

CARDIOGENESIS CORP /CA

Form 10-Q

May 15, 2003

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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 March 31, 2003**

Commission file number 0-28288

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**CARDIOGENESIS CORPORATION**

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

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**California**

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(State of incorporation)

**77-0223740**

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(I.R.S. Employer  
Identification Number)

**26632 Towne Centre 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.

37,120,925 shares of Common Stock, no par value  
As of April 30, 2003

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

	<u>March 31, 2003</u>	<u>December 31, 2002</u>
<b>ASSETS</b>		
Current assets:		
Cash and cash equivalents	\$ 1,576	\$ 1,490
Accounts receivable, net of allowance for doubtful accounts of \$440 and \$449 at March 31, 2003 and December 31, 2002, respectively	1,946	1,961
Inventories, net of reserves of \$406 and \$361 at March 31, 2003 and December 31, 2002, respectively	1,535	1,632
Prepays and other current assets	529	574
	<u>5,586</u>	<u>5,657</u>
Property and equipment, net	526	589
Other assets	1,460	1,509
	<u>1,460</u>	<u>1,509</u>
Total assets	<u>\$ 7,572</u>	<u>\$ 7,755</u>
<b>LIABILITIES AND SHAREHOLDERS EQUITY</b>		
Current liabilities:		
Accounts payable	\$ 1,388	\$ 1,241
Accrued liabilities	1,638	2,101
Customer deposits	50	50
Deferred revenue	641	621
Current portion of capital lease obligation	23	30
	<u>3,740</u>	<u>4,043</u>
Total current liabilities	3,740	4,043
Capital lease obligation, less current portion		1
	<u>3,740</u>	<u>4,044</u>
Total liabilities	<u>3,740</u>	<u>4,044</u>
Shareholders' equity:		
Preferred stock:		
no par value; 5,000 shares authorized; none issued and outstanding		
Common stock:		
no par value; 50,000 shares authorized; 37,121 shares issued and outstanding at March 31, 2003 and December 31, 2002		
	168,321	168,321
Accumulated deficit	(164,489)	(164,610)
	<u>3,832</u>	<u>3,711</u>
Total shareholders' equity	3,832	3,711
	<u>3,832</u>	<u>3,711</u>
Total liabilities and shareholders' equity	<u>\$ 7,572</u>	<u>\$ 7,755</u>

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

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## CARDIOGENESIS CORPORATION

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

	Three months ended March 31,	
	2003	2002
Net revenues	\$ 3,422	\$ 3,158
Cost of revenues	622	826
	<u>2,800</u>	<u>2,332</u>
Gross profit		
Operating expenses:		
Research and development	383	206
Sales, general and administrative	2,298	3,372
	<u>2,681</u>	<u>3,578</u>
Total operating expenses		
Operating income (loss)	119	(1,246)
Interest income, net	2	7
	<u>121</u>	<u>(1,239)</u>
Net income (loss)		
Other comprehensive income:		
Foreign currency translation adjustment		20
		<u>20</u>
Comprehensive income (loss)	\$ 121	\$ (1,219)
	<u>\$ 121</u>	<u>\$ (1,219)</u>
Net income (loss) per share:		
Basic and diluted	\$ 0.00	\$ (0.03)
	<u>\$ 0.00</u>	<u>\$ (0.03)</u>
Weighted average shares outstanding:		
Basic	37,121	36,507
	<u>37,121</u>	<u>36,507</u>
Diluted	37,145	36,507
	<u>37,145</u>	<u>36,507</u>

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

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

	<b>Three months ended March 31,</b>	
	<b>2003</b>	<b>2002</b>
<b>Cash flows from operating activities:</b>		
Net income (loss)	\$ 121	\$(1,239)
<b>Adjustments to reconcile net income (loss) to net cash used in operating activities:</b>		
Depreciation and amortization	65	85
Provision for doubtful accounts		200
Provision for inventory excess and obsolescence	121	291
Amortization of license fees	49	48
Loss on disposal of property and equipment		28
<b>Changes in operating assets and liabilities:</b>		
Accounts receivable	15	686
Inventories	(24)	191
Prepays and other current assets	45	137
Accounts payable	147	81
Accrued liabilities	(463)	(619)
Customer deposits		(4)
Deferred revenue	20	(233)
Long term liabilities		(247)
	<u>96</u>	<u>(595)</u>
<b>Net cash provided by (used in) operating activities</b>		
<b>Cash flows from investing activities:</b>		
Acquisition of property and equipment	(2)	(5)
	<u>(2)</u>	<u>(5)</u>
<b>Net cash used in investing activities</b>		
<b>Cash flows from financing activities:</b>		
Payments on short term borrowings		(162)
Repayments of capital lease obligations	(8)	(8)
	<u>(8)</u>	<u>(170)</u>
<b>Net cash used in financing activities</b>		
Effects of exchange rate changes on cash and cash equivalents		20
	<u>86</u>	<u>(750)</u>
<b>Net increase (decrease) in cash and cash equivalents</b>		
Cash and cash equivalents at beginning of year	1,490	2,629
	<u>1,576</u>	<u>\$ 1,879</u>
<b>Cash and cash equivalents at end of period</b>		
<b>Supplemental schedule of cash flow information:</b>		
Interest paid	\$ 1	\$ 5
	<u>3</u>	<u>2</u>
Taxes paid	\$ 3	\$ 2
	<u>3</u>	<u>2</u>

