CARDIOGENESIS CORP /CA
Form 10-Q
August 14, 2002

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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 June 30, 2002

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 [X] No[ ]

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

37,058,647 shares of Common Stock, no par value
As of July 31, 2002

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Item 1. ***Financial Statements.***

CARDIOGENESIS CORPORATION
CONSOLIDATED BALANCE SHEETS
(in thousands)

ASSETS

	June 30, 2002	December 31, 2001
	(unaudited)	
Current assets:		
Cash and cash equivalents	$ 2,569	$ 2,629
Accounts receivable, net of allowance for doubtful accounts of $1,314 and $1,114 at June 30, 2002 and December 31, 2001, respectively	1,880	2,330
Inventories, net of reserve of $1,153 and $1,246 at June 30, 2002 and December 31, 2001, respectively	2,369	3,215
Prepaids and other current assets	978	569
Total current assets	7,796	8,743
Property and equipment, net	709	863
Other assets	1,606	1,703
Total assets	$ 10,111	$ 11,309

LIABILITIES AND SHAREHOLDERS EQUITY

	June 30, 2002	December 31, 2001
Current liabilities:		
Accounts payable	$ 1,457	$ 1,548
Accrued liabilities	3,452	4,467
Customer deposits	50	54
Deferred revenue	648	931
Note payable	324	170
Current portion of capital lease obligation	30	30
Current portion of long-term liabilities	125	495
Total current liabilities	6,086	7,695
Capital lease obligation, less current portion	16	32
Total liabilities	6,102	7,727
Shareholders equity:		
Preferred stock:		
no par value; 6,600 shares authorized; none issued and outstanding		
Common stock:		
no par value; 50,000 shares authorized; 37,059 and 36,507 shares issued and outstanding at June 30, 2002 and December 31, 2001, respectively	168,236	167,750
Accumulated other comprehensive loss	(45)	(88)
Accumulated deficit	(164,182)	(164,080)

Total shareholders equity	4,009	3,582
Total liabilities and shareholders equity	$ 10,111	$ 11,309

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 June 30,		Six months ended June 30,	
	2002	**2001**	**2002**	**2001**
Net revenues	$ 3,010	$ 4,030	$ 6,168	$ 7,141
Cost of revenues	672	1,583	1,498	3,118
Gross profit	2,338	2,447	4,670	4,023
Operating expenses:				
Research and development	437	706	643	1,249
Sales, general and administrative	3,061	3,756	6,433	6,894
Restructuring costs		690		690
Total operating expenses	3,498	5,152	7,076	8,833
Operating loss	(1,160)	(2,705)	(2,406)	(4,810)
Interest, net	12	33	19	58
Gain on sale of equity investee	2,285		2,285	
Equity in net loss of investee		(295)		(652)
Net income (loss)	1,137	(2,967)	(102)	(5,404)
Other comprehensive income:				
Unrealized holding losses arising during period		(3)		
Foreign currency translation adjustment	23	60	43	33
Other comprehensive income	23	57	43	33
Comprehensive income (loss)	$ 1,160	$ (2,910)	$ (59)	$ (5,371)
Net income (loss) per share:				
Basic and diluted	$ 0.03	$ (0.09)	$ (0.00)	$ (0.17)
Weighted average shares outstanding:				
Basic	36,979	33,631	36,744	32,227
Diluted	37,098	33,631	36,744	32,227

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

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

	Six months ended June 30, 2002	2001
Cash flows from operating activities:		
Net loss	$ (102)	$ (5,404)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation and amortization	165	246
Gain from sale of equity investee	(2,285)	
Loss from equity in investee		652
Provision for doubtful accounts	200	109
Inventory reserves	339	670
Amortization of deferred compensation		56
Accretion of long-term liability		19
Amortization of license fees	97	98
Loss on disposal of property and equipment	28	
Changes in operating assets and liabilities:		
Accounts receivable short term	250	497
Inventories	507	127
Prepaids and other current assets	215	(249)
Accounts receivable long term		(138)
Accounts payable	(91)	(109)
Accrued liabilities	(1,015)	(100)
Current portion of long term liabilities	(370)	
Long term liabilities		(250)
Customer deposits	(4)	
Deferred revenue	(283)	(249)
Net cash used in operating activities	(2,349)	(4,025)
Cash flows from investing activities:		
Proceeds from sale of equity investee	2,285	
Acquisition of property and equipment	(39)	(19)
Net cash provided by (used in) investing activities	2,246	(19)
Cash flows from financing activities:		
Net proceeds from sales of common stock and from issuance of common stock from exercise of options	486	3,709
(Payments on) proceeds from short term borrowings	(470)	305
Repayments of capital lease obligations	(16)	(14)
Net cash provided by financing activities		4,000
Effects of exchange rate changes on cash and cash equivalents	43	33
Net decrease in cash and cash equivalents	(60)	(11)

