilities	2,129	2,421
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; 46,061 and 45,739 shares issued and outstanding, respectively	174,505	174,459
Accumulated deficit	(172,828)	(172,381)
Total shareholders' equity	1,677	2,078

Total liabilities and shareholders' equity	\$	3,806	\$	4,499
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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 March 31,</b>	
	<b>2011</b>	<b>2010</b>
Net revenues	\$ 3,053	\$ 3,233
Cost of revenues	430	528
Gross profit	2,623	2,705
Operating expenses:		
Research and development	521	288
Sales and marketing	1,357	1,731
General and administrative	1,174	699
Total operating expenses	3,052	2,718
Operating loss	(429)	(13)
Other income (expense):		
Interest expense	(1)	(1)
Interest income		
Total other expense, net	(1)	(1)
Loss before income taxes	(430)	(14)
Provision for income taxes	3	4
Net loss	\$ (433)	\$ (18)
Net loss per share:		
Basic and diluted	\$ (0.01)	\$ (0.00)
Weighted average shares outstanding:		
Basic and diluted	45,891	45,551

See accompanying notes.

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

	<b>Three months ended March 31,</b>	
	<b>2011</b>	<b>2010</b>
Cash flows from operating activities:		
Net loss	\$ (433)	\$ (18)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation and amortization	60	75
Stock-based compensation expense	65	61
Changes in operating assets and liabilities:		
Accounts receivable	(145)	(753)
Inventories	4	172
Prepays and other current assets	125	(26)
Accounts payable	(170)	102
Accrued liabilities	54	66
Deferred revenue	(144)	49
Net cash used in operating activities	(584)	(272)
Cash flows from investing activities:		
Acquisition of property and equipment	(14)	(14)
Proceeds from the sale of marketable securities		
Net cash used in investing activities	(14)	(14)
Cash flows from financing activities:		
Payments on note payable	(64)	(53)
Payments on capital lease obligations	(1)	(2)
Net cash used in financing activities	(65)	(55)
Net decrease in cash and cash equivalents	(663)	(341)
Cash and cash equivalents at beginning of period	1,810	2,568
Cash and cash equivalents at end of period	\$ 1,147	\$ 2,227
Supplemental schedule of cash flow information:		
Interest paid	\$ 1	\$ 1
Taxes paid	\$	\$ 12
Supplemental schedule of non-cash investing and financing activities:		
Reclassification of inventories to property and equipment	\$ 7	\$ 22

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Estimated fair value of shares surrendered to pay for tax withholding recorded to common stock	\$ 19	\$ 33
Estimated fair value of shares surrendered to pay for tax withholding recorded to accumulated deficit	\$ 14	\$ 15

See accompanying notes.

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**CARDIOGENESIS CORPORATION**

**NOTES TO UNAUDITED CONDENSED CONSOLIDATED FINANCIAL STATEMENTS**

**1. Nature of Operations:**

Cardiogenesis Corporation ( Cardiogenesis, the Company, we, our, or us ) 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.

On March 28, 2011, Cardiogenesis, CryoLife, Inc. ( Parent ) and CL Falcon, Inc., a wholly-owned subsidiary of Parent ( Merger Sub ), entered into an Agreement and Plan of Merger, which was subsequently amended and restated on April 14, 2011 (as amended and restated, the Merger Agreement ). Pursuant to the Merger Agreement, and upon the terms and subject to the conditions thereof, Merger Sub agreed to purchase 49.9 percent of the common stock, no par value, of the Company (the Shares ) at a price of \$0.457 per Share, net to the holder thereof in cash, without interest and subject to any applicable withholding taxes (the Offer Price ), and subject to the conditions set forth in the Offer to Purchase dated April 5, 2011 (as amended or supplemented, the Offer to Purchase ), and the related Letter of Transmittal (which, together with the Offer to Purchase, constitute the Offer ). Concurrently with the execution of the Merger Agreement, Paul McCormick, Richard Lanigan, William Abbott and all of the Company's directors entered into a Support Agreement with Parent (the Support Agreement ) pursuant to which they have agreed, among other things, to vote in favor of the Merger Agreement, and the Merger contemplated therein, as more fully described below.

On May 2, 2011, Merger Sub completed the Offer and as of such date owned approximately 23,235,890 Shares, representing 49.9 percent of the Company's outstanding Shares.

