

CARDIOGENESIS CORP /CA

Form 10-Q

November 15, 2004

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**SECURITIES AND EXCHANGE COMMISSION  
Washington, D.C. 20549**

**FORM 10-Q**

**Quarterly report pursuant to Section 13 or 15(d)  
of the Securities Exchange Act of 1934**

**For the quarterly period ended September 30, 2004**

Commission file number 0-28288

**CARDIOGENESIS CORPORATION**  
(formerly known as Eclipse Surgical Technologies, Inc.)  
(Exact name of Registrant as specified in its charter)

**California**

**77-0223740**

*(State of incorporation)*

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

**26632 Towne Center Drive  
Suite 320**

**Foothill Ranch, California 92610**

*(Address of principal executive offices)*

**(714) 649-5000**

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

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

Yes  No

Indicate by check mark whether the registrant is an accelerated filer (as defined in Exchange Act Rule 12b-2.)

Yes  No

Indicate the number of shares outstanding of each of the issuer's classes of common stock outstanding as of the latest practicable date.

41,388,994 shares of Common Stock, no par value  
As of October 31, 2004

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(unaudited)

	<b>September 30, 2004</b>	<b>December 31, 2003</b>
	<u>                    </u>	<u>                    </u>
ASSETS		
Current assets:		
Cash and cash equivalents	\$ 2,920	\$ 1,013
Accounts receivable, net of allowance for doubtful accounts of \$35 and \$26 at September 30, 2004 and December 31, 2003, respectively	1,578	1,830
Inventories, net of reserve of \$361 and \$373 at September 30, 2004 and December 31, 2003, respectively	1,706	1,339
Prepays and other current assets	499	453
	<u>                    </u>	<u>                    </u>
Total current assets	6,703	4,635
Property and equipment, net	497	408
Other assets	1,257	1,417
	<u>                    </u>	<u>                    </u>
Total assets	<u>\$ 8,457</u>	<u>\$ 6,460</u>
LIABILITIES AND SHAREHOLDERS EQUITY		
Current liabilities:		
Accounts payable	\$ 1,228	\$ 876
Accrued liabilities	970	1,159
Customer deposits	25	25
Deferred revenue	627	573
Note payable	133	
Current portion of capital lease obligation	5	1
	<u>                    </u>	<u>                    </u>
Total current liabilities	2,988	2,634
Capital lease obligation, less current portion	19	6
	<u>                    </u>	<u>                    </u>
Total liabilities	<u>3,007</u>	<u>2,640</u>
Shareholders equity:		
Preferred stock:		
no par value; 5,000 shares authorized; none issued and outstanding		
Common stock:		

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no par value; 75,000 shares authorized; 41,389 and 37,859 shares issued and outstanding at September 30, 2004 and December 31, 2003, respectively	171,329	168,778
Accumulated deficit	<u>(165,879)</u>	<u>(164,958)</u>
Total shareholders' equity	<u>5,450</u>	<u>3,820</u>
Total liabilities and shareholders' equity	<u>\$ 8,457</u>	<u>\$ 6,460</u>

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

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**CONDENSED CONSOLIDATED STATEMENTS OF OPERATIONS & COMPREHENSIVE LOSS**  
**(in thousands, except per share amounts)**  
**(unaudited)**

	Three months ended September 30,		Nine months ended September 30,	
	2004	2003	2004	2003
Net revenues	\$ 2,837	\$ 3,594	\$10,254	\$10,106
Cost of revenues	499	621	1,570	1,745
Gross profit	2,338	2,973	8,684	8,361
Operating expenses:				
Research and development	520	730	1,189	1,836
Sales, general and administrative	2,746	2,364	8,398	7,406
Total operating expenses	3,266	3,094	9,587	9,242
Operating loss	(928)	(121)	(903)	(881)
Interest income (expense), net	4	(8)	(18)	(5)
Net loss	(924)	(129)	(921)	(886)
Other comprehensive loss:				
Comprehensive loss	\$ (924)	\$ (129)	\$ (921)	\$ (886)
Per share information:				
Net loss available to common shareholders	\$ (924)	\$ (129)	\$ (921)	\$ (886)
Net loss per share:				
Basic and diluted	\$ (0.02)	\$ (0.00)	\$ (0.02)	\$ (0.02)
Shares used in computation of net loss per share:				
Basic and diluted	41,388	37,351	41,054	37,203



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

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

	<b>Nine months ended September 30,</b>	
	<b>2004</b>	<b>2003</b>
Cash flows from operating activities:		
Net loss	\$ (921)	\$ (886)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation and amortization	165	188
Provision for doubtful accounts	11	
Provision for inventory reserves	19	189
Amortization of license fees	146	146
Amortization of debt issue costs	31	13
Reduction of clinical trial accrual	(152)	(296)
Changes in operating assets and liabilities:		
Accounts receivable	241	172
Inventories	(386)	129
Prepays and other current and noncurrent assets	288	458
Accounts payable	352	(23)
Accrued liabilities	(37)	(266)
Customer deposits		(25)
Deferred revenue	54	18
	<u>          </u>	<u>          </u>
Net cash used in operating activities	<u>(189)</u>	<u>(183)</u>
Cash flows from investing activities:		
Acquisition of property and equipment	<u>(235)</u>	<u>(40)</u>
Net cash used in investing activities	<u>(235)</u>	<u>(40)</u>
Cash flows from financing activities:		
Net proceeds from sales of common stock and from issuance of common stock from exercise of options	2,551	194
Payments on short-term borrowings	(217)	(325)
Repayments of capital lease obligations	(3)	(23)
	<u>          </u>	<u>          </u>
Net cash provided by (used in) financing activities	2,331	(154)