Cash and cash equivalents at beginning of period	2,629	3,357
Cash and cash equivalents at end of period	$ 2,569	$ 3,346
Supplemental schedule of cash flow information:		
Interest paid	$ 7	$ 2
Taxes paid	$ 2	$ 26
Supplemental schedule of noncash investing and financing activities:		
Deferred compensation	$	$ 11
Issuance of warrants	$	$ 94
Financing of insurance premiums with note payable	$ 624	$ 554

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, 2001, 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 losses for the last several years and expects to continue to incur losses through 2002. Management believes its cash balance as of June 30, 2002 is sufficient to meet the Company s capital and operating requirements through the end of the fiscal year ending December 31, 2002.

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 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 3,436,303 and 3,186,412 shares of common stock were outstanding at June 30, 2002 and 2001, respectively. Warrants to purchase 75,000 shares of common stock at $1.63 per share were outstanding as of June 30, 2002 and 2001. For the three months ended June 30, 2002, potentially dilutive securities resulted in potential common shares of approximately 119,000 shares. For the six months ended June 30, 2002 and 2001, and the three months ended June 30, 2001, no potential common shares were included in the diluted per share amount as the effect 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):

	June 30, 2002	December 31, 2001
	(unaudited)	
Raw materials	$ 573	$ 917
Work-in-process	248	323
Finished goods	1,548	1,975
	$2,369	$3,215

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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 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 or the 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).

In 1999, we received approval from the Food and Drug Administration (FDA) to sell our TMR products in the U.S. on a commercial basis for use with certain medical indications. 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 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 PMR, and study results were submitted to the FDA in a Pre Market Approval (PMA) application in 1999 along with subsequent amendments. In July 2001, the FDA s Circulatory Devices Panel recommended against approval by the FDA of our PMR device for public sale and use in the United States. Following this recommendation, we continued to pursue FDA approval for PMR and in June 2002, we submitted a PMA amendment for PMR to the FDA. There can be no assurance, however, that we will receive a favorable decision from the agency.

As of June 30, 2002, we had an accumulated deficit of $164,182,000. We expect to continue to incur operating losses through 2002. 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 $3,010,000 for the quarter ended June 30, 2002 decreased $1,020,000, or 25%, when compared to net revenues of $4,030,000 for the quarter ended June 30, 2001.

For the quarter ended June 30, 2002, domestic handpiece revenue decreased by $564,000 compared to the quarter ended June 30, 2001. In the second quarter of 2002, domestic handpiece revenue consisted of $733,000 in sales to customers operating under the loaned laser program and $1,634,000 in sales to customers not operating under the loaned laser program. For those sales to customers operating under the loaner laser program, $167,000 was attributed to premiums associated with handpiece sales. In the second quarter of 2001, domestic handpiece revenue consisted of $1,434,000 in sales of product to customers operating under the loaned laser program and $1,497,000 of sales to customers not operating under the loaned laser program. For those sales to customers operating under the loaned laser program, $453,000 was attributed to premiums associated with the handpiece sales.

For the quarter ended June 30, 2002, domestic laser revenue decreased by $39,000 compared to the same quarter in 2001. International sales, accounting for approximately 1% of net revenues for the quarter ended June 30, 2002, decreased $393,000 from the prior year when international sales accounted for 11% of total sales. We define international sales as sales to customers located outside of the United States. In addition, service revenue of $215,000 decreased $24,000 or 10% for the quarter ended June 30, 2002 when compared to $239,000 for the quarter ended June 30, 2001.