As contemplated by the terms of the Merger Agreement, Parent expects to acquire the remaining Shares in a second-step merger in which each outstanding Share that was not acquired by Merger Sub in the Offer (and other than Shares as to which dissenters' rights under California law are properly exercised) will be converted into the right to receive the Offer Price, net to the holder thereof in cash, without interest and subject to any applicable withholding taxes, and the Company will become a wholly-owned subsidiary of Parent (the Merger ). The Merger will be completed following its approval at a special meeting of the Company's shareholders to be held on May 16, 2011. Merger Sub will vote all of the Shares it acquired in the Offer in favor of approving and adopting the Merger Agreement, and such vote, when combined with the vote of parties to the Support Agreement, is sufficient to assure approval and adoption of the Merger Agreement at the special meeting. As a result, the affirmative vote of other Company shareholders is not required to approve and adopt the Merger Agreement. After the Merger is completed, (i) Company shareholders (other than Parent and its affiliates) will no longer have any interest in, and no longer be shareholders of, Cardiogenesis, and will not participate in any of the Company's future earnings or growth, (ii) the Shares will no longer be quoted on the OTCBB and price quotations with respect to the Shares in the public market will no longer be available; and (iii) the registration of the Shares under the Securities Exchange Act of 1934, as amended, will be terminated.

The Company's shareholders are advised to read the proxy statement and other documents for use at the special meeting of shareholders of the Company because they contain important information. A definitive proxy statement and form of proxy has been mailed to the Company's shareholders and, along with other relevant documents, is available at no charge at the website of the Securities and Exchange Commission (the SEC ) at <http://www.sec.gov> or by contacting William R. Abbott, the Company's Chief Financial Officer, at 11 Musick, Irvine, California, 92618, or via telephone at (949) 420-1800. Information relating to the participants in the proxy solicitation in connection with the special meeting of shareholders is contained in the proxy statement.

**Table of Contents****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 SEC. Accordingly, they do not include all of the information and footnotes required by GAAP for complete financial statement presentation. In the opinion of management, all adjustments (consisting primarily of normal recurring accruals) considered necessary for a fair presentation have been included. The Company has evaluated subsequent events through the filing date of this Form 10-Q, and determined that no subsequent events have occurred that would require recognition in the condensed consolidated financial statements or disclosure in the notes thereto other than as disclosed in the accompanying notes. These unaudited condensed consolidated financial statements should be read in conjunction with the Company's audited consolidated financial statements and notes thereto for the year ended December 31, 2010, 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 March 31, 2011, it had an accumulated deficit of \$172.8 million. Management believes its cash balance as of March 31, 2011 and expected results of operations are sufficient to meet the Company's capital and operating requirements for the next 12 months.

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

*Net Earnings (Loss) Per Share:*

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

For the three months ended March 31, 2011, there were approximately 964,000 potentially dilutive shares that were excluded from diluted loss per share as their effect would have been anti-dilutive for the period then ended. For the three months ended March 31, 2010, there were 431,000 potentially dilutive shares.

*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, inventory reserves, valuation allowance relating to deferred tax assets, warranty reserve, the assessment of future

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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 primarily in the United States. Cardiogenesis performs ongoing credit evaluations of its customers and generally does not require collateral. Although Cardiogenesis maintains allowances for potential credit losses that it believes to be adequate, a payment default on a significant sale could materially and adversely affect its operating results and financial condition. At March 31, 2011, as a result of a capital equipment sale which occurred late in the quarter, one customer individually accounted for 17% of gross accounts receivable and 15% of quarterly net revenues. At December 31, 2010, one customer, who purchased a laser console in December individually accounted for more than 10% of gross accounts receivable. At March 31, 2010, as a result of a capital equipment sale which occurred late in the quarter, one customer individually accounted for 26% of gross accounts receivable and 17% of quarterly net revenues.

As of March 31, 2011, approximately \$719,000 of the Company's cash and cash equivalents were maintained in money market mutual funds, and approximately \$428,000 of the Company's cash and cash equivalents were maintained at a major financial institution in the United States. At times, deposits held with the financial institution may exceed the amount of insurance provided by the Federal Deposit Insurance Corporation (the "FDIC"), which provides deposit coverage with limits up to \$250,000 per owner through December 31, 2013. Generally, these deposits may be redeemed upon demand and, therefore, are believed to bear low risk.

After giving effect to the increased FDIC insurance, at March 31, 2011, the Company's uninsured cash totaled approximately \$1,036,000.

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

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

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

***Segment Disclosures:***

The Company operates in one segment. The principal market for the Company's products is in the United States. International sales occur primarily in Europe, Mexico and Asia and amounted to approximately \$38,000 and \$40,000 for the three months ended March 31, 2011 and 2010, respectively. International sales represented approximately 1% of total sales for the three months ended March 31, 2011 and 2010. 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 April 2010, the FASB issued an update to its accounting guidance regarding Stock Based Compensation. The guidance addresses the classification of a share-based payment award with an exercise price denominated in the currency of a market in which the underlying equity security trades. This update amends the guidance to clarify that a share-based payment award with an exercise price denominated in the currency of a market in which a substantial portion of the entity's equity securities trades shall not be considered to contain a market, performance, or service condition. Therefore, such an award is not to be classified as a liability if it otherwise qualifies as equity classification. The amendments in this update should be effective for fiscal years, and interim periods within those fiscal years, beginning on or after December 15, 2010. The guidance should be applied by recording a cumulative-effect adjustment to the opening balance of retained earnings for all outstanding awards as of the beginning of the fiscal year in which the amendments are initially applied. The Company adopted this guidance on January 1, 2011 and it did not have a material impact on its consolidated financial statements.

