

CARDIOGENESIS CORP /CA

Form 10QSB

November 13, 2006

**Table of Contents**

**UNITED STATES SECURITIES AND EXCHANGE COMMISSION**  
**Washington, D.C. 20549**  
**FORM 10-QSB**  
**Quarterly report pursuant to Section 13 or 15(d)**  
**of the Securities Exchange Act of 1934**  
**For the quarterly period ended September 30, 2006**  
**Commission file number 0-28288**

**CARDIOGENESIS CORPORATION**  
*(Exact name of small business issuer as specified in its charter)*

**California**

**77-0223740**

*(State of incorporation)*

*(I.R.S. Employer  
Identification Number)*

**11 Musick**

**Irvine, California 92618**

*(Address of principal executive offices)*

**(949) 420-1800**

*(Registrant's telephone number, including area code)*

26632 Towne Centre Drive, Suite 320

Foothill Ranch, CA 92610

*(Former address, if changed since last report)*

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 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 stock outstanding as of the latest practicable date.

45,273,701 shares of Common Stock, no par value as of October 31, 2006

Transitional Small Business Disclosure Format (Check One): Yes  No

**CARDIOGENESIS CORPORATION  
TABLE OF CONTENTS**

	<b>Page</b>
<b>PART I FINANCIAL INFORMATION</b>	
<u>Item 1.</u> <u>Financial Statements:</u>	
a. <u>Unaudited condensed consolidated balance sheet as of September 30, 2006</u>	1
b. <u>Unaudited condensed consolidated statements of operations for the three and nine months ended September 30, 2006 and 2005</u>	2
c. <u>Unaudited condensed consolidated statements of cash flows for the nine months ended September 30, 2006 and 2005</u>	3
d. <u>Notes to unaudited condensed consolidated financial statements</u>	4
<u>Item 2.</u> <u>Management's Discussion and Analysis or Plan of Operation</u>	13
<u>Item 3.</u> <u>Controls and Procedures</u>	33
<b>PART II OTHER INFORMATION</b>	
<u>Item 1.</u> <u>Legal Proceedings</u>	34
<u>Item 6.</u> <u>Exhibits</u>	34
<u>Signatures</u>	37
Certifications	
<u>EXHIBIT 31.1</u>	
<u>EXHIBIT 31.2</u>	
<u>EXHIBIT 32.1</u>	

---

**Table of Contents****Item 1. Financial Statements (unaudited)**

**CARDIOGENESIS CORPORATION**  
**CONDENSED CONSOLIDATED BALANCE SHEET**  
(in thousands)  
(unaudited)

	<b>September 30, 2006</b>
<b>ASSETS</b>	
Current assets:	
Cash and cash equivalents	\$ 1,528
Accounts receivable, net of allowance for doubtful accounts of \$98	3,123
Inventories, net of reserves of \$484	2,512
Prepays and other current assets	538
Total current assets	7,701
Property and equipment, net	738
Intangible asset, net	779
Other assets	68
Total assets	\$ 9,286
Current liabilities:	
Accounts payable	\$ 748
Accrued liabilities	1,640
Deferred revenue	859
Notes payable	255
Current portion of capital lease obligation	5
Secured convertible term note and related obligations, net of debt discount	1,774
Total current liabilities	5,281
Capital lease obligation, less current portion	8
Other long term liability	238
Total liabilities	5,527
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; 45,274 shares issued and outstanding	
Accumulated deficit	173,379 (169,620)
Total shareholders' equity	3,759

Total liabilities and shareholders' equity \$ 9,286

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

**Table of Contents**

**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>2006</b>	<b>2005</b>	<b>2006</b>	<b>2005</b>
Net revenues	\$ 4,212	\$ 4,392	\$ 13,453	\$ 12,268
Cost of revenues	1,007	809	2,728	2,339
Gross profit	3,205	3,583	10,725	9,929
Operating expenses:				
Research and development	461	350	1,100	1,387
Sales, general and administrative	3,541	2,771	10,156	11,422
Total operating expenses	4,002	3,121	11,256	12,809
Operating (loss)/income	(797)	462	(531)	(2,880)
Other income (expense):				
Interest expense	(52)	(167)	(724)	(421)
Interest income	21	28	110	114
Gain on insurance settlement	70		70	
Non-cash interest expense	(31)	(338)	(802)	(1,184)
Change in fair value of derivative		744	290	1,413
Other non-cash income, net	2	78	101	96
Total other income (expense), net	10	345	(955)	18
Net (loss) income	\$ (787)	\$ 807	\$ (1,486)	\$ (2,862)
Net (loss)/income per share:				
Basic	\$ (0.02)	\$ 0.02	\$ (0.03)	\$ (0.07)
Diluted	\$ (0.02)	\$ 0.01	\$ (0.03)	\$ (0.07)
Weighted average shares outstanding:				
Basic	45,274	43,989	45,240	42,907
Diluted	45,274	54,537	45,240	42,907

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

**Table of Contents**

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

	<b>Nine months ended</b>	
	<b>September 30,</b>	
	<b>2006</b>	<b>2005</b>
Cash flows from operating activities:		
Net loss	\$ (1,486)	\$ (2,862)
Adjustments to reconcile net loss to net cash provided by (used in) operating activities:		
Derivative and warrant fair value adjustments	(391)	(1,510)
Amortization of discount on notes payable	644	660
Depreciation and amortization	450	360
Bad debt expense	183	13
Provision for obsolete inventory	147	
Amortization of intangible asset	146	146
Amortization of debt issuance costs	158	159
Loss on debt extinguishment		364
Stock-based compensation expense	313	
Stock-based compensation expense related to legal settlement	29	
Gain on insurance settlement	(70)	
Interest income on restricted cash	(39)	(50)
Changes in operating assets and liabilities:		
Accounts receivable	(239)	450
Inventories	65	(1,210)
Prepays and other current assets	227	378
Other assets	21	64
Accounts payable	(329)	335
Accrued liabilities	715	185
Deferred revenue	465	(89)
Net cash provided by (used in) operating activities	1,009	(2,607)
Cash flows from investing activities:		
Acquisition of property and equipment	(284)	(711)
Cash received from insurance proceeds	70	
Net cash used in investing activities	(214)	(711)
Cash flows from financing activities:		
Decrease in restricted cash, net of interest income		410
Net proceeds from issuance of common stock from exercise of options	37	98
Payments on secured convertible term note	(937)	(170)
Payments on capital lease obligations and short term note payable	(210)	(5)
Net cash (used in) provided by financing activities	(1,110)	333
Net decrease in cash and cash equivalents	(315)	(2,985)

Edgar Filing: CARDIOGENESIS CORP /CA - Form 10QSB

Cash and cash equivalents at beginning of period	1,843	4,740
Cash and cash equivalents at end of period	\$ 1,528	\$ 1,755
Supplemental schedule of cash flow information:		
Interest paid	\$ 70	\$ 6
Taxes paid	\$ 41	\$ 1
Supplemental schedule of non-cash financing activities:		
Issuance of common stock upon conversion of debt and accrued interest	\$	\$ 730
Financing of insurance premiums	\$ 445	\$ 295
Repayment of restricted cash portion of the secured convertible term note	\$ 2,547	\$

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



**Table of Contents**

**CARDIOGENESIS CORPORATION**

**NOTES TO UNAUDITED CONDENSED CONSOLIDATED FINANCIAL STATEMENTS**

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

*Interim Financial Information:*

The accompanying unaudited condensed consolidated financial statements have been prepared by Cardiogenesis Corporation (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-QSB and Item 301(b) of Regulation S-B 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 financial statements and notes thereto for the year ended December 31, 2005, contained in the Company's Annual Report on Form 10-K, as filed with the SEC.

These condensed consolidated financial statements contemplate the realization of assets and the satisfaction of liabilities in the normal course of business. The Company has sustained significant operating losses for the last several years and may continue to incur losses in the future. Management believes its cash balance as of September 30, 2006 and expected cash flows from operations will be 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 profitability. The failure to achieve these goals could have a material adverse effect on the business, operating results and financial condition.

*Net Income (Loss) Per Share:*

Basic earnings (loss) per share is computed by dividing the net income (loss) by the weighted average number of common shares outstanding for the period. Diluted income (loss) per share 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.

All potentially dilutive shares, approximately 2,851,000 and 15,395,000 as of September 30, 2006 and 2005, respectively, have been excluded from diluted loss per share as their effect would be anti-dilutive for the periods then ended.

*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 consolidated financial statements include (but are not limited to) the allowance for doubtful accounts, inventory reserves, warranty obligations, valuation of embedded derivatives, asset impairment valuations and deferred income taxes.

**Table of Contents***Reclassifications:*

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

*Derivative financial instruments:*

The Company's derivative financial instruments consist of embedded derivatives related to the \$6,000,000 Secured Convertible Term Note ( Note ). These embedded derivatives include certain conversion features and variable interest features. The accounting treatment of derivatives requires 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. Any change in fair value is recorded as non-operating, non-cash income or expense at each reporting date. If the fair value of the derivatives is higher at the subsequent balance sheet date, the Company will record a non-operating, non-cash charge. If the fair value of the derivatives is lower at the subsequent balance sheet date, the Company will record non-operating, non-cash income. As of September 30, 2006, the fair value of the embedded derivative was an asset of \$53,000. Conversion related derivatives were valued using the Binomial Option Pricing Model with the following assumptions as of September 30, 2006: dividend yield of 0%; annual volatility of 92.55%; and risk free interest rate of 4.91% as well as probability analysis related to trading volume restrictions. The remaining derivatives were valued using discounted cash flows and probability analysis. The derivatives are included in secured convertible term note and related obligations in the accompanying condensed consolidated balance sheet (see Note 6).

*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 charged the customer an additional amount (the Premium ) over the stated list price on its handpieces in exchange for the use of the laser or collected an upfront deposit that can be applied towards the purchase of a laser. Under these programs, the Premiums or deposits were recorded as deferred revenue and recognized into income generally in the lesser of: (a) the amount of the deferred premium as of the end of a month; or (b) the list price of a laser divided by 24 months.

However, subsequent to December 31, 2005, the Company determined that these arrangements met the definition of a lease and should have been recorded under 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. After considering the provisions of SFAS No. 13, the Company has concluded that the amounts should be classified as operating leases. In addition, the Premium is considered contingent rent under Statement of Financial Accounting Standards 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.

Based on the Company's analysis of the impact of lease accounting to its condensed consolidated financial statements for the nine months and quarter ended September 30, 2005, the Company determined that the impact between its historical accounting and the application of lease accounting was insignificant for restatement. However, the Company has reclassified the loaned lasers as property, plant and equipment at September 30, 2006. Such reclassification resulted in an increase to property, plant and equipment and a related decrease to inventories totaling \$505,000 at September 30, 2005. In addition, the Company has adjusted the statements of cash flows for the

**Table of Contents**

reclassifications. For the nine months ended September 30, 2005, the reclassifications resulted in an increase in depreciation and amortization expense in the amount of \$137,000, a decrease in inventory reserves in the amount of \$137,000, a decrease in the change in inventories of \$555,000 and an increase in the cash used in the acquisition of property and equipment of \$555,000.