	_____	_____
Net increase (decrease) in cash and cash equivalents	1,907	(377)
Cash and cash equivalents at beginning of period	1,013	1,490
	_____	_____
Cash and cash equivalents at end of period	\$2,920	\$1,113
	_____	_____
Supplemental schedule of cash flow information:		
Interest paid	\$ 6	\$ 11
	_____	_____
Taxes paid	\$ 42	\$ 25
	_____	_____
Supplemental schedule of noncash investing and financing activities:		
Purchase of property and equipment under a capital lease	\$ 20	\$
	_____	_____
Issuance of warrants	\$	\$ 75
	_____	_____
Financing of insurance premiums with note payable	\$ 349	\$ 535
	_____	_____

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

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**CARDIOGENESIS CORPORATION**

**NOTES TO UNAUDITED CONDENSED CONSOLIDATED FINANCIAL STATEMENTS**

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

*Interim Financial Information (unaudited):*

The interim financial statements in this report reflect all adjustments, consisting of normal recurring adjustments, that are, in the opinion of management, necessary for a fair presentation of the results of operations and cash flows for the interim periods covered and of the financial position of the Company at the interim balance sheet date. Results for interim periods are not necessarily indicative of results to be expected for the full fiscal year. The year-end balance sheet information was derived from audited financial statements but does not include all disclosures required by accounting principles generally accepted in the United States of America. These financial statements should be read in conjunction with CardioGenesis' audited financial statements and notes thereto for the year ended December 31, 2003, contained in the Company's Annual Report on Form 10-K, as filed with the U.S. Securities and Exchange Commission ( SEC ).

These financial statements contemplate the realization of assets and the satisfaction of liabilities in the normal course of business. CardioGenesis 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, 2004 is sufficient to meet the Company's capital and operating requirements for the next 12 months.

CardioGenesis may require additional financing in the future. There can be no assurance that CardioGenesis will be able to obtain additional debt or equity financing, if and when needed, on terms acceptable to the Company. Any additional debt or equity financing may involve substantial dilution to CardioGenesis' stockholders, restrictive covenants or high interest costs. The failure to raise needed funds on sufficiently favorable terms could have a material adverse effect on CardioGenesis' business, operating results and financial condition. CardioGenesis' 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 Loss Per Share:*

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

Options to purchase 4,175,710 and 4,477,290 shares of common stock were outstanding at September 30, 2004 and 2003, respectively. Warrants to purchase 275,000 shares of common stock at prices ranging from \$.35 to \$.44 per share were outstanding as of September 30, 2004. Warrants to purchase 75,000 shares of common stock at \$1.63 per share were outstanding as of September 30, 2004 and 2003. Warrants to purchase 3,139,535 shares of common stock at a price of \$1.37 per share were outstanding as of September 30, 2004. Both the options and warrants were not included in the calculation of diluted EPS because their inclusion would have been anti-dilutive.

**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,</b>	<b>December 31,</b>
	<b>2004</b>	<b>2003</b>
	<b>(unaudited)</b>	
Raw materials	\$ 974	\$ 1,042
Work-in-process	161	159
Finished goods	932	511

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	<b>September 30,</b>	<b>December 31,</b>
	<b>2004</b>	<b>2003</b>
	<b>(unaudited)</b>	
	2,067	1,712
Less reserves	(361)	(373)
	<b>\$ 1,706</b>	<b>\$ 1,339</b>

**3. Stock-Based Compensation:**

The Company has adopted the disclosure only provisions of SFAS 123, as amended by SFAS 148 Accounting for Stock-Based Compensation, Transition and Disclosure. CardioGenesis, however, continues to apply APB 25 and related interpretations in accounting for its plans and follows the aforementioned disclosure-only provisions of SFAS 123, as amended by SFAS 148. Had compensation cost for the Stock Option Plan, the Director's Stock Option Plan and the Employee Stock Purchase Plan been determined based on the fair value of the options at the grant date for awards in the three and nine months ended September 30, 2004 and 2003, consistent with the provisions of SFAS 123, CardioGenesis' net loss and net loss per share would have changed to the pro forma amounts indicated below (*in thousands, except per share amounts*):