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

**3. Inventories:**

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

	<b>March 31, 2011 (unaudited)</b>	<b>December 31, 2010 (audited)</b>
Raw materials	\$ 111	\$ 111
Work-in-process	218	163
Finished goods	287	353
Total	\$ 616	\$ 627

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

***Description of Plans***

The Company's stock option plans provide for grants of options to employees and directors of the Company to purchase the Company's shares at the fair value of such shares on the grant date (based on the closing price of the Company's common stock). The options vest immediately or up to four years beginning on the grant date and have a 10-year term. The terms of the option grants are determined by the Company's Board of Directors. As of March 31, 2011, 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 were reserved for issuance under the ESPP, as amended. The ESPP permitted 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 had two offering periods, the first one from May 16 through November 15 and the second one from November 16 through May 15. Employee purchases were nonetheless limited to 15% of eligible cash compensation, and other restrictions regarding the amount of annual purchases also apply. The Company suspended the ESPP effective at the end of the November 16, 2008 offering period.

The Company had treated the ESPP as a compensatory plan.

***Summary of Assumptions and Activity***

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

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.

There were no stock options granted in the three months ended March 31, 2011. The Company's fair value calculations for stock-based compensation awards to employees under its stock option plans for the three months ended March 31, 2010 were based on the following assumptions:

	<b>Three Months Ended</b>	
	<b>March 31, 2011</b>	<b>March 31, 2010</b>
Expected term	N/A	5.54 years
Expected volatility	N/A	97.56%
Risk-free interest rate	N/A	2.53%
Expected dividend yield		

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A summary of option activity as of March 31, 2011 and changes during the three months then ended, is presented below (in thousands except per share data):

	<b>Shares</b>	<b>Weighted Average Exercise Price</b>	<b>Weighted Average Remaining Contractual Term (Years)</b>	<b>Aggregate Intrinsic Value</b>
Options outstanding at January 1, 2011	3,200	\$0.43		\$
Options granted		\$		\$
Options exercised		\$		\$
Options forfeited/canceled	(53)	\$0.23		\$
Options outstanding and expected to vest at March 31, 2011	3,147	\$0.43	6.0	\$413
Options exercisable at March 31, 2011	2,451	\$0.47	5.2	\$304

The aggregate intrinsic value is calculated as the difference between the exercise price of the stock options and the quoted price of the Company's common stock at period end. There were no stock options exercised during the quarter ended March 31, 2011. There were 2,142,440 options at March 31, 2011 that were in-the-money. The aggregate intrinsic value for in-the-money options at March 31, 2011 was \$413,000. There were 2,120,634 options outstanding at March 31, 2010 that were in-the-money. The aggregate intrinsic value for in-the money options at March 31, 2010 was \$286,000.

The weighted average grant date fair value of options granted during the three months ended March 31, 2010 was \$0.25.

As of March 31, 2011, there was approximately \$61,000, net of forfeitures, of total unrecognized compensation cost related to employee and director stock option compensation arrangements. That cost is expected to be recognized over the weighted average remaining vesting period of approximately 1.3 years. For the three months ended March 31, 2011 and 2010, the amount of stock-based compensation expense related to stock options was approximately \$36,000 and \$34,000, respectively.

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

During the three month period ended March 31, 2011, the Company repurchased and cancelled 73,511 shares of its common stock in connection with the vesting of 246,151 shares of restricted stock. The value of the shares repurchased was approximately \$33,000, based on the closing market price on the measurement date. In lieu of remitting the value of the shares to the holders, the Company used such amount to remit payroll taxes associated with

the vested shares. Accordingly, the Company recorded the aggregate original issue price of approximately \$19,000 to equity and the difference of the fair value at vesting and the original issue price of approximately \$14,000 to accumulated deficit. As such amount was not remitted as of March 31, 2011, such amount has been included as non-cash financing activity in the accompanying 2011 statement of cash flows

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During the three month period ended March 31, 2010, the Company repurchased and cancelled 125,983 shares of its common stock in connection with the vesting of 315,324 shares of restricted stock. The value of the shares repurchased was approximately \$48,000, based on the closing market price on the measurement date. In lieu of remitting the value of the shares to the holders, the Company used such amount to remit payroll taxes associated with the vested shares. Accordingly, the Company recorded the aggregate original issue price of approximately \$33,000 to equity and the difference of the fair value at vesting and the original issue price of approximately \$15,000 to accumulated deficit. As such amount was not remitted as of March 31, 2010, such amount had been included as non-cash financing activity in the accompanying 2010 statement of cash flows

For the three months ended March 31, 2011 and 2010, the amount of stock based compensation expense related to restricted stock was approximately \$29,000 and \$27,000, respectively. As of March 31, 2011, there was approximately \$76,000 of total unrecognized compensation cost related to restricted stock that is expected to be recognized over the weighted average remaining vesting period of 0.7 years. Since shares of restricted stock are subject to cliff vesting, those shares that have not vested as of March 31, 2011 and 2010 have been excluded from the respective issued and outstanding shares and basic earnings per share computations.

