CARDIOGENESIS CORP /CA
Form 424B3
May 18, 2004

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File No. 333-113578

CARDIOGENESIS CORPORATION

Prospectus Supplement No. 1 dated May 17, 2004

to the Prospectus dated March 30, 2004

On May 17, 2004, we filed with the Securities and Exchange Commission the attached Quarterly Report on Form 10-Q for the quarter ended March 31, 2004. The attached information supplements and supersedes, in part, the information in the prospectus.

This prospectus supplement no. 1 should be read in conjunction with the prospectus, which is required to be delivered with this prospectus supplement no. 1.

Investing in our common stock involves a high degree of risk. See Risk Factors beginning on page 2 of the prospectus for a discussion of the risks associated with our business.

Neither the Securities and Exchange Commission nor any state securities commission has approved or disapproved of these securities or determined if this prospectus supplement no. 1 is truthful or complete. Any representation to the contrary is a criminal offense.

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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, 2004

Commission file number 0-28288

CARDIOGENESIS CORPORATION

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

California	**77-0223740**
(State of incorporation)	*(I.R.S. Employer Identification Number)*

26632 Towne 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 x No o

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

Yes o No x

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

41,208,672 shares of Common Stock, no par value
As of April 30, 2004

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CARDIOGENESIS CORPORATION

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Item 1. Financial Statements (unaudited)

CARDIOGENESIS CORPORATION

CONSOLIDATED BALANCE SHEETS
(in thousands)
(unaudited)

	March 31, 2004	December 31, 2003
ASSETS		
Current assets:		
Cash and cash equivalents	$ 3,051	$ 1,013
Accounts receivable, net of allowance for doubtful accounts of $25 and $26 at March 31, 2004 and December 31, 2003, respectively	2,501	1,830
Inventories, net of reserves of $373 and $373 at March 31, 2004 and December 31, 2003, respectively	1,294	1,339
Prepaids and other current assets	493	453
Total current assets	7,339	4,635
Property and equipment, net	496	408
Other assets	1,363	1,417
Total assets	$ 9,198	$ 6,460
LIABILITIES AND SHAREHOLDERS EQUITY		
Current liabilities:		
Accounts payable	$ 966	$ 876
Accrued liabilities	775	1,159
Customer deposits	25	25
Deferred revenue	557	573
Notes payable	171	
Current portion of capital lease obligation	5	1
Total current liabilities	2,499	2,634
Capital lease obligation, less current portion	21	6
Total liabilities	2,520	2,640

Shareholders equity:		
Preferred stock:		
no par value; 5,000 shares authorized; none issued and outstanding		
Common stock:		
no par value; 75,000 shares authorized; 41,238 and 37,859 shares issued and outstanding at March 31, 2004 and December 31, 2003, respectively	171,369	168,778
Accumulated deficit	(164,691)	(164,958)
Total shareholders equity	6,678	3,820
Total liabilities and shareholders equity	$ 9,198	$ 6,460

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

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CARDIOGENESIS CORPORATION

CONSOLIDATED STATEMENTS OF INCOME
(in thousands, except per share amounts)
(unaudited)

	Three months ended March 31,	
	2004	**2003**
Net revenues	$ 4,041	$ 3,422
Cost of revenues	553	622
Gross profit	3,488	2,800
Operating expenses:		
Research and development	291	383
Sales, general and administrative	2,928	2,298
Total operating expenses	3,219	2,681
Operating income	269	119
Interest (expense) income, net	(2)	2
Net income	267	121
Net income per share:		
Basic and diluted	$ 0.01	$ 0.00
Weighted average shares outstanding:		
Basic	40,490	37,121
Diluted	41,204	37,145

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)

	Three months ended March 31,	
	2004	**2003**
Cash flows from operating activities:		
Net income	$ 267	$ 121
Adjustments to reconcile net income to net cash (used in) provided by operating activities:		
Depreciation and amortization	60	65
Provisions for excess and obsolescence	6	121
Amortization of license fees	49	49
Amortization of debt issue costs	6	
Reduction of clinical trial accrual	(117)	
Changes in operating assets and liabilities:		
Accounts receivable	(671)	15
Inventories	39	(24)
Prepaids and other current assets	124	45
Other assets	5	
Accounts payable	90	147
Accrued liabilities	(267)	(463)
Deferred revenue	(16)	20
Net cash (used in) provided by operating activities	(425)	96
Cash flows from investing activities:		
Acquisition of property and equipment	(128)	(2)
Net cash used in investing activities	(128)	(2)
Cash flows from financing activities:		
Net proceeds from issuance of common stock from exercise of options	159	
Net proceeds from sale of common stock, net of costs of $267	2,433	
Payments on capital lease obligations	(1)	(8)
Net cash provided by (used in) financing activities	2,591	(8)