*Segment Disclosures*

The Company operates in one segment. The principal markets for the Company's products are in the United States. International sales occur in Europe, Canada, Mexico and Asia and amounted to \$120,000 and \$85,000 for the three months ended September 30, 2006 and 2005, respectively. International sales amounted to \$282,000 and \$538,000 for the nine months ended September 30, 2006 and 2005, respectively. The international sales represent 3% and 2% of total sales for the three months ended September 30, 2006 and 2005, respectively. The international sales represent 2% and 4% of total sales for the nine months ended September 30, 2006 and 2005, respectively. The majority of international sales are denominated in Euros and any related foreign currency gains and losses are considered insignificant.

*Recently Issued Accounting Standards*

Recent accounting pronouncements, other than SFAS No. 123(R) disclosed in Note 4, issued by the Financial Accounting Standards Board ( FASB ) (including its Emerging Issues Task Force), the American Institute of Certified Public Accountants, and the SEC did not or are not believed by management to have a material impact on the Company's present or future consolidated financial statements.

**2. Inventories:**

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

	<b>September 30, 2006</b>
Raw materials	\$ 697
Work-in-process	166
Finished goods	1,649
Total	\$ 2,512

**3. Intangible Asset:**

On January 5, 1999, the Company entered into an agreement ( the PLC agreement ) with PLC Systems, Inc. ( PLC ), which granted the Company a non-exclusive worldwide use of certain PLC patents. In return, the Company paid PLC a fee totaling \$2,500,000 between January 1999 and July 2002. The present value of those payments of \$2,300,000 was recorded as an intangible asset and is being amortized over the life of the underlying patents. The Company has included the related amortization expense of approximately \$50,000 and \$146,000 in sales, general and administrative expenses in the accompanying condensed consolidated statements of operations for the three and nine months ended September 30, 2006 and 2005, respectively.

**4. Adoption of SFAS 123 (R):**

On January 1, 2006, the Company adopted Statement of Financial Accounting Standards No. 123 (revised 2004), *Share-Based Payment*, ( SFAS 123(R) ) 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 123(R) 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 123(R) 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 Securities and Exchange Commission issued Staff Accounting Bulletin No. 107 (SAB 107) relating to SFAS 123(R). The Company has applied

the provisions of SAB 107 in its adoption of SFAS 123(R).

**Table of Contents**

The Company adopted SFAS 123(R) 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 condensed consolidated financial statements as of and for the three and nine months ended September 30, 2006 reflect the impact of SFAS 123(R). In accordance with the modified prospective transition method, the Company's condensed consolidated financial statements for prior periods have not been restated to reflect, and do not include, the impact of SFAS 123(R).

SFAS 123(R) 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 consolidated statement of operations. Prior to the adoption of SFAS 123(R), the Company accounted for stock-based awards to employees and directors using the intrinsic value method in accordance with APB 25 as allowed under Statement of Financial Accounting Standards No. 123, *Accounting for Stock-Based Compensation* (SFAS 123). Under the intrinsic value method, stock-based compensation expense was recognized in the Company's consolidated statements of operations for option grants to employees and consultants 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 condensed consolidated statement of operations for the three and nine months ended September 30, 2006 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 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 123(R). As stock-based compensation expense recognized in the condensed consolidated statements of operations for the three and nine months ended September 30, 2006 is based on awards ultimately expected to vest, it has been reduced for estimated forfeitures. SFAS 123(R) 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 months ended September 30, 2006 was 20% for all options and was based on historical forfeiture experience. The estimated term of option grants for the nine months ended September 30, 2006 and 2005 was 4.09 and 4.48 years, respectively. In the Company's pro forma information required under SFAS 123 for the periods prior to fiscal 2006, the Company accounted for forfeitures as they occurred.

SFAS 123(R) 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. Due to the Company's loss position, there were no such tax benefits during the three and nine months ended September 30, 2006 and 2005. Prior to the adoption of SFAS 123(R) 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 three 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, 2006, 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. A total of 1,500,000 common shares are reserved for issuance under this plan, as amended. Future increases may occur on the first day of each year until 2015, in amounts that the Board of Directors determines. 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.



**Table of Contents**

The Company has treated the ESPP as a compensatory plan and has recorded compensation expense of approximately \$87,000 during the three and nine months ended September 30, 2006 in accordance with SFAS No. 123(R).

During the three and nine months ended September 30, 2006, the Company's employees have elected not to purchase any shares under the ESPP. However, at September 30, 2006, the Company has accrued approximately \$56,000 for the potential issuance of common stock under the ESPP at November 15, 2006.

**Summary of Assumptions and Activity**

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

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

The Company's fair value calculations for stock-based compensation awards to employees under its stock option plans for the nine months ended September 30, 2006 and 2005 were based on the following assumptions:

	<b>Nine Months Ended September 30, 2006</b>	<b>Nine Months Ended September 30, 2005</b>
Expected term	4.09 years	4.48 years
Expected volatility	106.27%	95.39%
Risk-free interest rate	4.89%	3.84%
Expected dividends	\$	\$

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 September 30, 2006</b>	<b>Nine Months Ended September 30, 2005</b>
Expected term	0.50 years	0.50 years
Expected volatility	106.27%	95.39%
Risk-free interest rate	4.89%	3.84%
Expected dividends	\$	\$

**Table of Contents**

A summary of option activity as of September 30, 2006 and changes during the nine months then ended, is presented below (dollars and shares in thousands, except per share data):

		<b>Weighted Average Exercise Price</b>	<b>Weighted Average Remaining Contractual Term (Years)</b>	<b>Aggregate Intrinsic Value</b>
	<b>Shares</b>			
Options outstanding at January 1, 2006	4,537	\$ 1.16	7.1	
Options granted	1,268	\$ 0.49	10.0	
Options exercised	(116)	\$ 0.32		
Options forfeited/canceled	(1,111)	\$ 0.79		
Options outstanding at September 30, 2006	4,578	\$ 1.03	6.8	\$ 43
Vested or expected to vest	4,455	\$ 1.10	6.4	\$ 34
Options exercisable at September 30, 2006	3,962	\$ 1.11	6.4	\$ 41

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 469,000 outstanding and 415,000 exercisable stock options that were in-the-money at September 30, 2006.

The weighted average grant date fair value of options granted during the three and nine months ended September 30, 2006 was \$0.30 and \$0.35 per option, respectively. The aggregate intrinsic value of options exercised during the three and nine months ended September 30, 2006 was approximately zero and \$22,000, respectively.

As of September 30, 2006 there was approximately \$203,000 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 2.3 years. For the three and nine month periods ended September 30, 2006, the amounts of stock-based compensation expense related to stock options were approximately \$99,000 and \$226,000, respectively. For the nine month period ended September 30, 2006, the amount of stock-based compensation expense related to ESPP purchases was approximately \$87,000.

As a result of adopting SFAS 123(R) on January 1, 2006, both the Company's operating loss and net loss for the three and nine months ended September 30, 2006, was approximately \$186,000 and \$313,000 higher, respectively, than if it had continued to account for share-based compensation under APB 25. The Company's net loss per common share, basic and diluted, was approximately \$0.01 greater for the nine months ended September 30, 2006, than if it had continued to account for share-based compensation under APB 25. There was no per share effect for the three months ended September 30, 2006. The net cash provided by operating activities did not change as a result of the adoption of SFAS 123(R).

The following table summarizes stock-based compensation expense related to stock options and ESPP purchases under SFAS 123(R) for the three and nine months ended September 30, 2006 which was allocated as follows (in thousands):

<b>Three Months Ended</b>	<b>Nine Months Ended</b>
-----------------------------------	------------------------------



	<b>September 30, 2006</b>	<b>September 30, 2006</b>
Stock-based compensation expense included in:		
Research and development	\$ 21	\$ 31
Sales, general and administrative	165	282
	\$ 186	\$ 313
Stock-based compensation expense related to employee and director stock options	\$ 99	\$ 226
Stock-based compensation expense related to the ESPP	87	87
	\$ 186	\$ 313

**Table of Contents**

The following table illustrates the effect on net loss and net loss per share for the three and nine months ended September 30, 2005 as if the Company had applied the fair value recognition provisions of SFAS 123 to options granted under the Company's stock option plans. For purposes of this pro forma disclosure, the fair value of the options is estimated using the Black-Scholes option-pricing model and amortized on a straight-line basis to expense over the options' vesting period (dollars in thousands, except per share data):

	<b>Three Months Ended September 30, 2005</b>	<b>Nine Months Ended September 30, 2005</b>
Net income (loss) as reported	\$ 807	\$ (2,862)
Add: Share-based employee compensation expense included in net income (loss), net of tax effects		
Deduct: Share-based employee compensation expense determined under fair value method, net of tax effects	(67)	(470)
Net income (loss) pro forma	\$ 740	\$ (3,332)
Net income (loss) per common share as reported		
Basic	\$ 0.02	\$ (0.07)
Diluted	\$ 0.01	\$ (0.07)
Net income (loss) per common share pro forma		
Basic	\$ 0.02	\$ (0.08)
Diluted	\$ 0.01	\$ (0.08)

**5. Legal Matters:**

On July 12, 2006, Cardiogenesis terminated Michael Quinn as its Chairman, Chief Executive Officer and President in accordance with the terms of his employment agreement. At the time of termination, Mr. Quinn stated that he intended to bring claims against the Company relating to his termination, including claims for payment of severance he claimed was owed to him under the terms of his employment agreement.

On October 12, 2006, Cardiogenesis and Mr. Quinn entered into a Memorandum of Understanding (the "MOU") pursuant to which the parties agreed to settle certain disputes between them relating to Mr. Quinn's termination from employment.

Pursuant to the terms of the MOU, the Company will pay Mr. Quinn a total of approximately \$500,000 in 72 equal bi-monthly installments and will also pay approximately \$51,000 to Mr. Quinn's counsel as attorney's fees. At September 30, 2006, the entire balance, plus \$28,000 of related payroll taxes, was accrued for and included in accrued liabilities. Mr. Quinn will be entitled to retain 689,008 previously issued stock options having the following exercise prices:

89,008 shares at \$0.32 per share

150,000 shares at \$0.70 per share

200,000 shares at \$0.54 per share

250,000 shares at \$0.50 per share

The exercise period of these options has been extended so that each option shall terminate on October 12, 2009. In the three and nine months ended September 30, 2006, the Company recognized stock-based compensation expense, net of forfeitures, of \$103,000 related to the vesting of these options which is included in sales, general, and administrative expenses, of which \$29,000 related to the modification of the original terms of these options.

In addition, Mr. Quinn will be entitled to statutory indemnification and any indemnification required by the Company's bylaws relating to his services on the Board of Directors of the Company. The MOU also provides that both parties will not disparage each other.

**Table of Contents**

On October 24, 2006, the Company and Mr. Quinn entered into a Settlement Agreement and General Release that formalizes the settlement contemplated by the MOU and includes customary releases and other provisions.