The following table summarizes the restricted stock activity for the three months ended March 31, 2011 (in thousands):

	<b>March 31, 2011</b>
Unvested Restricted Stock Outstanding at January 1, 2011	782
Granted	
Forfeited	(32)
Vested	(246)
Unvested Restricted Stock Outstanding at March 31, 2011	504

The following table summarizes stock-based compensation expense related to stock options, restricted stock and ESPP purchases for the three months ended March 31, 2011 and 2010 which was allocated as follows (in thousands):

	<b>Three Months Ended March</b>	
	<b>31, 2011</b>	<b>March 31, 2010</b>
Stock-based compensation expense included in:		
Research and development	\$ 7	\$ 4
Sales and marketing	11	30
General and administrative	47	27
	<b>\$ 65</b>	<b>\$ 61</b>

***Treatment of Equity Awards in the Merger and under the Merger Agreement***

Any stock options held by the Company's non-employee directors will be treated in accordance with the Merger Agreement. The Merger Agreement provides that each stock option that is outstanding immediately prior to the Effective Time (as defined in the Merger Agreement), whether vested or unvested, will be canceled and, in exchange therefore, Parent will pay to each person who was holding such canceled stock option, an amount in cash (without interest and subject to deduction for any required withholding taxes) equal to the product of (i) the excess, if any, of the Offer Price over the exercise price per share of such stock option and (ii) the number of shares subject to such stock option. However, if the exercise price per share under any such stock option is equal to or greater than the Offer Price, then such stock option will be canceled without any cash payment being made in respect thereof. The Merger



Agreement further provides that each share of restricted stock of the Company that is not fully vested and that is outstanding immediately prior to the closing of the Offer shall automatically become fully vested immediately prior to such closing, but subject to the occurrence of the closing of the Offer. This occurred on May 2, 2011. The Merger Agreement requires the Company to amend its equity incentive plans, as necessary, to provide for the above described treatment of the Options in the Merger.

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### **5. Legal Matters:**

#### ***Patent Litigation***

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 Cardiogenesis and a number of other companies. In the complaint, CardioFocus alleges that Cardiogenesis and the other defendants had previously violated patent rights allegedly held by CardioFocus. All of the asserted patents have now expired and we are the sole remaining defendant in the action.

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

Thereafter, the Court, at a status conference held on April 22, 2010, issued a scheduling order scheduling dates in connection with the litigation regarding discovery, law and motion practice, a briefing schedule and hearing for patent claim construction proceedings, and other key events. Fact discovery concluded in January 2011 and the parties have fully briefed the issues on the construction/interpretation of certain disputed terms of the remaining asserted claims. A Claim Construction hearing had been set for April 1, 2011 and trial was set to commence on November 7, 2011.

Cardiogenesis as previously reported has also filed four (4) further reexamination requests seeking to invalidate the remaining claims of the 780 Patent and 073 Patent being asserted against Cardiogenesis. Two (2) of the reexamination requests were filed on June 30, 2010, and two (2) others were filed on October 15, 2010. These further reexamination requests are based, in part, on newly identified prior art not previously considered by the USPTO and on March 16, 2011, the USPTO issued Office Actions rejecting the three (3) remaining claims in view of multiple combinations of prior art. In light of the rejection of the three (3) remaining claims being asserted and because a final ruling that such claims are invalid would be potentially dispositive of the entire litigation, the parties requested and the Court granted a stay of the litigation pending the outcome of Cardiogenesis reexaminations. The stay was ordered in effect on March 24, 2011 and all dates previously set, including the claim construction hearing, have been suspended. The parties are to provide the Court with a Joint Status Report by September 30, 2011.

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

#### ***Litigation Related to the Merger and Merger Agreement***

On April 7, 2011, two plaintiffs filed purported class actions against the Company, its directors, and Parent and Merger Sub, in connection with the proposed Offer and Merger. These suits were filed in California Superior Court for Orange County and allege that the defendants breached and/or aided and abetted the breach of their fiduciary duties to the Company by seeking to sell the Company through an allegedly unfair process and for an unfair price and on unfair terms. The suits seek various equitable relief that would delay or enjoin the Merger based on allegations regarding the process by which offers or potential offers were evaluated by the Company, as well as fees and expenses of the plaintiffs attorneys and experts.