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





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**CARDIOGENESIS CORPORATION**

**NOTES TO 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 generally accepted accounting principles. These financial statements should be read in conjunction with CardioGenesis' audited financial statements and notes thereto for the year ended December 31, 2002, 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. Although the Company has achieved profitability in the quarter ended March 31, 2003, CardioGenesis has had significant losses for the last several years and may incur losses in the future. Management believes its cash balance as of March 31, 2003 is sufficient to meet the Company's capital and operating requirements for the next 12 months. CardioGenesis has additional funding available through a \$2,000,000 revolving convertible note credit facility.

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 to sustain 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 per share (EPS) is computed by dividing the net income (loss) by the weighted average number of common shares outstanding for the period. Dilutive 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 4,556,285 and 2,972,673 shares of common stock were outstanding at March 31, 2003 and 2002, respectively. Warrants to purchase 75,000 shares of common stock at \$1.63 per share were outstanding as of March 31, 2003 and 2002. For the three months ended March 31, 2003, potentially dilutive securities resulted in potential common shares of approximately 24,000 shares. For the three months ended March 31, 2002, no potential common shares were included in the diluted per share amount as the effect would have been anti-dilutive.

**Table of Contents****2. Inventories:**

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

	<b>March 31, 2003</b>	<b>December 31, 2002</b>
	<u>(unaudited)</u>	
Raw materials	\$ 1,120	\$ 1,121
Work-in-process	191	136
Finished goods	630	736
	<u>1,941</u>	<u>1,993</u>
Less reserves	(406)	(361)
	<u>\$ 1,535</u>	<u>\$ 1,632</u>

**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. 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 quarter ended March 31, 2003 and 2002 consistent with the provisions of SFAS 123, CardioGenesis net income (loss) and net income (loss) per share would have changed to the pro forma amounts indicated below (in thousands, except per share amounts):

	<b>Three Months Ended March 31,</b>	
	<b>2003</b>	<b>2002</b>
Net income (loss) as reported	\$ 121	\$ (1,219)
Stock-based employee compensation	\$ (309)	\$ (354)
Pro forma net loss	\$ (188)	\$ (1,573)
Basic and diluted net income (loss) per share as reported	\$ 0.00	\$ (0.03)
Pro forma basic and diluted net loss per share	\$ (0.01)	\$ (0.04)

The above pro-forma disclosures are not necessarily representative of the effects on reported net income (loss) for future years. The aggregate fair value and weighted average fair value per share of options granted in the three months ended March 31, 2003 and 2002 were \$241,000 and \$158,000 and \$0.20 and \$0.53, respectively. The fair value of each option grant is estimated on the date of grant using the Black-Scholes option pricing model.

**4. Recently Issued Accounting Standards**

In December 2002, the FASB issued Statement of Financial Accounting Standards, or SFAS, No. 148, Accounting for Stock-Based Compensation, Transition and Disclosure. SFAS No. 148 provides alternative methods of transition for a voluntary change to the fair value based method of accounting for stock-based employee compensation. SFAS No. 148 also requires that disclosures of the pro forma effect of using the fair value method of accounting for stock-based employee compensation be displayed more prominently and in a tabular format. Additionally, SFAS No. 148 requires disclosure of the pro forma effect in interim financial statements. The transition and annual disclosure requirements of SFAS No. 148 are effective immediately. The interim disclosure requirements became effective for the first quarter of 2003. The adoption of SFAS No. 148 did not have a material effect on our results of operations or financial condition.