**6. Secured Convertible Term Note and Related Obligations:**

In connection with the Company's October 2004 financing transaction with Laurus Master Fund, Ltd, a Cayman Islands corporation ( Laurus ), it issued a secured convertible term note (the Note ) in the aggregate principal amount of \$6.0 million and a warrant to purchase an aggregate of 2,640,000 shares of the Company's common stock at a price of \$0.50 per share to Laurus in a private offering. The Note includes embedded derivative financial instruments. Both the warrant and the derivatives are required to be accounted for separately from the related debt instrument and recorded as liabilities on the consolidated balance sheet at fair value. In the consolidated statements of operations, changes in the estimated fair value of the Laurus warrant are charged under the caption Other non-cash income, net and resulted in expense of \$54,000 and \$5,000 for the three and nine months ended September 30, 2006, respectively, and expense of \$114,000 and \$93,000 for the three and nine months ended September 30, 2005, respectively. In addition, changes in the estimated fair value of the derivatives are charged under the caption Change in fair value of derivative and resulted in income of \$0 and \$290,000 for the three and nine months ended September 30, 2006, respectively, and in income of \$744,000 and \$1,413,000 for the three and nine months ended September 30, 2005, respectively.

The initial fair value assigned to the embedded derivatives was \$1,075,000 and the initial fair value assigned to the warrant was \$631,000, both of which were recorded as discounts to the Note and are being amortized to interest expense over the expected term of the debt, using the effective interest method. The Company amortized \$25,000 and \$644,000 of the discount to interest expense during the three and nine month period ended September 30, 2006, respectively, and the unamortized discount on the Note was \$95,000 at September 30, 2006. The Company amortized \$179,000 and \$577,000 of the discount to interest expense during the three and nine month period ended September 30, 2005 and the unamortized discount on the Note was \$905,000 at September 30, 2005,

Debt issuance costs of \$417,000 were incurred in connection with the transaction. During the three and nine months ended September 30, 2006, the Company amortized \$6,000 and \$158,000, respectively, of debt issuance costs to interest expense and the unamortized balance was \$24,000 at September 30, 2006. During the three and nine months ended September 30, 2005, the Company amortized \$44,000 and \$138,000 of debt issuance costs to interest expense and the unamortized balance was \$223,000 at September 30, 2005.

During the nine months ended September 30, 2006, Laurus did not convert any debt amounts into shares of common stock. Each conversion of debt into equity is recorded as an extinguishment of debt and an increase in equity valued at the fair market value on the date of conversion. A gain or loss on extinguishment of debt is recorded at time of conversion and represents the difference in fair market value at the date of conversion less the actual conversion price. However, in May 2006, the Company repaid \$2,417,000 of the Note's outstanding principal amount out of the restricted cash account and related interest of \$314,000. In connection with the repayment, the Company was required to pay a prepayment penalty of \$483,000 and amortized \$381,000 of the corresponding unamortized debt discount to interest expense.

The following table presents a reconciliation between the principal amount of the Note and the current carrying amount of the Note on the consolidated balance sheet (in thousands):

	<b>September 30, 2006</b>
Original Note balance	\$ 6,000
Principal conversions	(1,184)
Cash payments	(3,461)
Total secured convertible term note	1,355
Unamortized discount on Note	(95)
Derivative valuation	(53)
Warrant valuation	567

Secured convertible term note and related obligations, net	\$	1,774
--	----	-------

11

---

**Table of Contents**

Pursuant to the terms of the note, an event of default includes a suspension of trading of the Company's common stock on the OTC Bulletin Board which remains uncured within thirty (30) days of notice of the suspension. To the extent that the delisting of the Company's stock in May 2006 is deemed a suspension of trading, the Company could be deemed to be in default of its obligations under the note. If an event of default occurs under the note, interest on the note would accrue at the default rate which is the then current prime rate plus 12% per annum until the default is cured. In addition, the holder of the note will have the right to accelerate and declare it immediately due and payable and exercise its rights as a secured creditor under applicable law and the security agreement with the Company, including the right to foreclose upon the Company's assets that secure the note, which constitute substantially all of the Company's assets. Based on the potential event of default, the Company has recorded the entire principal balance as current in the accompanying condensed consolidated balance sheet.

**7. Other Long Term Liability:**

In January 2004, the Company sold 3,100,000 shares of common stock to private investors for a total price of \$2,700,000. The Company also issued a warrant to purchase 3,100,000 additional shares of common stock at a price of \$1.37 per share. The warrant is immediately exercisable and has a term of five years. At September 30, 2006, the fair value of the warrant liability was \$238,000 and is classified in the accompanying condensed consolidated balance sheet as other long term liability. For the three and nine months ended September 30, 2006, the loss on change in fair value of \$56,000 and \$106,000, respectively, is included in other non-cash expense. For the three and nine months ended September 30, 2005, the gain on fair value of \$36,000 and loss on fair value of \$3,000, respectively, is included in other non-cash expense.

**Table of Contents****Item 2. Management's Discussion and Analysis or Plan of Operation**

*This Management's Discussion and Analysis or Plan of Operation 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. Please read the section below titled "Factors Affecting Future Results" to review conditions which we believe could cause actual results to differ materially from those contemplated by the 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. 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 financial statements and notes thereto included in this Quarterly Report on Form 10-QSB.*

**Overview**

Cardiogenesis Corporation, incorporated in California in 1989, designs, develops and distributes laser-based surgical products and disposable fiber-optic accessories for the treatment of advanced cardiovascular disease through transmyocardial revascularization ( TMR ) and percutaneous myocardial channeling ( PMC ). PMC was formerly referred to as percutaneous myocardial revascularization ( PMR ). The new name PMC more literally depicts the acute physiologic tissue effect of the Cardiogenesis PMC system to ablate precise, partial thickness channels into the heart muscle from the inside of the left ventricle. TMR and PMC are recent laser-based heart treatments in which channels are made in the heart muscle. Published research indicates these procedures encourage new vessel formation, or angiogenesis in ischemic myocardium. TMR is performed by a cardiac surgeon through a small incision in the chest under general anesthesia. PMC is performed by an interventional cardiologist in a catheter-based procedure which utilizes local anesthesia. Clinical studies have demonstrated a significant reduction in angina and increase in exercise duration in patients treated with TMR or PMC plus medications, when compared with patients who received medications alone.

In May 1997, we received CE Mark approval for our TMR system and in April 1998 we received CE Mark approval for our PMC system. 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 products for treatment of stable patients with 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 any TMR as a primary and secondary procedure. As a result, hospitals and physicians are eligible to receive Medicare reimbursement for TMR equipment and procedures on indicated Medicare patients.

We have completed pivotal clinical trials involving PMC, and study results were submitted to the FDA in a pre market approval ( PMA ) application in December 1999 along with subsequent amendments. In July 2001, the FDA Advisory Panel recommended against approval for PMC. In February 2003, the FDA granted an independent panel review of our pending PMA application for PMC by the Medical Devices Dispute Resolution Panel ( MDDRP ). In July 2003, the FDA agreed to review additional data in support of our PMA supplement for PMC under the structure of an interactive review process between us and the FDA review team. The independent panel review by the MDDRP was cancelled in lieu of the interactive review, but the FDA has agreed to reschedule the MDDRP hearing in the future, if the dispute cannot be resolved.

In August 2004, we met with the FDA and agreed on the steps needed to design and initiate a new Investigational Device Exemption (IDE) clinical trial to confirm the safety and efficacy of PMC. In January 2005, we again met with the agency and agreed on major trial parameters. We came to agreement with the FDA on a final trial design and received formal FDA approval of the updated prospective, sham controlled, randomized, multi-center IDE clinical trial protocol in January 2006. We have initiated the pursuit of a corporate partner in the interventional cardiology arena to support the completion of this significant trial. There can be no assurance, however, that we will attract the

necessary capital required to support the trial or that we will ultimately receive a favorable determination from the FDA.



**Table of Contents**

In December 2004, we signed a distribution agreement to begin selling platelet rich plasma ( PRP ) products. The new autologous platelet and growth factor concentrating system, celleratOR, consisted of a general use centrifuge and cell separator tubes. The revenue generated from the PRP product line was less than 1% of total revenues for the nine months ended September 30, 2006 and 2005, and therefore in September 2006 we determined that this was not a profitable business venture for us to pursue and the remaining inventory on hand was written down to the estimated fair value.

As of September 30, 2006, we had an accumulated deficit of \$169,620,000. We may continue to 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, fiber optic handpiece delivery systems, and related services. Net revenues of \$4,212,000 for the quarter ended September 30, 2006 decreased \$180,000, or 4%, when compared to net revenues of \$4,392,000 for the quarter ended September 30, 2005.

For the quarter ended September 30, 2006, domestic disposable handpiece revenue decreased by \$117,000 and domestic laser revenue decreased by \$93,000 compared to the quarter ended September 30, 2005. In the third quarter of 2006, domestic handpiece revenue included \$675,000 in sales of product to customers operating under the loaned laser program, of which \$212,000 was attributed to premiums associated with such sales. In the third quarter of 2005, domestic handpiece revenue included \$484,000 in sales of product to customers operating under the loaned laser program, of which \$121,000 was attributed to premiums associated with such sales. In the third quarter of 2006 and 2005, sales of handpieces to customers not operating under the loaned laser program were \$2,115,000 and \$2,423,000, respectively. International sales, accounting for approximately 3% of net revenues for the quarter ended September 30, 2006, increased \$36,000 from the prior year. We define international sales as sales to customers located outside of the United States. In addition, service and other revenue of \$219,000 decreased \$6,000 for the quarter ended September 30, 2006 when compared to \$225,000 for the quarter ended September 30, 2005.

Net revenues of \$13,453,000 for the nine months ended September 30, 2006 increased \$1,185,000, or 10%, when compared to net revenues of \$12,268,000 for the nine months ended September 30, 2005. The increase is primarily related to increases in the number and sales price of laser units sold.

For the nine months ended September 30, 2006, domestic handpiece revenue increased by \$309,000 compared to the nine months ended September 30, 2005. In the first nine months of 2006, domestic handpiece revenue consisted of \$1,634,000 in sales to customers operating under the loaned laser program and \$7,243,000 in sales to customers not operating under the loaned laser program. For those sales to customers operating under the loaner laser program, \$567,000 was attributed to premiums associated with handpiece sales. In the first nine months of 2005, domestic handpiece revenue consisted of \$1,550,000 in sales to customers operating under the loaned laser program and \$6,961,000 in sales to customers not operating under the loaned laser program. For those sales to customers operating under the loaner laser program, \$320,000 was attributed to premiums associated with handpiece sales.

For the nine months ended September 30, 2006, domestic laser revenue increased by \$1,134,000 compared to the same period in 2005. International sales, accounting for approximately 2% of net revenues for the nine months ended September 30, 2006, decreased \$256,000 from the same period in the prior year when international sales accounted for 4% of total sales. In addition, service and other revenue of \$731,000 decreased \$58,000 or 7% for the nine months ended September 30, 2006 when compared to \$789,000 for the nine months ended September 30, 2005.

**Table of Contents***Gross Profit*

Gross profit represented 76% and 82% of net revenues for the quarter ended September 30, 2006 and 2005, respectively. Gross profit in absolute dollars decreased by \$378,000 to \$3,205,000 for the quarter ended September 30, 2006, as compared to \$3,583,000 for the quarter ended September 30, 2005. The decrease in gross profit as a percentage of sales resulted primarily from the impairment of inventories associated with the excess parts used to maintain and service TMR2000 lasers and the discontinued PRP product line. The revenue generated from the PRP product line was less than 1% of total revenues for the nine months ended September 30, 2006 and 2005, and therefore in September 2006 we determined that this was not a profitable business venture for us to pursue and the remaining inventory on hand was written down to the estimated fair value.