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Court	Filing Date	Case Name	Case Number
Superior Court of California, County of Orange	April 7, 2011	Patrick J. Grace vs. Paul McCormick	30-2011-00464472-CU-SL-CXC
Superior Court of California, County of Orange	April 7, 2011	Marion William Habiak vs. Cardiogenesis Corporation	30-2011-00464844-CU-SL-CXC

The Company believes the allegations in the lawsuits are without merit, intends to defend the actions vigorously. The absence of an injunction or court order preventing the consummation of the transaction is a condition to CryoLife's obligation to complete the Merger pursuant to the Merger Agreement.

***Other Litigation***

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

**6. Related Party Transactions:**

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

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

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

The Company entered into a consulting agreement with Dr. Marvin Slepian, a member of the Company's Board of Directors, dated April 1, 2010 and effective March 24, 2010. Pursuant to the agreement, Dr. Slepian provided consulting services at the Company's direction relating to basic and clinical scientific initiatives as well as development of certain scientific and educational materials. In consideration for such services, the Company will pay Dr. Slepian \$400 per hour up to a maximum of \$2,500 per day. The agreement may be terminated by either party upon thirty days' written notice. For both the three months ended March 31, 2011, and 2010 the Company did not pay Dr. Slepian for any consulting services.

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**7. Commitments:**

Effective September 15, 2010, the Company entered into an agreement with the Texas Heart Institute (THI), whereby the Company will sponsor biocompatibility and animal safety studies to support the PHOENIX Investigational Device Exemption to the Food and Drug Administration. In consideration for such services, the Company will pay THI total project funds not to exceed \$651,011. The agreement will terminate on June 30, 2011, but may be extended for an additional term by the mutual written consent of both parties. The agreement may be terminated by either party upon thirty days' written notice.

**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 may constitute forward-looking statements. Forward-looking statements are identified by words such as believes, anticipates, expects, intends, plans, will, 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. 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, 2010. 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 design, develop and distribute laser-based surgical products and disposable fiber-optic delivery systems, which we refer to throughout this report as handpieces, for the treatment of diffuse coronary artery disease. Transmyocardial revascularization, or TMR, is a surgical procedure, in which transmural channels are made in the heart muscle that cannot be treated by conventional methods and has been proven to reduce angina in selected patients.

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

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

In addition, we continue our research and development activities in an effort to develop new technologies for the treatment of cardiac ischemia. We have initiated a large animal safety study, as well as a human clinical feasibility trial outside of the U.S. for the PHOENIX System. The results of these will be used in support of an IDE submission in order to obtain FDA approval to begin a clinical trial for our PHOENIX Combination Delivery System. We believe that, if approved, the PHOENIX handpiece will be the core product to enable us to achieve our desired future growth.

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As of March 31, 2011, we had an accumulated deficit of approximately \$172.8 million. We may continue to incur operating losses. The timing and amounts of our expenditures will depend upon a number of factors, including the efforts required to develop our sales and marketing organization, the timing of market acceptance of our products and the status and timing of regulatory approvals.

On March 28, 2011, we entered into an Agreement and Plan of Merger with CryoLife, Inc., or Parent, and CL Falcon, Inc., or Merger Sub, which is a wholly-owned subsidiary of Parent ( Merger Sub ). Parent, Merger Sub, and us subsequently amended and restated such Agreement and Plan of Merger on April 14, 2011; we refer to the Agreement and Plan of Merger, as amended and restated, in this report as the Merger Agreement. Pursuant to the Merger Agreement, and upon the terms and subject to the conditions thereof, Merger Sub agreed to purchase 49.9 percent of our common stock, no par value, or the Shares, at a price of \$0.457 per Share, net to the holder thereof in cash, without interest and subject to any applicable withholding taxes, or the Offer Price, and subject to the conditions set forth in the Offer to Purchase dated April 5, 2011, which, as amended or supplemented from time to time, we refer to as the Offer to Purchase, and the related Letter of Transmittal (which, together with the Offer to Purchase, constitute the Offer ). Concurrently with the execution of the Merger Agreement, Paul McCormick, Robert Lanigan, William Abbott and all of our directors entered into a Support Agreement with Parent, or the Support Agreement, pursuant to which they have agreed, among other things, to vote in favor of the Merger Agreement, and the Merger contemplated therein, as more fully described below.

On May 2, 2011, Merger Sub completed the Offer and as of such date owned approximately 23,235,890 Shares, representing 49.9 percent of the our outstanding Shares.

As contemplated by the terms of the Merger Agreement, Parent expects to acquire the remaining Shares in a second-step merger in which each outstanding Share that was not acquired by Merger Sub in the Offer (and other than Shares as to which dissenters' rights under California law are properly exercised) will be converted into the right to receive the Offer Price, net to the holder thereof in cash, without interest and subject to any applicable withholding taxes, and we will become a wholly-owned subsidiary of Parent, which we refer to as the Merger. The Merger will be completed following its approval at a special meeting of our shareholders to be held on May 16, 2011. Merger Sub will vote all of the Shares it acquired in the Offer in favor of approving and adopting the Merger Agreement, and such vote, when combined with the vote of parties to the Support Agreement, is sufficient to assure approval and adoption of the Merger Agreement at the special meeting. As a result, the affirmative vote of our other shareholders is not required to approve and adopt the Merger Agreement. After the Merger is completed, (i) our shareholders (other than Parent and its affiliates) will no longer have any interest in, and no longer be our shareholders and will not participate in any of our future earnings or growth, (ii) the Shares will no longer be quoted on the OTCBB and price quotations with respect to the Shares in the public market will no longer be available; and (iii) the registration of the Shares under the Securities Exchange Act of 1934, as amended, will be terminated.