Net increase in cash and cash equivalents	2,038	86
Cash and cash equivalents at beginning of year	1,013	1,490
Cash and cash equivalents at end of period	$3,051	$1,576
Supplemental schedule of cash flow information:		
Interest paid	$ 7	$ 1
Taxes paid	$ 3	$ 3

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, 2003, contained in the Company s Annual Report on Form 10-K, as amended, 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, 2004, CardioGenesis has sustained significant operating losses for the last several years and may continue to incur losses in the future. Management believes its cash balance as of March 31, 2004 is sufficient to meet the Company s capital and operating requirements for the next 12 months.

CardioGenesis may require additional financing in the future. There can be no assurance that CardioGenesis will be able to obtain additional debt or equity financing, if and when needed, on terms acceptable to the Company. Any additional debt or equity financing may involve substantial dilution to CardioGenesis stockholders, restrictive covenants or high interest costs. The failure to raise needed funds on sufficiently favorable terms could have a material adverse effect on CardioGenesis business, operating results and financial condition. CardioGenesis long term liquidity also depends upon its ability to increase revenues from the sale of its products and 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 Per Share:

Basic earnings per share (EPS) is computed by dividing the net income 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 4,240,102 and 4,556,285 shares of common stock were outstanding at March 31, 2004 and 2003, respectively. Warrants to purchase 75,000 shares of common stock at $1.63 per share were outstanding as of March 31, 2004 and 2003. Warrants to purchase 275,000 shares of common stock at prices ranging from $.35 to $.44 per share were outstanding as of March 31, 2004 and 2003. For the three months ended March 31, 2004, potentially dilutive securities resulted in potential common shares of approximately 714,000 shares. For the three months ended March 31, 2003, 24,000 potential common shares were included in the diluted per share amount.

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2. Inventories:

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

	March 31, 2004	December 31, 2003
	(unaudited)	
Raw materials	$1,048	$1,042
Work-in-process	224	159
Finished goods	395	511
	1,667	1,712
Less reserves	(373)	(373)
	$1,294	$1,339

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 Directors 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, 2004 and 2003 consistent with the provisions of SFAS 123, CardioGenesis net income and net income per share would have changed to the pro forma amounts indicated below *(in thousands, except per share amounts):*

	Three Months Ended March 31,	
	2004	2003
Net income as reported	$ 267	$ 121
Stock-based employee compensation	$ (118)	$ (309)
Pro forma net income (loss)	$ 149	$ (188)
Basic and diluted net income per share as reported	$ 0.01	$ 0.00
Pro forma basic and diluted net income (loss) per share	$ 0.00	$ (0.01)

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, 2004 and 2003 were $406,000 and $241,000 and $0.74 and $0.20, respectively. The fair value of each option grant is estimated on the date of grant using the Black-Scholes option pricing model with the following weighted-average assumptions for grants in the three months ended March 31, 2004 and 2003:

	Three Months Ended March 31,	
	2004	**2003**
Expected life of option	7 years	7 years
Risk-free interest rate	3.54%	4.04%
Expected dividends		
Expected volatility	127%	75%

4. Shareholder s Equity:

On January 22, 2004, we entered into a Securities Purchase Agreement with certain institutional investors pursuant to which the Company issued in a private placement 3,139,535 shares of its common stock. In addition, the Company issued to the investors two sets of warrants to acquire common stock. The first set of warrants are immediately exercisable for a period of five years for up to an aggregate of 3,139,535 shares of common stock at an exercise price of $1.37 per share. The second set of warrants are exercisable for up to an aggregate of 1,569,768 shares of common stock at an exercise price of $1.00 per share for a period ending September 30, 2004. There were no underwriters involved in the issuance and sale of these securities. Commissions of $162,000 were paid to a placement agent. We relied on the exemption from registration provided by Section 4(2) of the Securities Act.

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 statement 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.

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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 permitted 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. As a result, hospitals and physicians are now eligible to receive Medicare reimbursement for TMR equipment and procedures performed on Medicare patients.