Gross profit represented 80% and 81% of net revenues for the nine months ended September 30, 2006 and 2005, respectively. The decrease in gross profit as a percentage of sales resulted primarily from the impairment of inventories associated with the discontinued PRP product line and parts used to maintain and service TMR2000 lasers. Gross profit in absolute dollars increased \$796,000 to \$10,725,000 for the nine months ended September 30, 2006, as compared to the nine months ended September 30, 2005. The increase in gross profit absolute dollars was primarily due to the increased sales.

*Research and Development*

Research and development expenditures of \$461,000 increased \$111,000 or 32% for the quarter ended September 30, 2006 when compared to \$350,000 for the quarter ended September 30, 2005. Research and development expenditures of \$1,100,000 decreased \$287,000 or 21% for the nine months ended September 30, 2006 when compared to \$1,387,000 for the nine months ended September 30, 2005. The increase in research and development expenditures for the three months ended September 30, 2006 was primarily the result of increased spending on research activity related to the efficacy of TMR and an additional \$21,000 associated with stock-based compensation expense related to stock options and ESPP purchases. The decrease in research and development expenditures for the nine months ended September 30, 2006 was primarily due to the fact that certain product development expenses related to our minimally invasive TMR platform incurred in 2005 did not recur in 2006.

*Sales, General and Administrative*

Sales, general and administrative expenditures of \$3,541,000 increased \$770,000 or 28% for the quarter ended September 30, 2006 when compared to \$2,771,000 for the quarter ended September 30, 2005. The increase in sales, general and administrative expenditures for the three months ended September 30, 2006 was primarily due to approximately \$682,000 of expense associated with the legal settlement reached with our former Chairman, Chief Executive Officer and President, Michael Quinn, which includes \$103,000 of stock-based compensation expense related to the settlement. In addition, there was \$91,000 associated with stock-based compensation expense related to other stock options and ESPP purchases. Sales, general and administrative expenditures of \$10,156,000 decreased \$1,266,000 or 11% for the nine months ended September 30, 2006 when compared to \$11,422,000 for the nine months ended September 30, 2005. The decrease in sales, general and administrative expense was primarily due to the fact that the nine months ended September 30, 2005 sales, general and administrative expense included a \$600,000 settlement agreement with our former President and Chief Operating Officer, in addition, we benefited from additional savings generated through the consolidation of sales territories, as well as reduced marketing expenses including expenses for exhibitions and meetings.

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

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

	Three months ended September 30,		Nine months ended September 30,	
	2006	2005	2006	2005(1)
	(\$ In thousands)			
Interest expense Secured Convertible Term Note	\$ (41)	\$ (166)	\$ (208)	\$ (338)
Interest expense other	(11)	(1)	(33)	(83)
Interest expense prepayment penalty			(483)	
Interest income	21	28	110	114
Insurance settlement	70		70	
Non-cash interest expense Accretion of discount on Note	(25)	(179)	(644)	(577)
Non-cash interest expense Amortization of debt issuance costs relating to the Note	(6)	(44)	(158)	(138)
Non-cash interest expense- Loss on conversion of debt		(115)		(469)
Change in fair value of derivative		744	290	1,413
Other non-cash income (expense) Change in fair value of warrants	2	78	101	96
Total other income (expense), net	\$ 10	\$ 345	\$ (955)	18

(1) In the nine months ended September 30, 2005, we reported other expense of \$582,000. However, we subsequently have determined that a \$600,000 legal settlement originally included in non-operating expense should have been included in operating expenses. Therefore, we have reduced the

September 30,  
2005 other  
expense and  
increased the  
selling, general  
and  
administrative  
expenses to  
reflect this  
reclassification.

**Table of Contents****Liquidity and Capital Resources**

At September 30, 2006, we had cash and cash equivalents of \$1,528,000 compared to \$1,843,000 at December 31, 2005, a decrease of \$315,000. During the nine months ended September 30, 2006, we had a net loss of \$1,486,000 and had net cash provided by operating activities of \$1,009,000. The net cash provided by operating activities is primarily due to an increase in accrued liabilities and deferred service revenue. The increase in Accrued liabilities as of September 30, 2006 results primarily from the settlement agreement reached with our former Chairman, Chief Executive Officer and President, Michael Quinn. The settlement agreement resulted in an accrual of \$579,000 for compensation and associated payroll taxes and legal fees. The compensation and associated payroll taxes will be paid out over a three year period beginning in the fourth quarter of 2006. The increase in deferred service revenue is primarily due to the increase in sales of service contracts.

Cash used in investing activities during the nine months ended September 30, 2006 was \$214,000 primarily related to property and equipment purchases.

In October 2004, we completed a financing transaction with Laurus Master Fund, Ltd, a Cayman Islands corporation ( Laurus ), pursuant to which we issued a Secured Convertible Term Note (the Note ) in the aggregate principal amount of \$6.0 million and a warrant to purchase an aggregate of 2,640,000 shares of our common stock at a price of \$0.50 per share to Laurus in a private offering. Net proceeds to us from the financing, after payment of fees and expenses to Laurus and its affiliates, were \$5,752,500. Of this amount, \$2,877,000 was deposited in a restricted cash account and was not available for use in our operations. In May 2006, the entire restricted cash balance had been repaid.

The Note matures in October 2007, absent earlier redemption by us or earlier conversion by Laurus. Annual interest on the Note is equal to the prime rate published in The Wall Street Journal from time to time, plus two percent (2.0%), provided that such annual rate of interest may not be less than six and one-half percent (6.5%), subject to certain downward adjustments resulting from certain increases in the market price of our common stock. Since November 2004, interest on the Note is payable monthly in arrears on the first day of each month during the term of the Note. In addition, since May 2005, we have been required to make monthly principal payments of \$104,091 per month. The Note is convertible into shares of our common stock at the option of Laurus and, in certain circumstances, at our option.

Pursuant to the terms of the Note, an event of default includes a suspension of trading of our common stock on the OTC Bulletin Board which remains uncured within thirty (30) days of notice of the suspension. As previously reported by us, to the extent that the delisting of our stock in May 2006 is deemed a suspension of trading, we could be deemed to be in default of our obligations under the Note. If an event of default occurs under the Note, interest on the Note would accrue at the default rate which is the then current prime rate plus 12% per annum until the default is cured. In addition, the holder of the Note will have the right to accelerate and declare it immediately due and payable and exercise its rights as a secured creditor under applicable law and the security agreement with us, including the right to foreclose upon our assets that secure the Note, which constitute substantially all of our assets. To the extent that a default is declared and we repay the note in full out of cash and other current assets, our liquidity and capital resources would be materially and adversely affected. In such event, to the extent that we were unable to generate sufficient working capital from operations, we would be required to seek additional debt and/or equity financing to satisfy our ongoing working capital requirements. There can be no assurances that such financing would be available on favorable terms, if at all.

The Note includes embedded derivative financial instruments. In conjunction with the Note, we issued a warrant to purchase 2,640,000 shares of common stock. The accounting treatment of the derivatives and warrant requires that we record the derivatives and warrant at their relative fair value as of the inception date of the agreement, and at fair value as of each subsequent balance sheet date. Any change in fair value will be recorded as non-operating, non-cash income or expense at each reporting date. If the fair value of the derivatives and warrant is higher at the subsequent balance sheet date, we will record a non-operating, non-cash charge. If the fair value of the derivatives and warrant is lower at the subsequent balance sheet date, we will record non-operating, non-cash income.

We have incurred significant losses for the last several years and at September 30, 2006 we have an accumulated deficit of \$169,620,000. Our ability to maintain current operations is dependent upon maintaining our sales at least at

the same levels achieved in prior years, increasing our sales through direct sales channels and marketing efforts on existing products and achieving timely regulatory approval for certain other products.

**Table of Contents**

Currently, our primary goal is to achieve consistent profitability at the operating level. Our actions have been guided by this initiative, and as a result, cost containment measures have been implemented to help 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, 2006 and expected cash from operations will be sufficient to meet our capital, debt and operating requirements through the next 12 months. However, if revenues from sales or new funds from debt or equity instruments are insufficient to maintain the current expenditure rate, it will be necessary to significantly reduce our operations until an appropriate solution is implemented.

We will have a continuing need for new infusions of cash if we continue to incur losses 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. 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. We may be required to seek additional sources of financing, which could include short-term debt, long-term debt or equity. There is a risk that we may be unsuccessful in obtaining such financing and that we will not have sufficient cash to fund our operations.

**Critical Accounting Policies and Estimates**

The preparation of financial statements in conformity with accounting principles generally accepted in the United States of America 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 asset, warranty reserve, the assessment of future cash flows in evaluating intangible assets for impairment and assumptions used in fair value determination of warrants and derivatives.

***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 charged the customer an additional amount (the Premium ) over the stated list price on our handpieces in exchange for the use of the laser or collected an upfront deposit that can be applied towards the purchase of a laser. Under these programs, the Premiums or deposits were recorded as deferred revenue and recognized into income generally in the lesser of: (a) the amount of the deferred premium as of the end of a month; or (b) the list price of a laser divided by 24 months.

**Table of Contents**

However, subsequent to December 31, 2005, we determined that these arrangements met the definition of a lease and should have been recorded under 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 our handpieces. After considering the provisions of SFAS No. 13, the Company has concluded that the amounts should be classified as operating leases. In addition, the Premium is considered contingent rent under Statement of Financial Accounting Standards 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.

Based on our analysis of the impact of lease accounting to our consolidated financial statements for the quarter ended September 30, 2005 we determined that the impact between our historical accounting and the application of lease accounting was insignificant for restatement. However, we have reclassified the loaned lasers as property, plant and equipment resulting in an increase to property, plant and equipment and a related decrease to inventories in the amount \$505,000 at September 30, 2005. We have adjusted the statements of cash flows for the reclassifications. For the quarter ended September 30, 2005, the reclassifications resulted in an increase in depreciation and amortization expense in the amount of \$137,000, a decrease in inventory reserves in the amount of \$137,000, a decrease in the change in inventories of \$555,000 and an increase in the cash used in the acquisition of property and equipment of \$555,000.

We have not restated current or prior year financial presentation to reflect the effects of lease accounting under SFAS No. 13. Beginning in January 2006, we recorded these transactions as leases in compliance with SFAS No. 13. ***Stock Based Compensation:***

On January 1, 2006, we adopted Statement of Financial Accounting Standards No. 123 (revised 2004), *Share-Based Payment*, ( SFAS 123(R) ) 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 123(R) 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 123(R) supersedes our 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 Securities and Exchange Commission issued Staff Accounting Bulletin No. 107 (SAB 107) relating to SFAS 123(R). We have applied the provisions of SAB 107 in our adoption of SFAS 123(R).

We adopted SFAS 123(R) 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 condensed consolidated financial statements as of and for the three and nine months ended September 30, 2006 reflect the impact of SFAS 123(R). In accordance with the modified prospective transition method, our condensed consolidated financial statements for prior periods have not been restated to reflect, and do not include, the impact of SFAS 123(R).