	<b>Three Months Ended September 30,</b>	
	<b>2004</b>	<b>2003</b>
	<b>(unaudited)</b>	
Net loss as reported	\$ (924)	\$ (129)
Stock-based employee compensation, net of related tax effects	\$ (147)	\$ (218)
	<b>\$ (1,071)</b>	<b>\$ (347)</b>
Basic and diluted net loss per share as reported	\$ (0.02)	\$ (0.00)
Pro forma basic and diluted net loss per share	\$ (0.03)	\$ (0.01)
	<b>Nine Months Ended September 30,</b>	
	<b>2004</b>	<b>2003</b>
	<b>(unaudited)</b>	

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Net loss as reported	\$ (921)	\$ (886)
Stock-based employee compensation, net of related tax effects	\$ (397)	\$ (989)
Pro forma net loss	\$ (1,318)	\$ (1,875)
Basic and diluted net loss per share as reported	\$ (0.02)	\$ (0.02)
Pro forma basic and diluted net loss per share	\$ (0.03)	\$ (0.05)

The above pro-forma disclosures are not necessarily representative of the effects on reported net (loss) income for future years. The aggregate fair value and weighted average fair value per share of options granted in the three months ended September 30, 2004 and 2003 were \$50,000 and \$86,000 and \$0.47 and \$0.86, respectively. The aggregate fair value and weighted average fair value per share of options granted in the nine months ended September 30, 2004 and 2003 were \$574,000 and \$590,000 and \$0.64 and \$0.31, respectively. The fair value of each option grant is estimated on the date of grant using the Black-Scholes option pricing model.

**4. Commitments and Contingencies:**

In November 2003, the Company's employment relationship with Darrell Eckstein, CardioGenesis' former President, Chief Operating Officer, Acting Chief Financial Officer, Chief Accounting Officer, Treasurer and Secretary was terminated. In connection with his departure, Mr. Eckstein has made certain breach of contract claims arising out of his employment agreement with the Company, as well as certain tort claims and is seeking unspecified monetary damages. Pursuant to the terms of Mr. Eckstein's employment agreement, the matter has been submitted to binding arbitration. The Company believes Mr. Eckstein's claims are without merit and is vigorously defending against these claims. However, if Mr. Eckstein were to prevail on some or all of his claims, the Company cannot give any assurances that such claims would not have a material adverse effect on the Company's financial condition, results of operations or cash flows. Because of the preliminary stage of this case, an estimate of potential damages, if any, would be premature and speculative. As a result, the Company has not made any such estimate.

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### **5. Recently Issued Accounting Standards**

In December 2003, the FASB issued Interpretation No. 46R ( FIN 46R ), a revision to FIN 46, Consolidation of Variable Interest Entities. FIN 46R clarifies some of the provisions of FIN 46 and exempts certain entities from its requirements. FIN 46R is effective at the end of the first interim period ending after March 15, 2004. Entities that have adopted FIN 46 prior to this effective date can continue to apply the provisions of FIN 46 until the effective date of FIN 46R. The adoption of FIN 46R did not have an effect on the Company's consolidated financial statements.

In March 2004, the Emerging Issues Task Force finalized its consensus on EITF Issue 03-6, Participating Securities and the Two-Class Method Under FASB Statement No. 128, Earnings Per share (EITF 03-6). EITF 03-6 clarifies what constitutes a participating security and requires the use of the two-class method for computing basic earnings per share when participating convertible securities exist. EITF 03-6 is effective for fiscal periods beginning after March 31, 2004. Adoption of EITF 03-6 is not expected to have a material effect on our consolidated financial statements.

### **6. Subsequent Event:**

On October 27, 2004, the Company completed a financing transaction with Laurus Master Fund, Ltd, a Cayman Islands corporation ( Laurus ), pursuant to which the Company issued a Secured Convertible Term Note (the Note ) 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 to Laurus in a private offering. Net proceeds to the Company from the financing, after payment of fees and expenses to Laurus and its affiliates, were \$5,754,500, \$2,877,250 of which was received by the Company and \$2,877,250 of which was deposited in a restricted cash account. Funds deposited in the restricted cash account will only be released to the Company, if at all, upon satisfaction of certain conditions.

The Note matures on October 26, 2007, absent earlier redemption by the Company 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 the Company's common stock. Interest on the Note is payable monthly in arrears on the first day of each month during the term of the Note, commencing November 1, 2004. In addition, commencing May 1, 2005, the Company is required to make monthly principal payments of \$100,000 per month. To the extent that funds are released from the restricted cash account prior to repayment in full of the unrestricted portion of the Note proceeds, the monthly payment amount may be increased by an amount equal to the amount released from the restricted cash account divided by the remaining number of monthly principal payments due on or prior to the maturity date. The note is convertible into shares of the Company's common stock at the option of Laurus and, in certain circumstances, at the Company's option.

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

*This Management's Discussion and Analysis of Financial Condition and Results of Operations 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 Risk Factors 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-Q.*

## **Overview**

CardioGenesis Corporation, formerly known as Eclipse Surgical Technologies, Inc. ( CardioGenesis , the Company ), 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 ), formerly referred to as percutaneous transluminal myocardial revascularization ( PMR ). The new name PMC more literally depicts the immediate physiologic tissue effect of the CardioGenesis Axcis(TM) Percutaneous Myocardial Channeling (PMC) system to ablate precise, partial thickness channels into the heart muscle from the inside of the left ventricle.