Net revenues of $6,168,000 for the six months ended June 30, 2002 decreased $973,000, or 14%, when compared to net revenues of $7,141,000 for the six months ended June 30, 2001.

For the six months ended June 30, 2002, domestic handpiece revenue decreased by $985,000 compared to the six months ended June 30, 2001. In the first six months of 2002, domestic handpiece revenue consisted of $1,289,000 in sales to customers operating under the loaned laser program and $2,843,000 in sales to customers not operating under the loaned laser program. For those sales to customers operating under the loaner laser program, $235,000 was attributed to premiums associated with handpiece sales. In the first six months of 2001, domestic handpiece revenue consisted of $2,249,000 in sales of product to customers operating under the loaned laser program and $2,868,000 of sales to customers not operating under the loaned laser program. For those sales to customers operating under the loaned laser program, $794,000 was attributed to premiums associated with the handpiece sales.

For the six months ended June 30, 2002, domestic laser revenue increased by $458,000 compared to the same period in 2001. International sales, accounting for approximately 6% of net revenues for the six months ended June 30, 2002, decreased $357,000 from the same period in 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 of $472,000 decreased $89,000 or 16% for the six months ended June 30, 2002 when compared to $561,000 for the six months ended June 30, 2001.

Gross Profit

Gross profit increased to 78% of net revenues for the quarter ended June 30, 2002 as compared to 61% of net revenues for the quarter ended June 30, 2001. Gross profit in absolute dollars decreased by $109,000 to $2,338,000 for the quarter ended June 30, 2002, as compared to $2,447,000 for the quarter ended June 30, 2001. Gross profit increased to 76% of net revenues for the six months ended June 30, 2002 as compared to 56% of net revenues for the six months ended June 30, 2001. Gross profit in absolute dollars increased by $647,000 to $4,670,000 for the six months ended June 30, 2002, as compared to $4,023,000 for the six months ended June 30, 2001. The increase in gross margin as a percent of net revenues for the quarter and year ended June 30, 2002 resulted from improved margins on lasers sold as well as improved margins on disposable handpieces as a result of the outsourcing of disposables manufacturing which took place in the second half of 2001.

Research and Development

Research and development expenditures of $437,000 decreased $269,000 or 38% for the quarter ended June 30, 2002 when compared to $706,000 for the quarter ended June 30, 2001. The decrease in overall research and development expense was primarily attributed to a decrease in employee expenses of $136,000 related to reductions in workforce and decreases in outside services and facilities costs of $83,000 and $30,000, respectively.

Research and development expenditures of $643,000 decreased $606,000 or 49% for the six months ended June 30, 2002 when compared to $1,249,000 for the six months ended June 30, 2001. The decrease in overall research and development expense was primarily attributed to a decrease in employee expenses of approximately $378,000 related to reductions in workforce and decreases in outside services and facilities costs of $171,000 and

$60,000, respectively.

Sales, General and Administrative

Sales, general and administrative expenditures of $3,061,000 decreased $695,000 or 19% for the quarter ended June 30, 2002 when compared to $3,756,000 for the quarter ended June 30, 2001. The decrease in expenses resulted primarily from decreases in employee expenses, outside services and facilities costs of $504,000, $152,000 and $132,000, respectively, offset by an increase in advertising and marketing expenses of $73,000.

Sales, general and administrative expenditures of $6,433,000 decreased $461,000 or 7% for the six months ended June 30, 2002 when compared to $6,894,000 for the six months ended June 30, 2001. The decrease in expenses resulted primarily from decreases in employee expenses and facilities costs of $488,000 and $230,000, respectively, offset by increases in legal expenses and outside services costs of $132,000 and $122,000, respectively.

Non-Operating Expenses

In the second quarter of 2002, we recorded a gain of $2,285,000 resulting from the sale of our minority interest in Microheart.

Equity in net loss of investee of $295,000 and $652,000 for the three and six months ended June 30, 2001, respectively, represented our share of the net loss of Microheart, Inc., a privately-held company in which our ownership was approximately 30%. There was no net loss recorded for this investment in the same periods in 2002 because we carried no investment balance for Microheart in 2002.