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

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*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*

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*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-Q.*

### **Overview**

CardioGenesis Corporation, formerly known as Eclipse Surgical Technologies, Inc. ( CardioGenesis , Company ), incorporated in California in 1989, designs, develops, manufactures and distributes laser-based surgical products and disposable fiber-optic accessories for the treatment of advanced cardiovascular disease through transmyocardial revascularization ( TMR ) and percutaneous transluminal myocardial revascularization ( PMR ).

On February 11, 1999, we received final approval from the 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 PMR catheter system to customers in the European Community. Effective July 1, 1999, 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 PMR, and study results were submitted to the FDA in a Pre Market Approval ( PMA application ) in December of 1999 along with subsequent amendments. In July 2001, the FDA Advisory Panel recommended against approval of PMR 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 PMR by the Medical Devices Dispute Resolution Panel. We currently expect the Dispute Resolution Panel to convene in the third quarter of 2003. There can be no assurance, however, that we will receive a favorable decision from the FDA.

As of March 31, 2003, we had an accumulated deficit of \$164,489,000. We may incur operating losses in the future. The timing and amounts of our expenditures will depend upon a number of factors, including the efforts required to develop our sales and marketing organization, the timing of market acceptance of our products and the status and timing of regulatory approvals.

### **Results of Operations**

#### *Net Revenues*

Net revenues of \$3,422,000 for the quarter ended March 31, 2003 increased \$264,000, or 8%, when compared to net revenues of \$3,158,000 for the quarter ended March 31, 2002. The increase in net revenues is primarily attributed to an increase in disposable handpiece revenue.

For the quarter ended March 31, 2003, domestic disposable handpiece revenue increased by \$314,000 and domestic laser revenue decreased by \$12,000 compared to the quarter ended March 31, 2002. In the first quarter of 2003, domestic handpiece revenue consisted of \$567,000 in sales of product to customers operating under the loaned laser program, of which \$138,000 was attributed to premiums associated with such sales. In the first quarter of 2002, domestic handpiece revenue consisted of \$562,000 in sales of product to customers operating under the loaned laser program, of which \$90,000 was attributed to premiums associated with such sales. In the first quarter of 2003 and 2002, sales of handpieces to customers not operating under the loaned laser program were \$1,513,000 and \$1,204,000, respectively. International sales, accounting for approximately 8% of net revenues for the quarter ended March 31, 2003, decreased \$47,000 from the prior year when international sales accounted for 10% of total sales. We define international sales as sales to customers located outside of the United States. In addition, service revenue

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of \$267,000 increased \$10,000 for the quarter ended March 31, 2003 when compared to \$257,000 for the quarter ended March 31, 2002.

*Gross Profit*

Gross profit increased to 82% of net revenues for the quarter ended March 31, 2003 as compared to 74% of net revenues for the quarter ended March 31, 2002. Gross profit in absolute dollars increased by \$468,000 to \$2,800,000 for the quarter ended March 31, 2003, as compared to \$2,332,000 for the quarter ended March 31, 2002. The increase in gross profit, as a percentage of sales and in absolute terms, resulted from improved margins on lasers sold as well as improved margins on disposable handpieces.

*Research and Development*

Research and development expenditures of \$383,000 increased \$177,000 or 86% for the quarter ended March 31, 2003 when compared to \$206,000 for the quarter ended March 31, 2002. The increase in overall research and development expense was primarily attributed to expenses related to our pursuit of PMR approval.

*Sales, General and Administrative*

Sales, general and administrative expenditures of \$2,298,000 decreased \$1,074,000 or 32% for the quarter ended March 31, 2003 when compared to \$3,372,000 for the quarter ended March 31, 2002. The decrease in expenses resulted primarily from decreases in employee headcount and related expenses and outside services of \$613,000 and \$150,000, respectively, as well as lower expenses in other areas.

**Liquidity and Capital Resources**

At March 31, 2003, we had cash and cash equivalents of \$1,576,000 compared to \$1,490,000 at December 31, 2002, an increase of \$86,000. During the three months ended March 31, 2003, we had net income of \$121,000 which provided cash of \$96,000 to support operating activities.

On March 27, 2003, we entered into a Purchase and Security Agreement with a private equity fund and entered into a revolving Convertible Note credit facility (the Note) that matures on March 26, 2006. The Note, which is collateralized by our assets, provides for borrowings of up to \$2,000,000 based upon eligible accounts receivable. Advances under the Note will bear interest at prime plus 3.35%. The Note includes a right of conversion into common stock at a fixed conversion price of \$.30 per share, subject to adjustment. In conjunction with this transaction, we issued 275,000 five year warrants. The warrants are exercisable for common stock at exercise prices ranging from \$.35 to \$.44 per share. As of March 31, 2003, our borrowing capacity was approximately \$1,400,000 based on eligible accounts receivable and we had no outstanding borrowings on the Note.