SFAS 123(R) 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 our consolidated statement of operations. Prior to the adoption of SFAS 123(R), we accounted for stock-based awards to employees and directors using the intrinsic value method in accordance with APB 25 as allowed under Statement of Financial Accounting Standards No. 123, *Accounting for Stock-Based Compensation* (SFAS 123). Under the intrinsic value method, stock-based compensation expense was recognized in our consolidated statements of operations for option grants to employees and consultants 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 our condensed consolidated statement of operations for the three and nine months ended September 30, 2006 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





**Table of Contents**

SFAS 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 123(R). As stock-based compensation expense recognized in the condensed consolidated statements of operations for the three and nine months ended September 30, 2006 is based on awards ultimately expected to vest, it has been reduced for estimated forfeitures. SFAS 123(R) 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 months ended September 30, 2006 was 20% for all options and was based on historical forfeiture experience. The estimated term of option grants for the three and nine months ended September 30, 2006 and 2005 was 4.09 and 4.48 years respectively. In our pro forma information required under SFAS 123 for the periods prior to fiscal 2006, we accounted for forfeitures as they occurred.

As of September 30, 2006 there was approximately \$203,000 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 2.3 years. For the three and nine month periods ended September 30, 2006, the amounts of stock-based compensation expense related to stock options were approximately \$99,000 and \$226,000, respectively. For the nine month periods ended September 30, 2006, the amounts of stock-based compensation expense related to ESPP purchases were approximately \$87,000.

***Accounts Receivable:***

Accounts receivable consist of trade receivables recorded upon recognition of revenue for product sales, reduced 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 collectibility. 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 standard cost, which approximates 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 our inventory to its market value.

***Valuation of Long-lived Assets:***

We assess potential impairment of our finite lived, intangible assets and other 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 discounted estimated future cash flows. The amount of impairment would be recognized as the excess of the assets 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 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.

**Table of Contents**

**Factors Affecting Future Results**

The following is a description of some of the principal risks inherent in our business. The risks and uncertainties described below are not the only ones facing us. Additional risks and uncertainties not presently known to us, or that we currently deem immaterial, could negatively impact our results of operations or financial condition in the future. ***Our ability to maintain current operations is dependent upon sustaining profitable operations or obtaining financing in the future.***

We have incurred significant losses since inception. For example, for the fiscal years 2005, 2004 and 2003 we incurred net losses of \$1,857,000, \$1,319,000 and \$348,000 respectively. We will have a continuing need for new infusions of cash if we continue to incur losses in the future. We plan to increase our revenues 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. 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, including our sales and marketing efforts and research and development. If we are required to significantly reduce our operations, our business will be harmed.

Changes in our business, financial performance or the market for our products may require us to seek additional sources of financing, which could include short-term debt, long-term debt or equity. Although in the past we have been successful in obtaining financing, there is a risk that we may be unsuccessful in obtaining financing in the future on terms acceptable to us and that we will not have sufficient cash to fund our continued operations.

Our revenues and operating income may be constrained:

if commercial adoption of our TMR laser systems by healthcare providers in the United States declines;

until such time, if ever, as we obtain FDA and other regulatory approvals for our PMC laser systems; and

for an uncertain period of time after such approvals are obtained.

***We may not be able to successfully market our products if third party reimbursement for the procedures performed with our products is not available for our health care provider customers.***

Few individuals are able to pay directly for the costs associated with the use of our products. In the United States, hospitals, physicians and other healthcare providers that purchase medical devices generally rely on third party payors, such as Medicare, to reimburse all or part of the cost of the procedure in which the medical device is being used. Effective July 1, 1999, the Centers for Medicare and Medicaid Services ( CMS ), formerly the Health Care Financing Administration, commenced Medicare coverage for TMR procedures performed with FDA approved devices. Hospitals and physicians are eligible to receive Medicare reimbursement covering 100% of the costs for TMR procedures. If CMS were to materially reduce or terminate Medicare coverage of TMR procedures, our business and results of operation could be harmed.

In July 2004, CMS convened the Medicare Advisory Committee ( MCAC ) to review the clinical evidence regarding laser myocardial revascularization as a treatment option for Medicare patients. The MCAC meeting was a non-binding public hearing to consider the body of scientific evidence concerning the safety and efficacy of laser myocardial revascularization and to provide advice and recommendations to the CMS on clinical issues. The MCAC reviewed more than six years of clinical evidence on laser myocardial revascularization and heard testimony from a group of leading physicians regarding TMR. Subsequent to that public hearing, CMS has not initiated a pending National Coverage Determination relating to laser myocardial revascularization. In September 2004, we confirmed that CMS had no current intention to initiate any changes in the current national coverage decision and related memoranda regarding TMR.

**Table of Contents**

As PMC has not been approved by the FDA, the CMS has not approved reimbursement for PMC. If we obtain FDA approval for PMC in the future and CMS does not provide reimbursement, our ability to successfully market and sell our PMC products may be affected.

Even though Medicare beneficiaries appear to account for a majority of all patients treated with the TMR procedure, the remaining patients are beneficiaries of private insurance and private health plans. We have limited experience to date with the acceptability of our TMR procedures for reimbursement by private insurance and private health plans. If private insurance and private health plans do not provide reimbursement, our business will suffer.

If we obtain the necessary foreign regulatory registrations or approvals for our products, market acceptance in international markets would be dependent, in part, upon the availability of reimbursement within prevailing healthcare payment systems. Reimbursement is a significant factor considered by hospitals in determining whether to acquire new equipment. A hospital is more inclined to purchase new equipment if third-party reimbursement can be obtained. Reimbursement and health care payment systems in international markets vary significantly by country. They include both government sponsored health care and private insurance. Although we expect to seek international reimbursement approvals, any such approvals may not be obtained in a timely manner, if at all. Failure to receive international reimbursement approvals could hurt market acceptance of our TMR and PMC products in the international markets in which such approvals are sought, which would significantly reduce international revenue. ***We may fail to obtain required regulatory approvals in the United States to market our PMC laser system.***

The FDA has not approved our PMC laser system for any application in the United States. In July 2001, the FDA Advisory Panel recommended against approval of PMC for public sale and use in the United States. In February 2003, the FDA granted an independent panel review of our pending PMA application for PMC by the Medical Devices Dispute Resolution Panel ( MDDRP ). In July 2003, the FDA agreed to review additional data in support of our PMA supplement for PMC under the structure of an interactive review process between us and the FDA review team. The independent panel review by the MDDRP was cancelled in lieu of the interactive review, but the FDA has agreed to reschedule the MDDRP hearing in the future, if the dispute cannot be resolved.

In August 2004, we met with the FDA and agreed on the steps needed to design and initiate a new clinical trial to confirm the safety and efficacy of PMC. In January 2005, we again met with the agency and agreed on major trial parameters. We came to agreement with the FDA on a final trial design and received formal FDA approval in January 2006. We are currently working to understand the specific direct and indirect costs and are initiating our pursuit of a corporate partner in the interventional cardiology arena. There can be no assurance, however, that we will receive a favorable determination from the FDA.

We will not be able to derive any revenue from the sale of our PMC system in the United States until such time, if any, that the FDA approves the device. Such inability to realize revenue from sales of our PMC device in the United States may have an adverse effect on our results of operations.

***We may incur impairment charges on long-lived assets if future events indicate asset values may not be recoverable.***

On January 5, 1999, the Company entered into an agreement ( the PLC agreement ) with PLC Systems, Inc. ( PLC ), which granted the Company a non-exclusive worldwide use of certain PLC patents. In return, the Company paid PLC a fee totaling \$2,500,000 between January 1999 and July 2002. The present value of those payments of \$2,300,000 was recorded as an intangible asset and is being amortized over the life of the underlying patents. The PLC patents are valuable to our PMC product line. The PMC product line is not approved for sale in the United States but is sold internationally. If PMC product sales decline in the future, we may suffer an impairment of the asset's value.

**Table of Contents**

***We may fail to obtain required regulatory approvals in the United States to market our new minimally invasive and robotically assisted handpieces.***

Both the PEARL Robotic 5.0 and Thoracoscopic 8.0 Minimally Invasive Delivery Systems have achieved CE Mark and Health Canada approval, and are part of an FDA approved IDE study that is underway to validate the safety and feasibility of these advanced delivery systems and the minimally invasive approach. The PEARL 5.0 handpiece utilizes a robotically assisted technique in an FDA approved trial of advanced laser delivery systems to provide the significant patient benefits of Holmium: YAG TMR via minimally invasive port access. The trial is a single arm consecutive series (open label) validation study of the advanced port access delivery system. The PEARL 8.0 handpiece utilizes a thoracoscopic technique in an FDA approved trial of advanced laser delivery systems to provide the significant patient benefits of Holmium: YAG TMR via minimally invasive port access. The trial is a single arm consecutive series (open label) validation study of the advanced port access delivery system. We will not be able to derive any revenue from the sale of our new minimally invasive and robotically assisted handpieces in the United States until such time, if any, that the FDA approves these devices. Such inability to realize revenue from sales of these devices in the United States may have an adverse effect on our results of operations.

***In the future, the FDA could restrict the current uses of our TMR product and thereby restrict our ability to generate revenues.***

We currently derive approximately 99% of our revenues from our TMR product. The FDA has approved this product for sale and use by physicians in the United States. At the request of the FDA, we are currently conducting post-market surveillance of our TMR product. If we should fail to meet the requirements mandated by the FDA or fail to complete our post-market surveillance study in an acceptable time period, the FDA could withdraw its approval for the sale and use of our TMR product by physicians in the United States. Additionally, although we are not aware of any safety concerns during our on-going post-market surveillance of our TMR product, if concerns over the safety of our TMR product were to arise, the FDA could possibly restrict the currently approved uses of our TMR product. In the future, if the FDA were to withdraw its approval or restrict the range of uses for which our TMR product can be used by physicians in the United States, such as restricting TMR's use with the coronary artery bypass grafting procedure, either outcome could lead to reduced or no sales of our TMR product in the United States and our business could be materially and adversely affected.

***We must comply with FDA manufacturing standards or face fines or other penalties including suspension of production.***

We are required to demonstrate compliance with the FDA's current good manufacturing practices regulations if we market devices in the United States or manufacture finished devices in the United States. The FDA inspects manufacturing facilities on a regular basis to determine compliance. If we fail to comply with applicable FDA or other regulatory requirements, we can be subject to:

    fines, injunctions, and civil penalties;

    recalls or seizures of products;

    total or partial suspensions of production; and

    criminal prosecutions.

The impact on us of any such failure to comply would depend on the impact of the remedy imposed on us.

**Table of Contents**

***We may fail to comply with international regulatory requirements and could be subject to regulatory delays, fines or other penalties.***

Regulatory requirements in foreign countries for international sales of medical devices often vary from country to country. In addition, the FDA must approve the export of devices to certain countries. The occurrence and related impact of the following factors would harm our business:

delays in receipt of, or failure to receive, foreign regulatory approvals or clearances;

the loss of previously obtained approvals or clearances; or

the failure to comply with existing or future regulatory requirements.

To market in Europe, a manufacturer must obtain the certifications necessary to affix to its products the CE Marking. The CE Marking is an international symbol of adherence to quality assurance standards and compliance with applicable European medical device directives. In order to obtain and to maintain a CE Marking, a manufacturer must be in compliance with the appropriate quality assurance provisions of the International Standards Organization and obtain certification of its quality assurance systems by a recognized European Union notified body. However, certain individual countries within Europe require further approval by their national regulatory agencies.