Net Income

Net income of $1,137,000 increased $4,104,000 for the quarter ended June 30, 2002 when compared to a net loss of $2,967,000 for the quarter ended June 30, 2001. The increase in net income is primarily related to the gain of $2,285,000 on the sale of our ownership interest in Microheart, as well as an increase in gross profit and reduced operating expenses.

Net loss of $102,000 decreased $5,302,000 for the six months ended June 30, 2002 when compared to a net loss of $5,404,000 for the six months ended June 30, 2001. The decrease in net loss is primarily related to the gain of $2,285,000 on the sale of our ownership interest in Microheart coupled with a 50% decrease in operating expenses resulting from our cost containment efforts and improved margins on sales.

Liquidity and Capital Resources

Cash and cash equivalents were $2,569,000 at June 30, 2002 compared to $2,629,000 at December 31, 2001, a decrease of $60,000. We used $2,349,000 of cash for operating activities in the six months ended June 30, 2002 to fund our operating loss and to pay accrued liabilities. Accrued liabilities decreased by $1,015,000 to $3,452,000 at June 30, 2002 compared to $4,467,000 at December 31, 2001, primarily due to payments on obligations.

Cash provided by investing activities in the six months ended June 30, 2002 was $2,246,000, primarily from the proceeds of $2,285,000 from the sale of our ownership interest in Microheart, Inc. Cash used in financing activities consisted of $486,000 in payments on short term borrowings and capital lease obligations. This was offset by cash proceeds related to financing activities of $486,000 related to the sale of our common stock in the second quarter of 2002.

Since our inception, we have satisfied our capital requirements primarily through sales of our equity securities. In addition, our operations have been funded through sales of our products. In April 2002, we sold our ownership interest in Microheart, Inc. for $2,285,000. In April 2002, we sold 500,000 shares of common stock to a governmental entity at a negotiated purchase price of $1.00 per share. We have incurred significant operating losses for the last several years and at June 30, 2002 have an accumulated deficit of $164,182,000. The accompanying

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consolidated financial statements have been prepared assuming we will continue as a going concern. Our ability to continue as a going concern 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 believe our cash balance as of June 30, 2002 and the borrowing capacity of approximately $1,000,000 available under our receivable financing arrangement will be sufficient to meet our capital and operating requirements through the end of 2002. We believe that if revenues from sales or new funds from debt or equity instruments are insufficient to maintain the current expenditure rate, it will be necessary to significantly curtail our operations until an appropriate solution is implemented.

Factors Affecting Future Results

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 continue as a going concern is dependent upon achieving profitable operations in the future.

We will have a continuing need for new infusions of cash until revenues are increased to meet our operating expenses. We plan to increase our sales through increased direct sales and marketing efforts on existing products and achieving regulatory approval for other products. If we are unable to increase our sales or 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.

Our common stock could be delisted in the future by the Nasdaq National Market.

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. Our common stock could be delisted in the future by the Nasdaq National Market (Nasdaq) if we do not meet Nasdaq s continued listing standards. We have received notice from Nasdaq that we could be delisted because our common stock has traded under $1.00 for more than 30 consecutive days. If we are unable to regain compliance with the $1.00 Nasdaq listing standard, our common stock could be delisted from Nasdaq. In addition, if our net tangible assets fall below $4 million, or if we do not in the future meet Nasdaq s $10 million in stockholder s equity test starting November 1, 2002, we would be in violation of Nasdaq s continued listing standards. If our common stock were delisted from Nasdaq, then we could apply for listing on the Nasdaq SmallCap Market or explore becoming listed on an alternative market. Delisting from Nasdaq 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.

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 52-week period ended July 31, 2002, the closing prices of our common stock as reported on Nasdaq ranged from a high of $1.65 to a low of $0.61. 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;

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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 Food and Drug Administration has not approved our PMR laser systems for any application in the United States. The Circulatory Devices Panel of the Food and Drug Administration recommended in July 2001 that the Food and Drug Administration not approve our PMR device for public sale and use in the United States based on concerns related to the safety of the device and the data regarding adverse events in the clinical trials. Although we do not expect to conduct further clinical trials of our PMR device, this recommendation has necessitated the further investment of additional resources toward obtaining the Food and Drug Administration s approval of our PMR device. 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 Food and Drug Administration 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 Food and Drug Administration could restrict the current uses of our TMR product.