We have completed pivotal clinical trials involving PMR, and study results were submitted to the FDA in a PMA application in December of 1999 along with subsequent amendments. The PMR study compares PMR to conventional medical therapy in patients with no option other than treatment. In July 2001, the FDA Advisory Panel recommended against approval of PMR for public sale and use in the United States. In July 2003, the FDA agreed to an alternative process in which additional data in support of our PMA supplement for PMR could be submitted and reviewed by the FDA in an interactive review process. The data was submitted in August 2003 and the independent panel review by the MDDRP was cancelled. The FDA agreed to reschedule the MDDRP hearing in the future if the dispute cannot be resolved. The FDA has informed us that the data submitted in August 2003 in connection with the interactive review process is still not adequate to support approval by the FDA of our PMR system.

In March 2004, the FDA decided not to overturn their previous non-approvable recommendation. The FDA has agreed to meet with us to clarify the pathway for approval of PMR. After meeting with the FDA, we will be in position to determine the next steps for PMR, which may include a partnership to complete any necessary additional clinical trials with PMR or pursuit of a hearing with the Medical Device Dispute Resolution Panel. We are currently working with the FDA to establish a meeting date in the near term. There can be no assurance, however, that a suitable partner will be identified on favorable terms that we will receive an approvable determination from the Panel and the FDA.

As of March 31, 2004, we had an accumulated deficit of $164,691,000. We may continue to incur operating losses in the future. The timing and amounts of our expenditures will depend upon a number of factors, including the efforts required to develop our sales and marketing organization, the timing of market acceptance of our products and the status and timing of regulatory approvals.

Results of Operations

Net Revenues

We generate our revenues primarily through the sale of our TMR laser systems, fiber optic handpiece delivery systems, and related services. Net revenues of $4,041,000 for the quarter ended March 31, 2004 increased $619,000, or 18%, when compared to net revenues of $3,422,000 for the quarter ended March 31, 2003. The increase in net revenues is primarily attributed to an increase in laser and disposable handpiece revenue. Laser revenue increased as a result of a greater number of laser units sold this quarter and handpiece revenue increased as a result of a higher

average sales price on handpiece units.

For the quarter ended March 31, 2004, domestic disposable handpiece revenue increased by $437,000 and domestic laser revenue increased by $152,000 compared to the quarter ended March 31, 2003. In the first quarter of 2004, domestic handpiece revenue consisted of $604,000 in sales of product to customers operating under the loaned laser program, of which $201,000 was attributed to premiums associated with such sales. In the first quarter

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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 2004 and 2003, sales of handpieces to customers not operating under the loaned laser program were $1,912,000 and $1,513,000, respectively. International sales, accounting for approximately 8% of net revenues for the quarter ended March 31, 2004, increased $63,000 from the prior year. We define international sales as sales to customers located outside of the United States. In addition, service revenue of $234,000 decreased $33,000 for the quarter ended March 31, 2004 when compared to $267,000 for the quarter ended March 31, 2003.

Gross Profit

Gross profit increased to 86% of net revenues for the quarter ended March 31, 2004 as compared to 82% of net revenues for the quarter ended March 31, 2003. Gross profit in absolute dollars increased by $688,000 to $3,488,000 for the quarter ended March 31, 2004, as compared to $2,800,000 for the quarter ended March 31, 2003. The increase in gross profit, as a percentage of sales and in absolute terms, resulted from improved margins on lasers sold due to improved cost on conversions of loaner lasers which have a low net book value as well as improved margins on disposable handpieces due to higher average sales prices.

Research and Development

Research and development expenditures of $291,000 decreased $92,000 or 24% for the quarter ended March 31, 2004 when compared to $383,000 for the quarter ended March 31, 2003. The decrease in overall research and development expense was primarily attributed to a decrease in expenses related to our pursuit of PMR approval.

Sales, General and Administrative

Sales, general and administrative expenditures of $2,928,000 increased $630,000 or 27% for the quarter ended March 31, 2004 when compared to $2,298,000 for the quarter ended March 31, 2003. The increase in expenses resulted primarily from increases in employee headcount and related expenses and marketing expenses of $560,000 and $220,000, respectively, offset by cost cutting in other areas such as outside services and facilities costs.

Liquidity and Capital Resources

At March 31, 2004, we had cash and cash equivalents of $3,051,000 compared to $1,013,000 at December 31, 2003, an increase of $2,038,000. During the three months ended March 31, 2004, we had net income of $267,000 and used cash of $596,000 in operating activities such as our marketing campaign and trade show activities. Accounts receivable increased by $671,000 from $1,830,000 at December 31, 2003 to $2,501,000 at March 31, 2004, primarily due to increased sales revenue in the first three months of 2004.