Our shareholders are advised to read the proxy statement and other documents for use at the special meeting of our shareholders because they contain important information. A definitive proxy statement and form of proxy has been mailed to our shareholders and, along with other relevant documents, is available at no charge at the SEC's website at <http://www.sec.gov> or by contacting William R. Abbott, our Chief Financial Officer, at 11 Musick, Irvine, California, 92618, or via telephone at (949) 420-1800. Information relating to the participants in the proxy solicitation in connection with the special meeting of shareholders is contained in the proxy statement.

## **Results of Operations**

### *Net Revenues*

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

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Net revenues of \$3,053,000 for the three months ended March 31, 2011 decreased \$180,000, or 6%, when compared to net revenues of \$3,233,000 for the three months ended March 31, 2010. The decrease in sales was primarily attributed to a decrease in laser revenue for the three month period ended March 31, 2011 as compared to the prior year. Going forward, we anticipate continued growth in handpiece sales, however, we expect net revenue to fluctuate quarter to quarter depending on capital equipment sales.

For the three months ended March 31, 2011, domestic handpiece revenue increased by \$7,000, or 0%, and included \$185,000 in revenue which had been previously deferred in accordance with accounting rules and became recognizable during the quarter. In the first quarter of 2011, domestic handpiece revenue was \$2,197,000, inclusive of \$212,000 in sales of product to customers operating under our loaned laser program. In the first quarter of 2010, domestic handpiece revenue was \$2,190,000, inclusive of \$238,000 in sales of product to customers operating under our loaned laser program.

Domestic laser revenue decreased by \$174,000, or 24%, when compared to the three months ended March 31, 2010. In addition, service and other revenue of \$278,000 decreased \$11,000 for the quarter ended March 31, 2011, when compared to \$289,000 for the quarter ended March 31, 2010.

International sales, of \$38,000 accounted for approximately 1% of net revenues for the three months ended March 31, 2011, and were consistent with international sales of \$40,000 for the three months ended March 31, 2010. We do not have any sales initiatives in place to actively market our products outside of the United States.

### *Gross Margin*

Gross profit of 86% of net revenues for the quarter ended March 31, 2011 was higher than 84% of net revenues for the quarter ended March 31, 2010. Gross profit in absolute dollars decreased by \$82,000 to \$2,623,000 for the current year first quarter as compared with \$2,705,000 for the 2010 first quarter. The increase in gross margin percentage for the first quarter was primarily attributed to an increase in the average laser and handpiece sales prices and the recognition of \$185,000 of deferred revenue for which there is no associated cost of goods sold. The decrease in gross profit in absolute dollars is primarily attributed to a decrease in number of laser and handpiece units sold in the three months ended March 31, 2011 as compared to the three months ended March 31, 2010.

### *Research and Development*

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

For the three months ended March 31, 2011, research and development expenditures of \$521,000 increased 233,000 or 81%, when compared to \$288,000 for the three months ended March 31, 2010. As a percentage of revenues, research and development expenditures were 17% during the quarter ended March 31, 2011 as compared to 9% for the prior year period. The increase in expenditures was primarily attributable to the expenditures incurred conducting the PHOENIX feasibility trial outside of the U.S. and the biocompatibility and animal safety studies at the Texas Heart Institute. We anticipate research and development expenditures to continue to increase in 2011 as compared to the prior year as we continue the PHOENIX feasibility trial outside of the U.S. and wrap up the biocompatibility and animal safety studies at the Texas Heart Institute.

### *Sales and Marketing*

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

For the three months ended March 31, 2011, sales and marketing expenditures of \$1,357,000 decreased \$374,000, or 22%, when compared to \$1,731,000 for the three months ended March 31, 2010. As a percentage of revenues, sales and marketing expenditures were 44% during the three months ended March 31, 2011 as compared to 54% for the prior year period. The decrease in sales and marketing expenditures for the quarter ended March 31,

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2011 as compared to the prior year period was primarily due to a \$369,000 decrease in salary and other employee related expenses as a result of reduced headcount and lower commissions. As a large portion of sales and marketing expenses are directly related to revenue, we anticipate expenses to fluctuate with revenues but trend downward as a percent of net revenues as sales increase.