The Food and Drug Administration has approved our TMR product for sale and use by physicians in the United States. At the request of the Food and Drug Administration, we are currently conducting post-market surveillance of our TMR product. We received a letter from the Food and Drug Administration in January of 2001 expressing concern about the progress of our post-market surveillance study for our TMR product. We have submitted a plan to the Food and Drug Administration to enable the timely completion of our post-market surveillance study. However, if we should fail to meet the requirements mandated by the Food and Drug Administration or fail to complete our post-market surveillance study in an acceptable time period, the Food and Drug Administration 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 Food and Drug Administration could possibly restrict the currently approved uses of our TMR product. In the future, if the Food and Drug Administration 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 which occurs in more than half the procedures in which TMR is used, either outcome could lead to reduced or no sales of our TMR product in the United States and our business could be adversely affected.

The medical community has not broadly adopted our products, and unless our products are broadly adopted, our business will suffer.

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Our TMR products and PMR products have not yet achieved broad commercial and clinical adoption. We cannot predict whether or at what rate and how broadly our products will be adopted by the medical community. Our business would be harmed if our TMR and PMR systems fail to achieve significant market acceptance.

The receipt of positive endorsements by physicians is essential for the success of our products in the market place.

Positive endorsements by physicians are essential for clinical adoption of our TMR and PMR laser systems. Clinical adoption of these products will depend upon:

- our ability to facilitate training of cardiothoracic surgeons and interventional cardiologists in TMR and PMR therapy;
- willingness of such physicians to adopt and recommend such procedures to their patients; and
- raising the awareness of TMR and PMR with the targeted patient population.

Patient acceptance of the procedure will depend on:

- physician recommendations;
- the degree of invasiveness;
- the effectiveness of the procedure; and
- the rate and severity of complications associated with the procedure as compared to other procedures.

To expand our business, we must establish effective sales, marketing and distribution systems.

To expand our business, we must establish effective systems to sell, market and distribute products. To date, we have had limited sales which have consisted primarily of U.S. sales of our TMR lasers and disposable handpieces on a commercial basis since February 1999 and PMR lasers and disposable catheters outside of the U.S. through international distributors.

With Food and Drug Administration approval of our TMR laser system, we are marketing our products primarily through our direct sales force. If the sales force is not successful in increasing market share and selling our disposable handpieces, our business will suffer.

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.

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 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. Over the past year, our revenue has been lower than anticipated, largely attributable to the transition to our new sales strategy. 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.

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, our business will suffer. The market for TMR laser systems is characterized by rapid technical innovation. We currently compete with PLC Systems. PLC Systems recently announced that 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. Accordingly, 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 Food and Drug Administration 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.

We have a history of losses and may not be profitable in the future.

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 Food and Drug Administration and other regulatory approvals for our PMR laser systems; and
- for an uncertain period of time after such approvals are obtained.

We may not achieve or sustain profitability in the future.

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;

- 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

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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
- 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 must comply with Food and Drug Administration manufacturing standards or face fines or other penalties including suspension of production.

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

- fines, injunctions, and civil penalties;
- recalls or seizures of products;
- total or partial suspensions of production; and
- criminal prosecutions.

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

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 Food and Drug Administration 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 Food and Drug Administration 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.

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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.

During the last six months, we have had significant changes in our senior management team. In January 2002, our former Chief Financial Officer, J. Stephen Wilkins, resigned and was replaced by Darrell Eckstein who was originally hired in December 2000 as our Vice President of Operations. Also in January 2002, our Vice President of Sales, Thomas Kinder, resigned and was replaced by Michael A. Tuckerman. In May 2002, Mr. Eckstein was promoted to President and Chief Operating Officer, and he currently serves as Acting Chief Financial Officer.

Our future business could be harmed by our turnover in senior management if we have difficulty familiarizing and training our new management with respect to our business. 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 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 Food and Drug Administration 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.