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In February 1999, we received final approval from the Food and Drug Administration ( FDA ) for our TMR products for certain indications, and we are now able to sell those products in the U.S. on a commercial basis. We have also received the European Conforming Mark ( CE Mark ) allowing the commercial sale of our TMR laser systems and our PMC catheter system to customers in the European Community. Effective July 1999, the Health Care Financial Administration began providing Medicare coverage for TMR. Hospitals and physicians are now eligible to receive Medicare reimbursement for TMR equipment and procedures.

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 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. We are working closely with the FDA in clarifying and formalizing the clinical research requirements necessary to achieve approval. Once the requirements are clarified and the related costs are clearly understood, we expect to move forward, either on our own or with a corporate partner in the interventional cardiology arena. There can be no assurance, however, that we will receive a favorable determination from the FDA.

As of September 30, 2004, we had an accumulated deficit of \$165,879,000. We may incur operating losses in the future. The timing and amounts of our expenditures will depend upon a number of factors, including the costs incurred for the launch of new products, the timing of market acceptance of our products and the status and timing of regulatory approvals.

## **Results of Operations**

### *Net Revenues*

Net revenues were \$2,837,000 for the quarter ended September 30, 2004, a decrease of \$757,000, or 21%, when compared to net revenues of \$3,594,000 for the quarter ended September 30, 2003. The decrease in net revenues was primarily attributed to a decrease in laser revenue of \$662,000. Laser revenue was impacted by the Medicare Coverage Advisory Committee (MCAC) review by the Centers for Medicare & Medicaid Services (CMS) of laser myocardial revascularization. The MCAC review was announced in late May and the results of the review were not announced until late September, thus, affecting the entire span of the third quarter. The MCAC review, as well as the review conducted by Blue Cross/Blue Shield in the second quarter, caused a lot of confusion in the TMR marketplace, and our laser sales were negatively impacted.

For the quarter ended September 30, 2004, domestic handpiece revenue increased by \$24,000 for the quarter ended September 30, 2003. In the third quarter of 2004, domestic handpiece revenue consisted of \$527,000 in sales to customers operating under the loaned laser program and \$1,903,000 in sales to customers not operating under the loaned laser program. For those sales to customers operating under the loaned laser program, \$187,000 was attributed to premiums associated with handpiece sales. In the third quarter of 2003, domestic handpiece revenue consisted of \$833,000 in sales of product to customers operating under the loaned laser program and \$1,573,000 of sales to customers not operating under the loaned laser program. For those sales to customers operating under the loaned laser program, \$314,000 was attributed to premiums associated with the handpiece sales.



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For the quarter ended September 30, 2004, domestic laser revenue decreased by \$662,000 for the same quarter in 2003. International sales, accounting for less than 1% of net revenues for the quarter ended September 30, 2004 decreased \$62,000 from the prior year when international sales accounted for 3% of total sales. We define international sales as sales to customers located outside of the United States. In addition, service and other revenue of \$176,000 decreased \$57,000 or 24% for the quarter ended September 30, 2004 when compared to \$233,000 for the quarter ended September 30, 2003.

Net revenues were \$10,254,000 for the nine months ended September 30, 2004, an increase of \$148,000, or 1%, when compared to net revenues of \$10,106,000 for the nine months ended September 30, 2003.

For the nine months ended September 30, 2004, domestic handpiece revenue increased by \$508,000 compared to the nine months ended September 30, 2003. For the nine months ended September 30, 2004, domestic handpiece revenue consisted of \$1,487,000 in sales to customers operating under the

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loaned laser program and \$5,866,000 in sales to customers not operating under the loaned laser program. For those sales to customers operating under the loaner laser program, \$471,000 was attributed to premiums associated with handpiece sales. For the nine months ended September 30, 2003, domestic handpiece revenue consisted of \$1,990,000 in sales of product to customers operating under the loaned laser program and \$4,855,000 of sales to customers not operating under the loaned laser program. For those sales to customers operating under the loaned laser program, \$540,000 was attributed to premiums associated with the handpiece sales.

For the nine months ended September 30, 2004, domestic laser revenue decreased by \$325,000 compared to the same period in 2003. International sales, accounting for approximately 4% of net revenues for the nine months ended September 30, 2004, increased \$36,000 from the same period in the prior year when international sales accounted for 4% of total sales. In addition, service and other revenue of \$725,000 decreased \$71,000 or 9% for the nine months ended September 30, 2004 when compared to \$796,000 for the nine months ended September 30, 2003.