### *General and Administrative*

General and administrative expenditures represent all other operating expenses not included in research and development or sales and marketing expenses. For the three months ended March 31, 2011, general and administrative expenditures of \$1,174,000, increased \$475,000 or 68%, when compared to \$699,000 for the three months ended March 31, 2010. As a percentage of revenues, general and administrative expenditures were 38% during the three months ended March 31, 2011 as compared to 22% for the prior year period. The increase in general and administrative expenses was primarily due to legal fees related to business development activity.

### **Liquidity and Capital Resources**

Cash and cash equivalents were \$1,147,000 compared to \$1,810,000 at December 31, 2010, a decrease of \$663,000. Net cash used in operating activities was \$584,000 for the three months ended March 31, 2011, primarily due to a net loss of \$433,000, an increase in accounts receivable, decreases in accounts payable and deferred revenue, and partially offset by a decrease in prepaids and other current assets

Cash used in investing activities during the three months ended March 31, 2011 was \$14,000 due to property and equipment purchases and was consistent with \$14,000 used in investing activities during the three months ended March 31, 2010.

Cash used in financing activities during the three months ended March 31, 2011 was \$65,000 primarily due to the repayments of a short term note payable. Cash used in financing activities for the three months ended March 31, 2010 was \$55,000 due to the repayments of a short term note payable. Also, as mentioned above, on March 31, 2011 there was a non-cash financing activity related to the purchase and cancellation of 73,511 shares of our common stock for approximately \$33,000. Such cash was remitted during April 2011 to cover payroll tax obligations related to the vesting of restricted stock. In the three months ended March 31, 2010, there was a non-cash financing activity related to the purchase and cancellation of 125,983 shares of our common stock for approximately \$48,000. Such cash was remitted during April 2010 to cover payroll tax obligations related to the vesting of restricted stock.

We have incurred significant operating losses and as of March 31, 2011 we had an accumulated deficit of \$172.8 million. Our ability to maintain current operations is dependent upon increasing our sales from current levels. Our focus is executing upon our core and critical activities; thus we have reduced or eliminated operating expenses that are nonessential to our core operations.

We believe our cash balance as of March 31, 2011, our projected cash flows from operations and actions we have taken to manage sales and marketing and general and administrative expenses will be sufficient to meet our capital, debt and operating requirements through the next twelve months. However, our actual future capital requirements will depend on many factors, including the following:

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

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

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

- the rate of progress of our research and development programs;

- the time and expense necessary to obtain regulatory approvals;

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

- competitive, technological, market and other developments.





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

We will have a continuing need for new infusions of cash if we incur losses or are otherwise unable to generate positive cash flow from operations in the future. We plan to increase our sales through successful execution of our refocused sales strategy and achieving regulatory approval for the PEARL 8.0 and the PHOENIX handpiece. If these efforts are unsuccessful, we will be unable to significantly increase our revenues and may have to obtain additional financing to continue our operations or scale back our operations. Due to the current economic conditions, it has become very difficult for companies to obtain debt financing on reasonable terms, if at all. In addition, it may be difficult for us to obtain significant equity financing as a result of our low trading price and trading volume combined with our stock not being listed on a national securities exchange, such as NYSE, Amex, or NASDAQ. As a result, we may not be able to obtain additional financing if required, or even if we were to obtain any financing, it may contain burdensome restrictions on our business, in the case of debt financing, or result in significant dilution, in the case of equity financing.

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

The preparation of our financial statements requires that we make estimates and assumptions that affect the reported amounts of assets and liabilities and related disclosure of contingent assets and liabilities at the date of the financial statements and the reported amounts of revenues and expenses during the reporting periods. On an ongoing basis, we evaluate these estimates and assumptions, which are based on historical experience and on other assumptions that we believe to be reasonable. In the event that any of our estimates and assumptions are inaccurate in any material respect, it could have a material adverse effect on our reported amounts of assets and liabilities at the date of the financial statements and the reported amounts of revenues and expenses during the reporting periods. A summary of our critical accounting policies is included in Item 7 (Management's Discussion and Analysis of Financial Condition and Results of Operations) of Part II, of our Annual Report on Form 10-K for the fiscal year ended December 31, 2010. 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, 2010.

### **Item 4. 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 March 31, 2011. 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 March 31, 2011 were effective and would be timely in 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.

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

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**Changes in internal control over financial reporting**

There were no changes in our internal control over financial reporting that occurred during the quarter ended March 31, 2011 that have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

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**PART II  
OTHER INFORMATION**

**Item 1. Legal Proceedings**

***Patent Litigation***

As previously reported, CardioFocus, Inc. filed a complaint in the United States District Court for the District of Massachusetts (Case No. 1:08-cv-10285) against us and a number of other companies. In the complaint, CardioFocus alleges that we and the other defendants had previously violated patent rights allegedly held by CardioFocus. All of the asserted patents have now expired and we are the sole remaining defendant in the action.