We have completed CE Mark registration for all of our products in accordance with the implementation of various medical device directives in the European Union. Failure to maintain the right to affix the CE Marking or other requisite approvals could prohibit us from selling our products in member countries of the European Union or elsewhere. Any enforcement action by international regulatory authorities with respect to past or future regulatory noncompliance could cause our business to suffer. Noncompliance with international regulatory requirements could result in enforcement action such as prohibitions against us marketing our products in the European Union, which would significantly reduce international revenue.

***We may not be able to meet future product demand on a timely basis and may be subject to delays and interruptions to product shipments because we depend on single source third party suppliers and manufacturers.***

We purchase certain critical products and components for lasers and disposable handpieces from single sources. In addition, we are vulnerable to delays and interruptions, for reasons out of our control, because we outsource the manufacturing of our products to third parties. We may experience harm to our business if we cannot timely provide lasers to our customers or if our outsourcing suppliers have difficulties supplying our needs for products and components.

In addition, we do not have long-term supply contracts. As a result, our sources are not obligated to continue to provide these critical products or components to us. Although we have identified alternative suppliers and manufacturers, a lengthy process would be required to qualify them as additional or replacement suppliers or manufacturers. Also, it is possible some of our suppliers or manufacturers could have difficulty meeting our needs if demand for our TMR and PMC laser systems were to increase rapidly or significantly. We believe that we have an adequate supply of lasers to meet our expected demand for the next twelve months. However, if demand for our TMR laser is greater than we currently anticipate and there is a delay in obtaining production capacity, unless we are able to obtain lasers originally placed through our loaned laser program and no longer utilized by a hospital, we may not be able to meet the demand for our TMR laser. In addition, any defect or malfunction in the laser or other products provided by our suppliers and manufacturers could cause delays in regulatory approvals or adversely affect product acceptance. Further, we cannot predict:

if materials and products obtained from outside suppliers and manufacturers will always be available in adequate quantities to meet our future needs; or

whether replacement suppliers and/or manufacturers can be qualified on a timely basis if our current suppliers and/or manufacturers are unable to meet our needs for any reason.

**Table of Contents**

***Expansion of our business may put added pressure on our management and operational infrastructure affecting our ability to meet any increased demand for our products and possibly having an adverse effect on our operating results.***

Since 2001 we have attempted to minimize our workforce, research and development expenses, and other operating expenses in effort to keep our cost structure more in line with our revenues. To the extent we are successful in expanding our business, such growth may place a significant strain on our limited personnel, management, financial systems and other resources. The evolving growth of our business presents numerous risks and challenges, including:

the dependence on the growth of the market for our TMR and PMC systems;

our ability to successfully and rapidly expand sales to potential customers in response to potentially increasing clinical adoption of the TMR procedure;

the costs associated with such growth, which are difficult to quantify, but could be significant;

domestic and international regulatory developments;

rapid technological change;

the highly competitive nature of the medical devices industry; and

the risk of entering emerging markets in which we have limited or no direct experience.

To accommodate any such growth and compete effectively, we may need to obtain additional funding to improve information systems, procedures and controls and expand, train, motivate and manage our employees, and such funding may not be available in sufficient quantities, if at all. If we are not able to manage these activities and implement these strategies successfully to expand to meet any increased demand, our operating results could suffer.

***Our operating results are expected to fluctuate and quarter-to-quarter comparisons of our results may not indicate future performance.***

Our operating results have fluctuated significantly from quarter-to-quarter and are expected to continue to fluctuate significantly from quarter-to-quarter in future periods. We believe that quarter-to-quarter comparisons of our operating results are not a good indication of our future performance. Due to the emerging nature of the markets in which we compete, forecasting operating results is difficult and unreliable. It is likely or possible that our operating results for a future quarter will fall below the expectations of public market analysts that may cover our stock and investors. When this occurred in the past, the price of our common stock fell substantially, and if this occurs in the future, the price of our common stock may fall again, perhaps substantially.

***Until May 2006, our stock was listed on the OTC Bulletin Board and is currently listed on the Pink Sheets which, in either case, may have an unfavorable impact on our stock price and liquidity.***

Effective April 3, 2003 our common stock was delisted from The Nasdaq SmallCap Market and became quoted on the OTC Bulletin Board on the same day. In May of 2006, our common stock was delisted from the OTC Bulletin Board as a result of our failure to timely file our periodic reports. The Pink Sheets and the OTC Bulletin Board are significantly more limited markets in comparison to the Nasdaq SmallCap Market. The listing of our shares on the OTC Bulletin Board or the Pink Sheets will likely result in a significantly less liquid market available for existing and potential stockholders to trade shares of our common stock, could ultimately further depress the trading price of our common stock and could have a long-term adverse impact on our ability to raise capital in the future.

We expect to seek reinstatement of our common stock for trading on the OTC Bulletin Board in the near future. However, there can be no assurance that we will be able to successfully obtain or maintain such a listing. To the extent we are no able to obtain or maintain a listing on the OTC Bulletin Board, the liquidity and trading price of our common stock and our ability to raise capital in the future would be adversely affected.

**Table of Contents**

***The trading prices of many high technology companies, and in particular medical device companies, have been volatile which may result in large fluctuations in the price of our common stock.***

The stock market has experienced significant price and volume fluctuations that have particularly affected the trading prices of equity securities of many high technology companies. These fluctuations have often been unrelated or disproportionate to the operating performance of many of these companies. Any negative change in the public's perception of medical device companies could depress our stock price regardless of our operating results.

***The price of our common stock may fluctuate significantly, which may result in losses for investors.***

The market price of our common stock has been and may continue to be volatile. For example, during the 52-week period ended October 31, 2006, the closing prices of our common stock as reported on the OTC Bulletin Board or Pink Sheets ranged from a high of \$0.59 per share to a low of \$0.25 per share. We expect our stock price to be subject to fluctuations as a result of a variety of factors, including factors beyond our control. These factors include:

actual or anticipated variations in our quarterly operating results;

the timing and amount of conversions and subsequent sales of common stock issuable upon conversion of outstanding convertible promissory notes and warrants;

announcements of technological innovations or new products or services by us or our competitors;

announcements relating to strategic relationships or acquisitions;

additions or terminations of coverage of our common stock by securities analysts;

statements by securities analysts regarding us or our industry;

conditions or trends in the medical device industry;

the lack of liquidity in the market for our common stock; and

changes in the economic performance and/or market valuations of other medical device companies.

The prices at which our common stock trades will affect our ability to raise capital, which may have an adverse effect on our ability to fund our operations.

***We face competition from products of our competitors which could limit market acceptance of our products and render our products obsolete.***

The market for TMR laser systems is competitive. We currently compete with PLC Systems, a publicly traded company which uses a CO<sub>2</sub> laser and an articulated mechanical arm in its TMR products. Edwards Lifesciences, a well known, publicly traded provider of products and technologies to treat cardiovascular disease, has assumed full sales and marketing responsibility in the U.S. for PLC's TMR Heart Laser 2 System and associated kits pursuant to a co-marketing agreement between the two companies executed in January 2001. Through its significantly greater financial and human resources, including a well-established and extensive sales representative network, we believe Edwards has the potential to market to a greater number of hospitals and doctors that we currently can. If PLC, or any new competitor, is more effective than we are in developing new products and procedures and marketing existing and future products similar to ours, our business may suffer.



**Table of Contents**

The market for TMR laser systems is characterized by rapid technical innovation. Our current or future competitors may succeed in developing TMR products or procedures that:

are more effective than our products;

are more effectively marketed than our products; or

may render our products or technology obsolete.

If we obtain the FDA's approval for our PMC laser system, we will face competition for market acceptance and market share for that product. Our ability to compete may depend in significant part on the timing of introduction of competitive products into the market, and will be affected by the pace, relative to competitors, at which we are able to:

develop products;

complete clinical testing and regulatory approval processes;

obtain third party reimbursement acceptance; and

supply adequate quantities of the product to the market.

***Third party intellectual property rights may limit the development and protection of our intellectual property, which could adversely affect our competitive position.***

Our success is dependent in large part on our ability to:

obtain patent protection for our products and processes;

preserve our trade secrets and proprietary technology; and

operate without infringing upon the patents or proprietary rights of third parties.

The medical device industry has been characterized by extensive litigation regarding patents and other intellectual property rights. Companies in the medical device industry have employed intellectual property litigation to gain a competitive advantage. Certain competitors and potential competitors of ours have obtained United States patents covering technology that could be used for certain TMR and PMC procedures. We do not know if such competitors, potential competitors or others have filed and hold international patents covering other TMR or PMC technology. In addition, international patents may not be interpreted the same as any counterpart United States patents.

While we periodically review the scope of our patents and other relevant patents of which we are aware, the question of patent infringement involves complex legal and factual issues. Any conclusion regarding infringement may not be consistent with the resolution of any such issues by a court.

***Costly litigation may be necessary to protect intellectual property rights.***

We may have to engage in time consuming and costly litigation to protect our intellectual property rights or to determine the proprietary rights of others. In addition, we may become subject to patent infringement claims or litigation, or interference proceedings declared by the United States Patent and Trademark Office to determine the priority of inventions.

Defending and prosecuting intellectual property suits, United States Patent and Trademark Office interference proceedings and related legal and administrative proceedings are both costly and time-consuming. We may be required to litigate further to:

enforce our issued patents;

protect our trade secrets or know-how; or

determine the enforceability, scope and validity of the proprietary rights of others.

**Table of Contents**

Any litigation or interference proceedings will result in substantial expense and significant diversion of effort by technical and management personnel. If the results of such litigation or interference proceedings are adverse to us, then the results may:

subject us to significant liabilities to third parties;

require us to seek licenses from third parties;

prevent us from selling our products in certain markets or at all; or

require us to modify our products.

Although patent and intellectual property disputes regarding medical devices are often settled through licensing and similar arrangements, costs associated with such arrangements may be substantial and could include ongoing royalties. Furthermore, we may not be able to obtain the necessary licenses on satisfactory terms, if at all.

Adverse determinations in a judicial or administrative proceeding or failure to obtain necessary licenses could prevent us from manufacturing and selling our products. This would harm our business.

The United States patent laws have been amended to exempt physicians, other health care professionals, and affiliated entities from infringement liability for medical and surgical procedures performed on patients. We are not able to predict if this exemption will materially affect our ability to protect our proprietary methods and procedures.

***We rely on patent and trade secret laws, which are complex and may be difficult to enforce.***

The validity and breadth of claims in medical technology patents involve complex legal and factual questions and, therefore, may be highly uncertain. Issued patent or patents based on pending patent applications or any future patent application may not exclude competitors or may not provide a competitive advantage to us. In addition, patents issued or licensed to us may not be held valid if subsequently challenged and others may claim rights in or ownership of such patents.

Furthermore, we cannot assure you that our competitors:

have not developed or will not develop similar products;

will not duplicate our products; or

will not design around any patents issued to or licensed by us.

Because patent applications in the United States were historically maintained in secrecy until the patents are issued, we cannot be certain that:

others did not first file applications for inventions covered by our pending patent applications; or

we will not infringe any patents that may issue to others on such applications.