*Gross Profit*

Gross profit decreased to 82% of net revenues for the quarter ended September 30, 2004 as compared to 83% of net revenues for the quarter ended September 30, 2003. Gross profit in absolute dollars decreased by \$635,000 to \$2,338,000 for the quarter ended September 30, 2004, as compared to \$2,973,000 for the quarter ended September 30, 2003. The decrease in gross margin as a percent of net revenues for the quarter ended September 30, 2004 was primarily attributed to the decrease in laser sales during the quarter. This decrease in laser sales resulted in a smaller revenue base contributing to the decrease in gross margin because our fixed costs remained relatively unchanged from period to period. Gross profit increased to 85% of net revenues for the nine months ended September 30, 2004 as compared to 83% of net revenues for the nine months ended September 30, 2003. Gross profit in absolute dollars increased by \$323,000 to \$8,684,000 for the nine months ended September 30, 2004, as compared to \$8,361,000 for the nine months ended September 30, 2003. The increase in gross margin as a percent of net revenues for the nine months ended September 30, 2004 resulted from higher average selling prices of our products, ongoing improvements in manufacturing by our contract manufacturer, and lower net book values associated with the sale of our lasers.

*Research and Development*

Research and development expenditures of \$520,000 decreased \$210,000 for the quarter ended September 30, 2004 when compared to expenditures of \$730,000 for the quarter ended September 30, 2003. Research and development expenditures of \$1,189,000 decreased \$647,000 for the nine months ended September 30, 2004 when compared to \$1,836,000 for the nine months ended September 30, 2003. The decrease in overall research and development expense during the quarterly and nine month periods was primarily attributed to a decrease in the expenses related to our pursuit of PMC approval.

*Sales, General and Administrative*

Sales, general and administrative expenditures of \$2,746,000 increased \$382,000 or 16% for the quarter ended September 30, 2004 when compared to \$2,364,000 for the quarter ended September 30, 2003. The increase in expenses resulted primarily from a \$298,000 increase in employee related expenses due to additional headcount and a \$91,000 increase in physician training.

Sales, general and administrative expenditures of \$8,398,000 increased \$992,000 or 13% for the nine months ended September 30, 2004 when compared to \$7,406,000 for the nine months ended September 30, 2003. The increase in expenses resulted primarily from an \$810,000 increase in employee related expenses due to additional headcount, a \$215,000 increase in marketing costs and a \$114,000 increase in physician training costs. These increases were offset by a decrease in facilities and office expense of \$143,000 due to cost containment efforts.

*Net Loss*

The net loss for the quarter ended September 30, 2004 was \$924,000 compared to \$129,000 for the quarter

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ended September 30, 2003. The increase in net loss is primarily related to a decrease in revenue of \$757,000 and an increase in selling, general and administrative expenses of \$382,000.

The net loss for the nine months ended September 30, 2004 was \$921,000 compared to a net loss of \$886,000 for the nine months ended September 30, 2003. The increase in net loss is primarily related to an increase in selling, general, and administrative costs of \$992,000 offset by a decrease in research and development expenses of \$647,000 and an increase in gross profit of \$323,000.

## **Liquidity and Capital Resources**

Cash and cash equivalents were \$2,920,000 at September 30, 2004 compared to \$1,013,000 at December 31, 2003, an increase of \$1,907,000. We used \$189,000 of cash for operating activities in the nine months ended September 30, 2004 primarily to fund our operating loss and to purchase laser inventory. Net inventories increased \$367,000 to \$1,706,000 at September 30, 2004 compared to \$1,339,000 at December 31, 2003. This increase was primarily related to \$386,000 in purchases of laser inventory.

Cash used in investing activities in the nine months ended September 30, 2004 was \$235,000 due to the acquisition of property and equipment. Cash provided by financing activities was \$2,331,000 due to sales of common stock from the exercise of stock options as well as the sale of equity securities described below.

On January 22, 2004, we sold 3,139,535 shares of common stock to private investors for a total price of \$2,700,000. We also issued warrants to purchase 3,139,535 additional shares of common stock at a price of \$1.37 per share. The warrants are immediately exercisable and have a term of five years.

We have incurred significant losses for the last several years and at September 30, 2004 we have an accumulated deficit of \$165,879,000. Our ability to maintain current operations is dependent upon achieving profitable operations in the future. Our plans include increasing sales through increased direct sales and marketing efforts on existing products and achieving timely regulatory approval for certain other products.

We also plan to continue our cost containment efforts by focusing on sales, general and administrative expenses. Over the past three years, we have significantly reduced our cost of revenues, primarily due to the outsourcing of a significant portion of our manufacturing, which allows us to purchase products at lower costs. To reduce operating expenses, we have focused our efforts on reducing overall expenses in functions that are not essential to core and critical activities.

Currently, our primary goals are to increase revenues, further clinical adoption of the TMR procedure, develop new products for our TMR platform, and achieve consistent profitability. Our actions have been guided by this initiative, and the resulting cost containment measures have helped to conserve our cash. Our focus is upon core and critical activities, thus operating expenses that are nonessential to our core operations have been eliminated.

On October 27, 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 common stock of the Company to Laurus in a private offering. Net proceeds to the Company from the financing, after payment of fees and expenses to Laurus and its affiliates, were \$5,754,500, \$2,877,250 of which was received by the Company and \$2,877,250 of which was deposited in a restricted cash account. Funds deposited in the restricted cash account will only be released to the Company, if at all, upon satisfaction of certain conditions.