We have incurred significant losses for the last several years and at March 31, 2003 have an accumulated deficit of \$164,489,000. Our ability to maintain current operations is dependent upon sustaining 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 reducing sales, general and administrative expenses. We've 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 headcount and overall expenses in functions that are not essential to core and critical activities.

Currently, our primary goal is to sustain profitability. Our actions have been guided by this imperative, and the resulting cost containment measures have helped to conserve our cash. Our focus is upon core and critical activities, thus operating expenses that are nonessential to our core operations have been eliminated.

We believe our cash balance as of March 31, 2003 and the borrowing capacity available under our \$2,000,000 revolving convertible note credit facility, will be sufficient to meet our capital and operating

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requirements through the next 12 months. We believe that if revenues from sales or new funds from debt or equity instruments is insufficient to maintain the current expenditure rate, it will be necessary to significantly reduce our operations until an appropriate solution is implemented.

### **Recently Issued Accounting Standards**

In December 2002, the FASB issued Statement of Financial Accounting Standards, or SFAS, No. 148, Accounting for Stock-Based Compensation, Transition and Disclosure. SFAS No. 148 provides alternative methods of transition for a voluntary change to the fair value based method of accounting for stock-based employee compensation. SFAS No. 148 also requires that disclosures of the pro forma effect of using the fair value method of accounting for stock-based employee compensation be displayed more prominently and in a tabular format. Additionally, SFAS No. 148 requires disclosure of the pro forma effect in interim financial statements. The transition and annual disclosure requirements of SFAS No. 148 are effective immediately. The interim disclosure requirements became effective for the first quarter of 2003. The adoption of SFAS No. 148 did not have a material effect on our results of operations or financial condition.

### **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 in the future.*

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 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 will not have sufficient cash to fund our operations.

We have incurred significant losses since inception. Our revenues and operating income will be constrained:

until such time, if ever, as we obtain broad commercial adoption of our TMR laser systems by healthcare facilities in the United States;

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

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

We may not sustain profitability in the future.

*Our common stock has been delisted by the Nasdaq SmallCap Market which may have an unfavorable impact on our stock price and liquidity.*

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 delisting of our common stock from the Nasdaq SmallCap Market could adversely affect the liquidity and price of our common stock and it could have a long-term adverse impact on our ability to raise capital in the future. Our common stock is currently listed on the OTC Bulletin Board.

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*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 March 31, 2003, the closing prices of our common stock as reported on Nasdaq ranged from a high of \$1.20 to a low of \$0.22. 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;
- announcements of technological innovations or new products or services by us or our competitors;
- announcements relating to strategic relationships or acquisitions;
- changes in financial estimates 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.

*We may fail to obtain required regulatory approvals in the United States to market our PMR laser system.*

Our business could be harmed if any of the following events, circumstances or occurrences related to the regulatory process occurred thereby causing a reduction in our revenues:

- the failure to obtain regulatory approvals for our PMR system;
- any significant limitations in the indicated uses for which our products may be marketed; and
- substantial costs incurred in obtaining regulatory approvals.

The FDA has not approved our PMR laser system for any application in the United States. In February 2003, the FDA granted an independent panel review of our pending PMA application for PMR by the Medical Devices Dispute Resolution Panel. We currently expect the Dispute Resolution Panel to convene in the third quarter of 2003. There is no assurance, however, that we will receive a favorable decision from the FDA. We will not be able to derive any revenue from the sale of that device in the United States until such time, if any, that the FDA approves the device. Such inability to realize revenue from sales of our PMR 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.*

The FDA has approved our TMR 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. However, 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, though 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, 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 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;

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recalls or seizures of products;  
total or partial suspensions of production; and  
criminal prosecutions.

The impact on the company 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 not being allowed to market our product in the European Union, which would significantly reduce international revenue.

*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.*

The 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 PMR 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.



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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. 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 and investors. When this occurred in the past, the price of our common stock fell substantially, and if this occurs again, the price of our common stock may fall again, perhaps substantially.

*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 now eligible to receive Medicare reimbursement covering 100% of the costs for TMR procedures. The CMS has not approved reimbursement for PMR. If it does not in the future provide reimbursement, our ability to successfully market and sell our PMR products will be harmed.