***We may suffer losses from product liability claims if our products cause harm to patients.***

We are exposed to potential product liability claims and product recalls. These risks are inherent in the design, development, manufacture and marketing of medical devices. We could be subject to product liability claims if the use of our TMR or PMC laser systems is alleged to have caused adverse effects on a patient or such products are believed to be defective. Our products are designed to be used in life-threatening situations where there is a high risk of serious injury or death. We are not aware of any material side effects or adverse events arising from the use of our TMR product. Though we are in the process of responding to the FDA's Circulatory Devices Panel's recent recommendation against approval of our PMC product because of concerns over the safety of the device and the

**Table of Contents**

data regarding adverse events in the clinical trials, we believe there are no material side effects or adverse events arising from the use of our PMC product. When being clinically investigated, it is not uncommon for new surgical or interventional procedures to result in a higher rate of complications in the treated population of patients as opposed to those reported in the control group. In light of this, we believe that the difference in the rates of complications between the treated groups and the control groups in the clinical trials for our PMC product are not statistically significant, which is why we believe that there are no material side effects or material adverse events arising from the use of our PMC product.

Any regulatory clearance for commercial sale of these products will not remove these risks. Any failure to comply with the FDA's good manufacturing practices or other regulations could hurt our ability to defend against product liability lawsuits.

***Our insurance may be insufficient to cover product liability claims against us.***

Our product liability insurance may not be adequate for any future product liability problems or continue to be available on commercially reasonable terms, or at all.

If we were held liable for a product liability claim or series of claims in excess of our insurance coverage, such liability could harm our business and financial condition. We maintain insurance against product liability claims in the amount of \$10 million per occurrence and \$10 million in the aggregate.

We may require increased product liability coverage as sales of approved products increase and as additional products are commercialized. Product liability insurance is expensive and in the future may not be available on acceptable terms, if at all.

***We depend heavily on key personnel and turnover of key employees and senior management could harm our business.***

Our future business and results of operations depend in significant part upon the continued contributions of our key technical and senior management personnel. They also depend in significant part upon our ability to attract and retain additional qualified management, technical, marketing and sales and support personnel for our operations. If we lose a key employee or if a key employee fails to perform in his or her current position, or if we are not able to attract and retain skilled employees as needed, our business could suffer. Significant turnover in our senior management could significantly deplete our institutional knowledge held by our existing senior management team and could impair our ability to effectively operate and grow our business. For example, in April 2005, Christine Ocampo, our former Chief Financial Officer, resigned, and in July 2006 we terminated the employment of Michael Quinn, our former Chief Executive Officer, President and Chairman of the Board. We depend on the skills and abilities of our key management level employees in managing the manufacturing, technical, marketing and sales aspects of our business, any part of which could be harmed by further turnover. To the extent we are unable to identify or retain suitable management personnel, our business and prospects could be adversely affected.

***We sell our products internationally which subjects us to specific risks of transacting business in foreign countries.***

In future quarters, international sales may become a significant portion of our revenue if our products become more widely used outside of the United States. Our international revenue is subject to the following risks, the occurrence of any of which could harm our business:

foreign currency fluctuations;

economic or political instability;

foreign tax laws;

shipping delays;

**Table of Contents**

various tariffs and trade regulations;

restrictions and foreign medical regulations;

customs duties, export quotas or other trade restrictions; and

difficulty in protecting intellectual property rights.

***If an Event of Default Occurs Under the Convertible Note Issued to Laurus, It Could Seriously Harm Our Operations.***

On October 26, 2004, we issued a \$6,000,000 secured convertible term note to Laurus, of which \$1,355,000 remained outstanding as of September 30, 2006. Pursuant to the terms of the note, an event of default includes a suspension of trading of our common stock on the OTC Bulletin Board which remains uncured within thirty (30) days of notice of the suspension. To the extent that the delisting of our stock in May 2006 is deemed a suspension of trading, the Company could be deemed to be in default of its obligations under the note. If an event of default occurs under the note, interest on the note would accrue at the default rate which is the then current prime rate plus 12% per annum until the default is cured. In addition, the holder of the note will have the right to accelerate and declare it immediately due and payable and exercise its rights as a secured creditor under applicable law and the security agreement with us, including the right to foreclose upon our assets that secure the note, which constitute substantially all of our assets.

In addition to the requirements that we maintain our listing on the OTC Bulletin Board, the note and related agreements contain numerous events of default which include:

A failure to pay interest and principal payments when due;

a breach by us of any material covenant or term or condition of the note or any agreement made in connection therewith;

a breach by us of any material representation or warranty made in the note or in any agreement made in connection therewith;

if we make an assignment for the benefit of our creditors, or a receiver or trustee is appointed for us;

any form of bankruptcy or insolvency proceeding is instituted by or against us and is not dismissed within 60 days;

any money judgment entered or filed against us for more than \$50,000 and remains unresolved for 30 days;

our failure to timely deliver shares of common stock when due upon conversions of the note;

we experience an event of default under any other debt obligations; and

we experience a loss, damage or encumbrance upon collateral securing the Laurus debt which is valued at more than \$100,000 and is not timely mitigated.

If we default on the note and the holder demands all payments due and payable, the cash required to pay such amounts would most likely come out of working capital and non current assets, which may not be sufficient to repay the amounts due. In addition, since we rely on our working capital for our day to day operations, such a default on the note could materially adversely affect our business, operating results or financial condition to such extent that we are forced to restructure, file for bankruptcy, sell assets or cease operations. Further, our obligations under the note are secured by all of our assets. Failure to fulfill our obligations under the note and related agreements could lead to loss of these assets, which would be detrimental to our operations.



**Table of Contents*****We may continue to incur significant non-operating, non-cash charges resulting from changes in the fair value of warrants and derivatives.***

In October 2004, we entered into a Secured Convertible Term Note agreement with Laurus Funds. Pursuant to the Note agreement, a warrant totaling 2.6 million was issued to Laurus. This warrant, along with multiple embedded derivatives in the agreement, have been recorded at their relative fair value at the inception date of the agreement, October 27, 2004, and will continue to be recorded at fair value at each subsequent balance sheet date. Any change in value between reporting periods will be recorded as a non-operating, non-cash charge at each reporting date. The impact of these non-operating, non-cash charges could have an adverse effect on our stock price in the future.

The fair value of the warrant and derivatives is tied in large part to our stock price. If our stock price increases between reporting periods, the warrant and derivatives become more valuable. As such, there is no way to forecast what the non-operating, non-cash charges will be in the future or what the future impact will be on our financial statements.

***The restrictions on our activities contained in the Laurus financing documents could negatively impact our ability to obtain financing from other sources.***

The Laurus financing documents restrict us from obtaining additional debt financing, subject to certain specified exceptions. To the extent that Laurus declined to approve a debt financing that does not otherwise qualify for an exception to the consent requirement, we would be unable to obtain such debt financing. In addition, subject to certain exceptions, we have granted to Laurus a right of first refusal to provide additional financing to us in the event that we propose to engage in additional debt financing or to sell any of our equity securities. Laurus' s right of first refusal could act as a deterrent to third parties which may be interested in providing us with debt financing or purchasing our equity securities. To the extent that such a financing is required for us to conduct our operations, these restrictions could materially adversely impact our ability to achieve our operational objectives.

***Low market prices for our common stock would result in greater dilution to our shareholders, and could negatively impact our ability to convert the Laurus debt into equity***

The market price of our common stock significantly impacts the extent to which we are permitted to convert the unrestricted and restricted portions of the Laurus debt into shares of our common stock. The lower the market price of our common stock as of the respective times of conversion, the more shares we will need to issue to Laurus to convert the principal and interest payments then due on the unrestricted portion of the debt. If the market price of our common stock falls below certain thresholds, we will be unable to convert any such repayments of principal and interest into equity, and we will be forced to make such repayments in cash, which we currently forecast will be required to sustain our operations. Our operations could be materially adversely impacted if we are forced to make repeated cash payments on the unrestricted portion of the Laurus debt. Further, prior to the full repayment of the unrestricted portion of the Laurus debt, we will only be able to require conversions of the \$3,000,000 restricted cash amount to the extent the market price of our common stock exceeds certain levels. To the extent that the market price of our common stock does not reach such specified levels, we will be not be entitled to take possession of any of the restricted cash during the term of the Laurus note. The restricted portion of the debt will continue to accrue interest during the entire period that we are unable to require conversion. In addition, to the extent that conversions of the restricted portion of the debt are not effected during the term of the note, we have only a limited ability to convert a specified amount of the restricted debt (subject to meeting certain minimum market price thresholds and volume requirements), and we will be required to repay the remaining restricted principal and interest in cash. In May 2006, the Company repaid \$2,417,000 of the Note' s outstanding principal amount out of the restricted cash account created for the benefit of Laurus and the Company and related interest of \$314,000. In connection with the repayment, the Company was required to pay a prepayment penalty of \$483,000 out of the Company' s unrestricted cash. Therefore, the risks associated to the restricted debt are no longer applicable.

***Future sales of our common stock could lower our stock price.***

The sale of our common stock by the holders of the Laurus debt upon conversion of all or any portion of the Laurus debt could cause the market price of our common stock to decline. In addition, if our shareholders sell

**Table of Contents**

substantial amounts of our common stock, including shares issuable upon exercise of options or warrants or shares issued in previous financings, in the public market, the market price of our common stock could decline. If these sales were to occur, we may also find it more difficult to sell equity or equity-related securities in the future at a time and price that we deem appropriate and desirable.

In the future, we may issue additional shares in public or private offerings. We cannot predict the size of future issuances of our common stock or the effect, if any, that future issuances and sales of our common stock would have on the market price of our common stock. We expect that Laurus will generally promptly sell any shares into which the Laurus indebtedness is converted, and that the market price of our common stock could decline as a result of such sales.

***Provisions of our certificate of incorporation as well as our rights agreement could discourage potential acquisition proposals and could deter or prevent a change of control.***

Our articles of incorporation authorize our board of directors, subject to any limitations prescribed by law, to issue shares of preferred stock in one or more series without shareholder approval. On August 17, 2001 we adopted a shareholder rights plan, as amended, and under the rights plan, our board of directors declared a dividend distribution of one right for each outstanding share of common stock to shareholders of record at the close of business on August 30, 2001. Pursuant to the Rights Agreement, in the event (a) any person or group acquires 15% or more of our then outstanding shares of voting stock (or 21% or more of our then outstanding shares of voting stock in the case of State of Wisconsin Investment Board), (b) a tender offer or exchange offer is commenced that would result in a person or group acquiring 15% or more of our then outstanding voting stock, (c) we are acquired in a merger or other business combination in which we are not the surviving corporation or (d) 50% or more of our consolidated assets or earning power are sold, then the holders of our common stock are entitled to exercise the rights under the Rights Plan, which include, based on the type of event which has occurred, (i) rights to purchase preferred shares from us, (ii) rights to purchase common shares from us having a value twice that of the underlying exercise price, and (iii) rights to acquire common stock of the surviving corporation or purchaser having a market value of twice that of the exercise price. The rights expire on August 17, 2011, and may be redeemed prior thereto at \$0.001 per right under certain circumstances. The Board's ability to issue preferred stock without shareholder approval while providing desirable flexibility in connection with financings, acquisitions and other corporate purposes, and the existence of the rights plan might discourage, delay or prevent a change in the ownership of our company or a change in our management. In addition, these provisions could limit the price that investors would be willing to pay in the future for shares of our common stock.