The Note matures on October 26, 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. Interest on the Note is payable monthly in arrears on the first day of each month during the term of the Note, commencing November 1, 2004. In addition, commencing May 1, 2005, the Company is required to make monthly principal payments of \$100,000 per month. To the extent that funds are released from the restricted cash account prior to repayment in full of the unrestricted portion of the Note proceeds, the monthly payment amount may be

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increased by an amount equal to the amount released from the restricted cash account divided by the remaining number of monthly principal payments due on or prior to the maturity date. The note is convertible into shares of our common stock at the option of Laurus and, in certain circumstances, at our option. A more detailed discussion of the terms of such financing is contained in our Current Report on Form 8-K filed on October 28, 2004.

We believe our cash balance as of September 30, 2004, when coupled with the proceeds of the Note financing described above, will be sufficient to meet our capital and operating requirements through the next 12 months. We will have a continuing need for new infusions of cash if we 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 revenues or from debt or equity issuances to maintain our current expenditure rate, it will be necessary to significantly reduce our operations until an appropriate solution is implemented. We may be required to seek additional sources of financing in addition to the convertible debt financing described above, 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.

The following summarizes our contractual obligations at September 30, 2004, and the effect, if any, such obligations are expected to have on our liquidity and cash flow in future periods:

	<b>Payments due by period (In Thousands)</b>				
	<b>Total</b>	<b>Less than 1 year</b>	<b>1-3 years</b>	<b>3-5 years</b>	<b>More than 5 years</b>
<b>Contractual Obligations</b>					
Long Term Debt					
Capital Lease Obligations	\$ 24	\$ 5	\$ 11	\$ 8	
Operating Leases	758	364	394		
Purchase Obligations					
Other Long Term Liabilities Reflected on the Registrant's Balance Sheet under GAAP					
<b>Total</b>	<b>\$782</b>	<b>\$ 369</b>	<b>\$ 405</b>	<b>\$ 8</b>	<b>\$</b>

**Critical Accounting Policies**

The preparation of the financial statements requires estimation and judgment that affect the reported amounts of net revenues, expenses, assets and liabilities. We base our estimates on historical experience and on various other assumptions that we believe to be reasonable under the circumstances and which form the basis for making judgments about the carrying values of assets and liabilities. Critical accounting policies are defined as those that are reflective of significant judgments and uncertainties, and could potentially result in materially different results under different assumptions and conditions. If these estimates differ significantly from actual results, the impact to the financial statements may be material.

We have identified the following as critical accounting policies: revenue recognition, allowance for doubtful accounts, inventories and income taxes:

*Revenue Recognition:*

We recognize revenue on product sales upon receipt of a purchase order, shipment of the products, the price is fixed or determinable and collection of sales proceeds is reasonably assured. Where purchase orders allow

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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 that an arrangement exists, delivery has occurred under the Company's standard FOB shipping point terms, the sales price is fixed or determinable and the ability to collect 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 return for the hospital purchasing a minimum number of handpieces at a premium over the list price. The loaned lasers are depreciated to cost of revenues over a useful life of 24 months.

The revenue on the handpieces is recognized upon shipment at an amount equal to the list price. The premium over the list price represents revenue related to the use of the laser unit and is recognized ratably, generally over the 24-month useful life of the placed lasers.

Revenues from service contracts, rentals, and per procedure fees are recognized upon performance or over the terms of the contract as appropriate.

### *Allowance for Doubtful Accounts:*

We regularly evaluate the collectability of accounts receivable based upon our knowledge of customers and compliance with credit terms. The allowance for doubtful accounts is adjusted based on such evaluation, with a corresponding provision included in general and administrative expenses.

### *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.

### *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.

## **Risk Factors**

In addition to the other information included in this Form 10-Q, the following risk factors should be considered carefully in evaluating us and our business.

*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 2003, 2002 and 2001 we incurred net losses of \$348,000, \$530,000 and \$10,247,000 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.

We have recently obtained \$6.0 million of convertible debt financing which we believe will be sufficient to

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satisfy our capital needs for at least the next 12 months. However, 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 systems for any manufacturer's TMR procedures. 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 would 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. CMS does not have a pending National Coverage Determination relating to laser myocardial revascularization. In September 2004, we confirmed that CMS does not intend to commence any action on TMR coverage at this time.

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.*

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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 an alternative process in which additional data in support of our PMA supplement for PMC could be submitted and reviewed by the FDA in an interactive review process. The data was submitted in August 2003 and the panel review by the MDDRP was cancelled. The FDA agreed to reschedule the MDDRP hearing in the future if the dispute cannot be resolved.

In March 2004, the FDA informed us that the data submitted in August 2003 was not adequate to support approval by the FDA of our PMC system. In August 2004, we met with the FDA in an effort to clearly define a workable clinical pathway to move the PMA application for PMC forward in an effort to gain FDA clearance. We came to an agreement with the FDA on the steps needed to design and initiate a new clinical trial to confirm the safety and efficacy of PMC. We expect to submit the protocol for review by the FDA before the end of the fourth quarter. The final design and size of the trial will determine the resources required to support the trial. Once the requirements are clarified and the related costs are clearly understood, we expect to move forward, either on our own or with a corporate partner in the interventional cardiology arena. There can be no assurance, however, that we will obtain additional debt or equity financing with acceptable terms or that we will receive an approvable determination on PMC from the FDA.