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. 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 health care 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 PMR products in the international markets in which such approvals are sought, which would significantly reduce international revenue.

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

The market for TMR laser systems is competitive. If our competitor is more effective 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. We currently compete with PLC Systems. Edwards Life Sciences has exercised its option to assume 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 that was signed in January 2001. 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

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may render our products or technology obsolete.

If we obtain the FDA's approval for our PMR 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 parties 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 PMR procedures. We do not know if such competitors, potential competitors or others have filed and hold international patents covering other TMR or PMR 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.

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;

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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 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.*

Certain critical products and components for lasers and disposable handpieces are purchased from single sources. In addition, we are vulnerable to delays and interruptions, for reasons out of our control, because we outsource the manufacturing of some of these products to third parties. We may experience harm to our business if these sources have difficulties supplying our needs for these products and components. In addition, we do not have long-term supply contracts. As a result, these 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 PMR laser systems were to increase rapidly or significantly. In addition, any defect or malfunction in the laser or other products provided by such suppliers and manufacturers could cause a delay 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

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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.

*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 PMR 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 PMR product because of concerns over the safety of the device and the 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 PMR 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 PMR 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 PMR 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.*

During the last 15 months, we have had significant changes in our senior management team. 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. Further significant turnover in our senior management could significantly deplete our institutional knowledge held by our existing senior management team. 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:

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foreign currency fluctuations;

economic or political instability;

foreign tax laws;

shipping delays;

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.

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

The Company is exposed to market risks inherent in its 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. The Company does not use derivatives to alter the interest characteristics of its marketable securities or its debt instruments. The Company has no holdings of derivative or commodity instruments.

*Interest Rate Risk.* The Company is subject to interest rate risks on cash and cash equivalents and any future financing requirements. The long-term debt at March 31, 2003 consists of an outstanding balance on a lease obligation.

The following table presents the future principal cash flows or amounts and related weighted average interest rates expected by year for the Company's existing cash and cash equivalents and long-term debt instruments:

In Thousands	2003	2004	2005	2006	2007	Total Fair Value
<b>Assets</b>						
Cash, cash equivalents	\$ 1,576	\$	\$	\$	\$	\$ 1,576
Weighted average interest rate	1.0%					1.0%
<b>Liabilities</b>						
<b>Fixed Rate Debt</b>						
Lease obligation	\$ 23	\$	\$	\$	\$	\$ 23
Weighted average interest rate	6.8%					6.8%

*Qualitative Disclosures*

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

The Company manages interest rate risk on its outstanding long-term debts through the use of fixed rate debt. Management evaluates the Company's financial position on an ongoing basis.

The Company does not hedge any balance sheet exposures and intercompany balances 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**

(a) Evaluation of Disclosure Controls and Procedures:

The Company's Chief Executive Officer and Chief Financial Officer have evaluated the effectiveness of the Company's disclosure controls and procedures (as such term is defined in Rules 13a-14(c) and 15d-14(c) under the Securities Exchange Act of 1934, as amended (the Exchange Act)) as of a date within 90 days prior to the filing date of this quarterly report (the Evaluation Date). Based on such evaluation, such officers have concluded that, as of the Evaluation Date, the Company's disclosure controls and procedures are effective in alerting them on a timely basis to material information relating to the Company to be included in the Company's periodic filings under the Exchange Act.

(b) Changes in Internal Controls:

Since the Evaluation Date, there have not been any significant changes in the Company's internal controls or in other factors that could significantly affect such controls.

## **Part II Other Information**

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

There are no pending legal proceedings against us other than ordinary litigation incidental to our business, the outcome of which, individually or in the aggregate, is not expected to have a material adverse effect on our business or financial condition.

### **Item 2. Changes in Securities and Use of Proceeds**

On March 27, 2003, the Company entered into a Purchase and Security Agreement (the Agreement) with Laurus Master Fund, Ltd. (Laurus), a Cayman Islands corporation, pursuant to which Laurus will make revolving credit advances to the Company from time to time up to an aggregate amount of \$2 million. Pursuant to the terms of the Agreement, Laurus received a three-year convertible note (the Note) from the Company secured by the Company's assets. To the extent advances have been made under the Note, the principal portion of the amount advanced and any interest or fees due and payable are convertible into shares of the Company's common stock. The conversion price per share is \$0.30, subject to terms and conditions set forth in the Agreement and the Note. As of the date of this report, no advances have been made under the Note. The Company also issued Laurus a Common Stock Purchase Warrant (the Warrant) dated March 27, 2003 exercisable for 275,000 shares of the Company's common stock, with exercise prices ranging from \$0.35 to \$0.44 per share.