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;
- restrictions and foreign medical regulations;
- customs duties, export quotas or other trade restrictions; and
- difficulty in protecting intellectual property rights.

We may not achieve wide acceptance of our products in foreign markets if we fail to obtain third party reimbursement for the procedures performed with our products.

If we obtain the necessary foreign regulatory registrations or approvals, market acceptance of our products 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.

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 June 30, 2002 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	2002	2003	2004	2005	2006	Total Fair Value
Assets						
Cash, cash equivalents	$2,569	$	$	$	$	$2,569
Weighted average interest rate	1.0%					1.0%
Liabilities						
Fixed Rate Debt						
Lease obligation	$ 30	$ 16	$	$	$	$ 46
Weighted average interest rate	6.8%	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.

Part II Other Information

Item 1. Legal Proceedings

None.

Item 2. Changes in Securities and Use of Proceeds

a) Pursuant to the Share Purchase Agreement (the Share Purchase Agreement), dated April 10, 2002, between the Company and the State of Wisconsin Investment Board (the Agreement), the Company issued and sold 500,000 shares of its common stock to the State of Wisconsin Investment Board in a transaction exempt from the registration requirements of the Securities Act of 1933, as amended (the Securities Act). The exemption was claimed in reliance on Section 4(2) of the Securities Act based upon the fact that the securities were sold to a sophisticated offeree provided with sufficient information regarding the securities and the Company in a non-public offering. In connection with the sale the Company received net proceeds of $486,000. The Company used the proceeds from the sale for general corporate purposes.

Item 3. Defaults Upon Senior Securities

None.

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

At CardioGenesis Corporation s Annual Meeting of Shareholders held on May 31, 2002, the following proposals were adopted by the margins indicated.

1. To elect five (5) directors to serve until the next Annual Meeting of Shareholders or until their

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successors are elected and qualified. Other than the directors listed below there were no other directors whose term of office continued.

	Number of Shares Voted:	
	For	Withheld
Michael J. Quinn	34,970,192	1,109,752
Jack M. Gill, Ph.D.	34,984,160	1,095,784
Joseph R. Kletzel, II	34,978,860	1,101,084
Robert L. Mortensen	34,988,660	1,091,284
Robert C. Strauss	34,985,360	1,094,584

2. To ratify the appointment of PricewaterhouseCoopers LLP as the independent auditors of CardioGenesis Corporation for the fiscal year ending December 31, 2002.

Number of Shares Voted:		
For	Against	Abstain/ Broker Non-Vote
35,906,867	99,027	74,050

3. To approve an amendment to the Stock Option Plan to increase the number of shares of Common Stock reserved for issuance by 1,500,000 shares.

Number of Shares Voted:		
For	Against	Abstain/ Broker Non-Vote
32,650,458	3,361,332	68,154

4. To approve an amendment to the Director Stock Option Plan to increase the number of shares of Common Stock reserved for issuance by 250,000 shares.

Number of Shares Voted:		
For	Against	Abstain/ Broker Non-Vote
32,526,709	3,434,013	119,222

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:

EXHIBIT NUMBER	DESCRIPTION

10.12	Employment agreement dated June 1, 2002 between the Company and Darrell F. Eckstein, President, Chief Operating Officer and Acting Chief Financial Officer.
10.13	Amendment to employment agreement between the Company and Michael J. Quinn, Chief Executive Officer, dated July 3, 2002.
99.1	Certification pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.

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EXHIBIT NUMBER	DESCRIPTION
99.2	Certification pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.

b) Reports on Form 8-K
A report was filed on April 5, 2002, to report under Item 2, Acquisition of Assets, the sale of CardioGenesis Corporation s ownership of Microheart, Inc., a privately owned entity in which the ownership was approximately 30%, and under Item 5, Other Events, CardioGenesis sale of common stock to the State of Wisconsin Investment Board.

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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: August 14, 2002	/s/ Michael J. Quinn
	Michael J. Quinn Chief Executive Officer and Chairman of the Board (Principal Executive Officer)
Date: August 14, 2002	/s/ Darrell F. Eckstein
	Darrell F. Eckstein President, Chief Operating Officer and Acting Chief Financial Officer (Principal Accounting and Financial Officer)

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