In August 2004, we decided to rename the PMC platform to Percutaneous Myocardial Channeling ( PMC ). The new name more literally depicts the immediate physiologic tissue effect of the percutaneous procedure.

We may 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.

*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:

finances, injunctions, and civil penalties;

recalls or seizures of products;

total or partial suspensions of production; and

criminal prosecutions.

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

*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.

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*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.*

In 2001 we began a restructuring of our business to bring our cost structure more in line with our revenues. As part of this restructuring we significantly reduced our workforce. Growth in our business 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.

*Our common stock is listed on the OTC Bulletin Board which 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. The OTC Bulletin Board is a significantly more limited market in comparison to the Nasdaq system. The listing of our shares on the OTC Bulletin Board may result in a 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.



*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

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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, 2004, the closing prices of our common stock as reported on the OTC Bulletin Board ranged from a high of \$1.87 per share to a low of \$0.46 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; 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 affect 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 CO2 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 will suffer.

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:

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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.

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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 data

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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. For example, in November 2003, our employment relationship with Darrell Eckstein, our former President, Chief Operating Officer, Acting Chief Financial Officer, Chief Accounting Officer, Treasurer and Secretary was terminated. We depend on the skills and abilities of these key employees in managing the manufacturing, technical, marketing and sales aspects of our business, any part of which could be harmed by further turnover.

*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;

various tariffs and trade regulations;



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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. 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

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

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 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 effect 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.

**Item 3. Quantitative and Qualitative Disclosures About Market Risk**

*Quantitative Disclosures*

We are exposed to market risks inherent in our operations, primarily related to interest rate risk and currency risk. These risks arise from transactions and operations entered into in the normal course of business. We do not use derivatives to alter the interest characteristics of its marketable securities or its debt instruments. We have no holdings of derivative or commodity instruments.

We are subject to interest rate risks on cash and cash equivalents and any future financing requirements. The long-term debt at September 30, 2004 consists of an outstanding balance on a lease obligation. As noted in our Current Report on Form 8-K filed on October 28, 2004, we completed a financing transaction pursuant to which we issued a \$6.0 secured convertible promissory note to an investment fund. Interest on such promissory note is adjustable based on changes in the applicable prime rate. Accordingly, in future quarters, we will be subject to increased interest rate risks as a result of such financing.

The following table presents the future principal cash flows or amounts and related weighted average interest rates expected by year for our existing cash and cash equivalents and long-term debt instruments as of September 30, 2004:

<b>In Thousands, unaudited</b>	<b>2004</b>	<b>2005</b>	<b>2006</b>	<b>2007</b>	<b>2008</b>	<b>Total Fair Value</b>
<b>Assets</b>						
Cash, cash equivalents	\$2,920	\$	\$	\$	\$	\$2,920
Weighted average interest rate	1.4%					1.4%
<b>Liabilities</b>						
<b>Fixed Rate Debt</b>						
Lease obligation	\$ 19	\$	\$	\$	\$	\$ 19
Weighted average interest rate	7.0%					7.0%

#### *Qualitative Disclosures*

*Interest Rate Risk.* Our primary interest rate risk exposures relate to the impact of interest rate movements on our ability to obtain adequate financing to fund future operations.

We have traditionally managed interest rate risk on our outstanding long-term debts through the use of fixed rate debt. Management evaluates our financial position on an ongoing basis. As noted above, in October 2004, we issued a \$6.0 million secured convertible promissory note having an adjustable interest rate that will be adjusted based on movements in the applicable prime rate.

*Currency Rate Risk.* We do not hedge any balance sheet exposures against future movements in foreign exchange rates. The exposure related to currency rate movements would not have a material impact on future net income or cash flows.

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### **Item 4. Controls and Procedures**

We maintain disclosure controls and procedures designed to ensure that we are able to collect the information we are required to disclose in the reports we file with the Securities and Exchange Commission, or SEC, and to process, summarize and disclose this information within the time periods specified in the rules of the SEC. Based on their evaluation of our disclosure controls and procedures, our management, with the participation of the Chief Executive and Chief Financial Officer, has concluded that, as of the end of the period covered by this Quarterly Report on Form 10-Q, these disclosure controls and procedures were effective to ensure that we are able to record, process, summarize and report the information we are required to disclose in the reports we file with the SEC within the required time periods.