The Company claimed that the offering and sale of the Note, the Warrant and the shares of common stock underlying the Note and the Warrant were exempt from the registration requirements of the Securities Act of 1933, as amended (the Securities Act) pursuant to Regulation D under the Securities Act. In order to claim this exemption, the Company relied on, among other things, a representation that Laurus is an accredited investor within the meaning of Regulation D.

For additional information regarding the transaction described above, please see our current report on Form 8-K filed on April 4, 2003.

### **Item 3. Defaults Upon Senior Securities**

None.

### **Item 4. Submission of Matters to a Vote of Security Holders**

None.

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**Item 5. Other Information**

None.

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

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

None.

- b) Reports on Form 8-K

None.

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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.

**CARDIOGENESIS CORPORATION**

Registrant

Date: May 15, 2003

/s/ Michael J. Quinn

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

Date: May 15, 2003

/s/ Darrell F. Eckstein

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Darrell F. Eckstein  
President, Chief Operating Officer and  
Acting Chief Financial Officer  
(Principal Accounting and Financial Officer,  
Secretary and Treasurer)



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**CERTIFICATIONS**

I, Michael J. Quinn, certify that:

1. I have reviewed this quarterly report on Form 10-Q of CardioGenesis Corporation;
2. Based on my knowledge, this quarterly report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this quarterly report;
3. Based on my knowledge, the financial statements, and other financial information included in this quarterly report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this quarterly report;
4. The registrant's other certifying officer and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-14 and 15d-14) for the registrant and we have:
  - (a) designed such disclosure controls and procedures to ensure that material information relating to the registrant, is made known to us, particularly during the period in which this quarterly report is being prepared;
  - (b) evaluated the effectiveness of the registrant's disclosure controls and procedures as of a date within 90 days prior to the filing date of this quarterly report (the Evaluation Date);
  - (c) presented in this quarterly report our conclusions about the effectiveness of the disclosure controls and procedures based on our evaluation as of the Evaluation Date;
5. The registrant's other certifying officer and I have disclosed, based on our most recent evaluation, to the registrant's auditors and the audit committee of registrant's board of directors:
  - (a) all significant deficiencies in the design or operation of internal controls which could adversely affect the registrant's ability to record, process, summarize and report financial data and have identified for the registrant's auditors any material weaknesses in internal controls; and
  - (b) any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal controls; and
6. The registrant's other certifying officer and I have indicated in this quarterly report whether or not there were significant changes in internal controls or in other factors that could significantly affect internal controls subsequent to the date of our most recent evaluation, including any corrective actions with regard to significant deficiencies and material weaknesses.

/s/ MICHAEL J. QUINN

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Michael J. Quinn  
Chief Executive Officer  
May 15, 2003

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I, Darrell F. Eckstein, certify that:

1. I have reviewed this quarterly report on Form 10-Q of CardioGenesis Corporation;
2. Based on my knowledge, this quarterly report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this quarterly report;
3. Based on my knowledge, the financial statements, and other financial information included in this quarterly report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this quarterly report;
4. The registrant's other certifying officer and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-14 and 15d-14) for the registrant and we have:
  - (a) designed such disclosure controls and procedures to ensure that material information relating to the registrant, is made known to us, particularly during the period in which this quarterly report is being prepared;
  - (b) evaluated the effectiveness of the registrant's disclosure controls and procedures as of a date within 90 days prior to the filing date of this quarterly report (the Evaluation Date);
  - (c) presented in this quarterly report our conclusions about the effectiveness of the disclosure controls and procedures based on our evaluation as of the Evaluation Date;
5. The registrant's other certifying officer and I have disclosed, based on our most recent evaluation, to the registrant's auditors and the audit committee of registrant's board of directors:
  - (a) all significant deficiencies in the design or operation of internal controls which could adversely affect the registrant's ability to record, process, summarize and report financial data and have identified for the registrant's auditors any material weaknesses in internal controls; and
  - (b) any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal controls; and
6. The registrant's other certifying officer and I have indicated in this quarterly report whether or not there were significant changes in internal controls or in other factors that could significantly affect internal controls subsequent to the date of our most recent evaluation, including any corrective actions with regard to significant deficiencies and material weaknesses.

/s/ DARRELL F. ECKSTEIN

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Darrell F. Eckstein  
Acting Chief Financial Officer  
May 15, 2003