***Changes in, or interpretations of, accounting rules and regulations could result in unfavorable accounting charges.***

We prepare our consolidated financial statements in conformity with generally accepted accounting principles. These principles are subject to interpretation by the SEC and various bodies formed to interpret and create appropriate accounting policies. A change in these policies can have a significant effect on our reported results and may even retroactively affect previously reported transactions. To the extent that such interpretations or changes in policies negatively impact our reported financial results, our results of stock price could be adversely affected.

***Recent rulemaking by the Financial Accounting Standards Board requires us to expense equity compensation given to our employees and could significantly harm our operating results and may reduce our ability to effectively utilize equity compensation to attract and retain employees.***

We historically have used stock options as a component of our employee compensation program in order to align employees' interests with the interests of our stockholders, encourage employee retention, and provide competitive compensation packages. The Financial Accounting Standards Board has adopted changes that will require companies to record a charge to earnings for employee stock option grants and other equity incentives beginning in the first quarter ending March 31, 2006. The adoption of this accounting change has reduced our reported earnings and may require us to reduce the availability and amount of equity incentives provided to employees, which may make it more difficult for us to attract, retain and motivate key personnel. Each of these results could materially and adversely affect our business.





**Table of Contents**

*While we believe that we currently have adequate internal controls over financial reporting, we are exposed to risks from recent legislation requiring companies to evaluate those internal controls.*

Section 404 of the Sarbanes-Oxley Act of 2002 requires our management to report on, and our independent registered public accounting firm to attest to, the effectiveness of our internal control structure and procedures for financial reporting. We are developing a program to perform the system and process evaluation and testing necessary to comply with these requirements on a sustained basis. Companies do not have significant experience in complying with these requirements on an ongoing and sustained basis. As a result, we expect to continue to incur increased expense and to devote management resources to Section 404 compliance. In the event that our chief executive officer, chief financial officer or our independent registered public accounting firm determine that our internal controls over financial reporting are not effective as defined under Section 404, investor perceptions of Cardiogenesis may be adversely affected and could cause a decline in the market price of our stock.

**Item 3. Controls and Procedures**

(a) As of September 30, 2006, an evaluation was carried out under the supervision and with the participation of the Company's management, including our Chief Executive Officer 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). Based upon that evaluation, the Chief Executive Officer and the Chief Financial Officer concluded that the design and operation of these disclosure controls and procedures during the three months ended September 30, 2006 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 CEO and CFO, as appropriate to allow timely decisions regarding required disclosure.

The Company's management has concluded that the condensed consolidated financial statements included in this Quarterly Report on Form 10-QSB fairly present in all material respects the Company's financial condition, results of operations and cash flows for the periods presented in conformity with accounting principles generally accepted in the United States of America.

**Remediation of Material Weakness in Internal Control**

As reported in our 2005 Form 10-KSB, and our March 31, 2006 and June 30, 2006 Forms 10-QSB, we determined that the Company did not maintain effective controls over cash disbursements. The Company determined that certain employee expense reports were not reviewed and the expenses were not authorized.

The foregoing led our management to conclude that our disclosure controls and procedures were not effective as of June 30, 2006 because of a material weakness in our internal controls over financial reporting.

In the third quarter of 2006, the Company implemented an appropriate level of review for each employee expense report and will implement a new expense policy that will specifically address the issues that were identified. Management believes that these procedures, implemented upon the identification of the material weakness, will allow the Company to maintain effective internal control over financial reporting.

As such, we believe that the remediation initiative outlined above was sufficient to eliminate the material weakness in internal control over financial reporting as discussed above.

(b) Changes in internal control over financial reporting. Other than as noted above, there were no changes in the Company's internal control over financial reporting that occurred during the quarter ended September 30, 2006 that has materially affected, or are reasonably likely to materially affect, the Company's internal control over financial reporting.

**Table of Contents**

**Part II Other Information**

**Item 1. Legal Proceedings**

On July 12, 2006, we terminated Michael Quinn as our Chairman, Chief Executive Officer and President in accordance with the terms of his employment agreement. At the time of termination, Mr. Quinn stated that he intended to bring claims against us relating to his termination, including claims for payment of severance he claimed was owed to him under the terms of his employment agreement

On October 12, 2006, Cardiogenesis and Mr. Quinn entered into a Memorandum of Understanding (the MOU ) pursuant to which the parties agreed to settle certain disputes between them relating to Mr. Quinn s termination from employment.

Pursuant to the terms of the MOU, we will pay Mr. Quinn a total of approximately \$500,000 in 72 equal bi-monthly installments and will also pay approximately \$51,000 to Mr. Quinn s counsel as attorney s fees. At September 30, 2006 the entire balance, plus \$28,000 of related payroll taxes, was accrued for and included in accrued liabilities. Mr. Quinn will be entitled to retain 689,008 previously issued stock options having the following exercise prices:

- 89,008 shares at \$0.32 per share
- 150,000 shares at \$0.70 per share
- 200,000 shares at \$0.54 per share
- 250,000 shares at \$0.50 per share

The exercise period of these options has been extended so that each option shall terminate on October 12, 2009. In the three and nine months ended September 30, 2006, we recognized stock-based expense, net of forfeitures, of \$103,000 related to the vesting of these options which is included in sales, general, and administrative expenses, of which \$29,000 related to the modifications of the original terms of these options.

In addition, Mr. Quinn will be entitled to statutory indemnification and any indemnification required by our bylaws relating to his services on our Board of Directors. The MOU also provides that both parties will not disparage each other.

On October 24, 2006, we entered into a Settlement Agreement and General Release with Mr. Quinn that formalizes the settlement contemplated by the MOU and includes customary releases and other provisions.

**Item 6. Exhibits**

The exhibits below are filed or incorporated herein by reference.

**Exhibit No. Description**

- 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



**Table of Contents**

**Exhibit No. Description**

- 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
- 4.5 (10) Securities Purchase Agreement, dated as of January 21, 2004, by and among Cardiogenesis Corporation and each of the investors identified therein
- 4.6 (11) Registration Rights Agreement, dated as of January 21, 2004, by and among Cardiogenesis Corporation and the investors identified therein
- 4.7 (12) Form of Common Stock Purchase Warrant, dated January 21, 2004, having an exercise price of \$1.37 per share
- 4.8 (13) Securities Purchase Agreement, dated October 26, 2004, between the Company and Laurus Master Fund, Ltd.
- 4.9 (14) Secured Convertible Term Note, dated October 26, 2004, in favor of Laurus Master Fund, Ltd.
- 4.10 (15) Registration Rights Agreement, dated October 26, 2004, between the Company and Laurus Master Fund, Ltd.
- 4.11 (16) Common Stock Purchase Warrant, dated October 26, 2004, in favor of Laurus Master Fund, Ltd.
- 4.12 (17) Security Agreement, dated October 26, 2004, in favor of Laurus Master Fund, Ltd.
- 10.1 (18) Standard Industrial/Commercial Multi-Tenant Lease Net by and between John Robert Meehan and Cardiogenesis Corporation
- 31.1 (19) 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 (19) 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 (19) 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 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

Edgar Filing: CARDIOGENESIS CORP /CA - Form 10QSB

- (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 3.1.5 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 4.4 to the Registrant's Current Report on Form 8-K filed January 22, 2004

**Table of Contents**

(11) Incorporated by reference to Exhibit 4.5 to the Registrant's Current Report on Form 8-K filed January 22, 2004

(12) Incorporated by reference to Exhibit 4.6 to the Registrant's Current Report on Form 8-K filed January 22, 2004

(13) Incorporated by reference to Exhibit 4.2 to the Registrant's Current Report on Form 8-K filed October 28, 2004

(14) Incorporated by reference to Exhibit 4.3 to the Registrant's Current Report on Form 8-K filed October 28, 2004

(15) Incorporated by reference to Exhibit 4.4 to the Registrant's Current Report on Form 8-K filed October 28, 2004

(16)

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

(17) Incorporated by  
reference to  
Exhibit 4.6 to  
the Registrant's  
Current Report  
on Form 8-K  
filed  
October 28,  
2004

(18) Incorporated by  
reference to  
Exhibit 10.1 to  
the Registrant's  
Current Report  
on Form 8-k  
Filed August 25,  
2006

(19) Filed herewith

**Table of Contents**

**CARDIOGENESIS CORPORATION  
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, 2006

/s/ JOSEPH R. KLETZEL, II

Joseph R. Kletzel, II  
Interim Chief Executive Officer, Interim Chief  
Operating Officer, and Chairman of the Board

Date: November 13, 2006

/s/ William R. Abbott

William R. Abbott  
Senior Vice President, Chief Financial Officer  
(Principal Financial and Accounting Officer,  
Secretary and  
Treasurer)

37

---



**Table of Contents**

**Exhibit Index**

**Exhibit No. Description**

- 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
- 4.5 (10) Securities Purchase Agreement, dated as of January 21, 2004, by and among Cardiogenesis Corporation and each of the investors identified therein
- 4.6 (11) Registration Rights Agreement, dated as of January 21, 2004, by and among Cardiogenesis Corporation and the investors identified therein
- 4.7 (12) Form of Common Stock Purchase Warrant, dated January 21, 2004, having an exercise price of \$1.37 per share
- 4.8 (13) Securities Purchase Agreement, dated October 26, 2004, between the Company and Laurus Master Fund, Ltd.
- 4.9 (14) Secured Convertible Term Note, dated October 26, 2004, in favor of Laurus Master Fund, Ltd.
- 4.10 (15) Registration Rights Agreement, dated October 26, 2004, between the Company and Laurus Master Fund, Ltd.
- 4.11 (16) Common Stock Purchase Warrant, dated October 26, 2004, in favor of Laurus Master Fund, Ltd.
- 4.12 (17) Security Agreement, dated October 26, 2004, in favor of Laurus Master Fund, Ltd.
- 10.1(18) Standard Industrial/Commercial Multi-Tenant Lease Net by and between John Robert Meehan and Cardiogenesis Corporation

Edgar Filing: CARDIOGENESIS CORP /CA - Form 10QSB

- 31.1 (19) 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 (19) 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 (19) 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

38

---

**Table of Contents**

- (1) Incorporated by reference to Exhibit 3.1 to the Registrant's Registration Statement on Form S-1/A (File No. 33-03770), filed 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 3.1.5 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 4.4 to the Registrant's Current Report on Form 8-K filed January 22, 2004
- (11) Incorporated by reference to Exhibit 4.5 to the Registrant's Current Report on Form 8-K filed January 22, 2004
- (12) Incorporated by reference to Exhibit 4.6 to the Registrant's Current Report on Form 8-K filed January 22, 2004
- (13) Incorporated by reference to Exhibit 4.2 to the Registrant's Current Report on Form 8-K filed October 28, 2004
- (14) Incorporated by reference to Exhibit 4.3 to the Registrant's Current Report on Form 8-K filed October 28, 2004
- (15) Incorporated by reference to Exhibit 4.4 to the Registrant's Current Report on Form 8-K filed October 28, 2004
- (16) Incorporated by reference to Exhibit 4.5 to the Registrant's Current Report on Form 8-K filed October 28, 2004
- (17) Incorporated by reference to Exhibit 4.6 to the Registrant's Current Report on Form 8-K filed October 28, 2004
- (18) Incorporated by reference to Exhibit 10.1 to the Registrant's Current Report on Form 8-k Filed August 25, 2006
- (19) Filed herewith