There were no changes in our internal controls over financial reporting that occurred during the period covered by this Quarterly Report on Form 10-Q that have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

## **Part II Other Information**

### **Item 1. Legal Proceedings**

In November 2003, our employment relationship with Darrell Eckstein, our former President, Chief Operating Officer, Acting Chief Financial Officer, Chief Accounting Officer, Treasurer and Secretary was terminated. In connection with his departure, Mr. Eckstein has made certain breach of contract claims arising out of his employment agreement with us, as well as certain tort claims and is seeking unspecified monetary damages. Pursuant to the terms of Mr. Eckstein's employment agreement, the matter has been submitted to binding arbitration. We believe Mr. Eckstein's claims are without merit and we are vigorously defending against these claims. However, if Mr. Eckstein were to prevail on some or all of his claims, we cannot assure you that such claims would not have a material adverse effect on our financial condition, results of operations or cash flows. Because of the preliminary stage of this case, an estimate of potential damages, if any, would be premature and speculative. As a result, we have not made any such estimate.

### **Item 2. Unregistered Sales of Equity Securities and Use of Proceeds**

The information required by this item was included in the Company's Current Report on Form 8-K filed on October 28, 2004.

### **Item 6. Exhibits and Reports on Form 8-K**

Exhibits required to be filed by Item 601 of Regulation S-K:

Exhibit 3.1(1) Restated Articles of Incorporation, as filed with the California Secretary of State on May 1, 1996.

Exhibit 3.2(2) Certificate of Amendment of Restated Articles of Incorporation, as filed with California Secretary of State on July 18, 2001

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- Exhibit 3.3(3) Certificate of Determination of Preferences of Series A Preferred Stock, as filed with the California Secretary of State on August 23, 2001
- Exhibit 3.4(4) Certificate of Amendment of Restated Articles of Incorporation, as filed with the California Secretary of State on January 23, 2004
- Exhibit 3.5(5) Amended and Restated Bylaws
- Exhibit 4.1(6) Form of Common Stock Purchase Warrant issued in connection with Facilities Lease for 26632 Towne Center Drive, Suite 320, Foothill Ranch, California
- Exhibit 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

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- Exhibit 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
- Exhibit 4.4(9) Rights Agreement, dated as of August 17, 2001, between CardioGenesis Corporation and EquiServe Trust Company, N.A., as Rights Agent
- Exhibit 4.5(10) Share Purchase Agreement dated April 10, 2002 between the CardioGenesis Corporation and the State of Wisconsin Investment Board
- Exhibit 4.6(11) Securities Purchase Agreement, dated as of January 21, 2004, by and among CardioGenesis Corporation and each of the investors identified therein
- Exhibit 4.7(12) Registration Rights Agreement, dated as of January 21, 2004, by and among CardioGenesis Corporation and the investors identified therein
- Exhibit 4.8(13) Form of Common Stock Purchase Warrant, dated January 21, 2004, having an exercise price of \$1.37 per share
- Exhibit 4.9(14) Form of Common Stock Purchase Warrant, dated January 21, 2004, having an exercise price of \$1.00 per share
- Exhibit 4.10(15) Third Amendment to Rights Agreement, dated October 26, 2004, between the Company and Equiserve Trust Company N.A
- Exhibit 4.11(16) Securities Purchase Agreement, dated October 26, 2004, between the Company and Laurus Master Fund, Ltd.
- Exhibit 4.12(17) Secured Convertible Term Note, dated October 26, 2004, in favor of Laurus Master Fund, Ltd.
- Exhibit 4.13(18) Registration Rights Agreement, dated October 26, 2004, between the Company and Laurus Master Fund, Ltd.
- Exhibit 4.14(19) Common Stock Purchase Warrant, dated October 26, 2004, in favor of Laurus Master Fund, Ltd.
- Exhibit 4.15(20) Security Agreement, dated October 26, 2004, in favor of Laurus Master Fund, Ltd.
- Exhibit 31A Certification of the Principal Executive Officer Pursuant to 17 CFR 240.13a-14(a), as Adopted Pursuant to § 302 of the Sarbanes-Oxley Act of 2002.
- Exhibit 31B Certification of the Principal Financial Officer Pursuant to 17 CFR 240.13a-14(a), as Adopted Pursuant to § 302 of the Sarbanes-Oxley Act of 2002.
- Exhibit 32 Certification Pursuant to 18 U.S.C. Section 1350, as Adopted Pursuant to § 906 of the Sarbanes-Oxley Act of 2002.

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

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(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 14, 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

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- (5) Incorporated by reference to Exhibit 3.2 to the Registrant's Annual Report on Form 10-K filed on March 10, 2004
- (6) Incorporated by reference to Exhibit 10.1 to the Registrant's Quarterly Report on Form 10-Q/A filed on August 16, 2001
- (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 4.2 to the Registrant's Current Report on Form 8-K filed April 12, 2002
- (11) Incorporated by reference to Exhibit 4.4 to the Registrant's Current Report on Form 8-K filed January 22, 2004
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**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.

Date: November 15, 2004

**CARDIOGENESIS CORPORATION**  
Registrant

/s/ Michael J. Quinn

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Michael J. Quinn  
Chief Executive Officer, Chairman of the  
Board and Director  
(Principal Executive Officer)

Date: November 15, 2004

/s/ Christine Ocampo

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Christine Ocampo  
Vice President, Chief Financial Officer  
(Principal Accounting and Financial Officer,  
Secretary and Treasurer)



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