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

Thereafter, the Court, at a status conference held on April 22, 2010, issued a scheduling order scheduling dates in connection with the litigation regarding discovery, law and motion practice, a briefing schedule and hearing for patent claim construction proceedings, and other key events. Fact discovery concluded in January 2011 and the parties have fully briefed the issues on the construction/interpretation of certain disputed terms of the remaining asserted claims. A Claim Construction hearing had been set for April 1, 2011 and trial was set to commence on November 7, 2011.

As previously reported, we have also filed four (4) further reexamination requests seeking to invalidate the remaining claims of the 780 Patent and 073 Patent being asserted against us. Two (2) of the reexamination requests were filed on June 30, 2010, and two (2) others were filed on October 15, 2010. These further reexamination requests are based, in part, on newly identified prior art not previously considered by the USPTO and on March 16, 2011, the USPTO issued Office Actions rejecting the three (3) remaining claims in view of multiple combinations of prior art. In light of the rejection of the three (3) remaining claims being asserted and because a final ruling that such claims are invalid would be potentially dispositive of the entire litigation, the parties requested and the Court granted a stay of the litigation pending the outcome of our reexaminations. The stay was ordered in effect on March 24, 2011 and all dates previously set, including the claim construction hearing, have been suspended. The parties are to provide the Court with a Joint Status Report by September 30, 2011.

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

***Litigation Related to the Merger and Merger Agreement***

On April 7, 2011, two plaintiffs filed purported class actions against the Company, its directors, and Parent and Merger Sub, in connection with the proposed Offer and Merger. These suits were filed in California Superior Court for Orange County and allege that the defendants breached and/or aided and abetted the breach of their fiduciary duties to the Company by seeking to sell the Company through an allegedly unfair process and for an unfair price and on unfair terms. The suits seek various equitable relief that would delay or enjoin the Merger based on allegations regarding the process by which offers or potential offers were evaluated by the Company, as well as fees and expenses of the plaintiffs attorneys and experts.

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Court	Filing Date	Case Name	Case Number
Superior Court of California, County of Orange	April 7, 2011	Patrick J. Grace vs. Paul McCormick	30-2011-00464472-CU-SL-CXC
Superior Court of California, County of Orange	April 7, 2011	Marion William Habiak vs. Cardiogenesis Corporation	30-2011-00464844-CU-SL-CXC

The Company believes the allegations in the lawsuits are without merit, intends to defend the actions vigorously. The absence of an injunction or court order preventing the consummation of the transaction is a condition to CryoLife's obligation to complete the Merger pursuant to the Merger Agreement.

***Other Litigation***

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

**Item 6. Exhibits**

The exhibits below are filed or incorporated herein by reference.

**Exhibit No. Description**

- |          |  |
|----------|--|
| 2.1 (1)  | Amended and Restated Agreement and Plan of Merger, dated as of April 14, 2011, by and among CryoLife, Inc., CL Falcon, Inc. and Cardiogenesis Corporation.       |
| 10.1 (2) | Support Agreement, dated as of March 28, 2011, by and between CryoLife, Inc. and certain shareholders of Cardiogenesis Corporation listed on Schedule A thereto. |
| 31.1 (3) | Certification of the Principal Executive Officer pursuant to Rule 13a-14(a)/15d-14(a) of the Securities Exchange Act of 1934.                                    |
| 31.2 (3) | Certification of the Chief Financial Officer pursuant to Rule 13a-14(a)/15d-14(a) of the Securities Exchange Act of 1934.  |
| 32.1 (3) | 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 (3) | 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) Incorporated by reference to Exhibit 2.1 to the Company's Current Report on Form 8-K filed with the Securities and Exchange Commission on April 15, 2011.
- (2) Incorporated by reference to Exhibit 10.1 to the Company's Current Report on Form 8-K filed with the Securities and Exchange Commission on March 29, 2011.
- (3) 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: May 16, 2011

/s/ Paul J. McCormick

Paul J. McCormick

Executive Chairman

(Principal Executive Officer)

Date: May 16, 2011

/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**

- |          |  |
|----------|--|
| 2.1 (1)  | Amended and Restated Agreement and Plan of Merger, dated as of April 14, 2011, by and among CryoLife, Inc., CL Falcon, Inc. and Cardiogenesis Corporation.       |
| 10.1 (2) | Support Agreement, dated as of March 28, 2011, by and between CryoLife, Inc. and certain shareholders of Cardiogenesis Corporation listed on Schedule A thereto. |
| 31.1 (3) | Certification of the Principal Executive Officer pursuant to Rule 13a-14(a)/15d-14(a) of the Securities Exchange Act of 1934.                                    |
| 31.2 (3) | Certification of the Chief Financial Officer pursuant to Rule 13a-14(a)/15d-14(a) of the Securities Exchange Act of 1934.  |
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| (3)      | Incorporated by reference to Exhibit 10.1 to the Company's Current Report on Form 8-K filed with the Securities and Exchange Commission on March 29, 2011.       |
| (3)      | Filed herewith.  |