Cash used in investing activities during the three months ended March 31, 2004 was $148,000. Cash provided by financing activities during the same period was $2,781,000 due to the sales of common stock related to the exercise of stock options as well as the sale of equity securities described below.

On January 22, 2004, we sold 3,139,535 shares of common stock to private investors for a total price of $2,700,000. We also issued warrants to purchase 3,139,535 additional shares of common stock at a price of $1.37 per share. The warrants are immediately exercisable and have a term of five years. The investors also have an option to purchase approximately 1,570,000 shares of common stock at $1.00 per share for a period ending September 30, 2004.

In March 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. In conjunction with this transaction, we issued warrants to acquire 275,000 shares of our common stock. The warrants are exercisable for five years from the date of grant at exercise prices ranging from $.35 to $.44 per share. As of December 31, 2003, we had no outstanding borrowings on the Note. We intend to cancel the Note in the second quarter of 2004.

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We have incurred significant losses for the last several years and at March 31, 2004 have an accumulated deficit of $164,291,000. Our ability to maintain current operations is dependent upon sustaining profitable operations or obtaining additional debt or equity financing. Our plans include increasing sales through increased direct sales and marketing efforts on existing products and achieving timely regulatory approval for certain other products.

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

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

We believe our cash balance as of March 31, 2004 will be sufficient to meet our capital and operating requirements through the next 12 months. We will have a continuing need for new infusions of cash if we incur losses in the future. We plan to increase our sales through increased direct sales and marketing efforts on existing products and achieving regulatory approval for other products. If our direct sales and marketing efforts are unsuccessful or we are unable to achieve regulatory approval for our products, we will be unable to significantly increase our revenues. We believe that if we are unable to generate sufficient funds from sales revenues or from debt or equity issuances to maintain our current expenditure rate, it will be necessary to significantly reduce our operations until an appropriate solution is implemented. We may be required to seek additional sources of financing, which could include short-term debt, long-term debt or equity. There is a risk that we may be unsuccessful in obtaining such financing and that we will not have sufficient cash to fund our operations.

The following summarizes our contractual obligations at March 31, 2004, and the effect, if any, such obligations are expected to have on our liquidity and cash flow in future periods:

	Payments due by period (In Thousands)				
Contractual Obligations	**Total**	**Less than 1 year**	**1-3 years**	**3-5 years**	**More than 5 years**
Long Term Debt					
Capital Lease Obligations	$ 30	$ 6	$ 13	$ 11	
Operating Leases	940	364	576		
Purchase Obligations					
Other Long Term Liabilities Reflected on the Registrant s Balance Sheet under GAAP					
Total	$961	$ 370	$ 589	$ 11	$

Critical Accounting Policies

The preparation of the financial statements requires estimation and judgment that affect the reported amounts of net revenues, expenses, assets and liabilities. We base our estimates on historical experience and on

various other assumptions that we believe to be reasonable under the circumstances and which form the basis for making judgments about the carrying values of assets and liabilities. Critical accounting policies are defined as those that are reflective of significant judgments and uncertainties, and could potentially result in materially different results under different assumptions and conditions. If these estimates differ significantly from actual results, the impact to the financial statements may be material.

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

Revenue Recognition:

We recognize revenue on product sales upon receipt of a purchase order, shipment of the products, the price is fixed or determinable and collection of sales proceeds is reasonably assured. Where purchase orders allow customers an acceptance period or other contingencies, revenue is recognized upon the earlier of acceptance or removal of the contingency.

Revenues from sales to distributors and agents are recognized upon shipment when there is evidence that an arrangement exists, delivery has occurred under the Company s standard FOB shipping point terms, the sales price is fixed or determinable and the ability to collect sales proceeds is reasonably assured. The contracts regarding these sales do not include any rights of return or price protection clauses.

We frequently loan lasers to hospitals in return for the hospital purchasing a minimum number of handpieces at a premium over the list price. The loaned lasers are depreciated to cost of revenues over a useful life of 24 months.

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

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

Allowance for Doubtful Accounts:

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

Inventories:

Inventories are stated at the lower of cost (principally standard cost, which approximates actual cost on a first-in, first-out basis) or market value.

Income Taxes:

We account for income taxes using the liability method under which deferred tax assets or liabilities are calculated at the balance sheet date using current tax laws and rates in effect for the year in which the differences are expected to affect taxable income. Valuation allowances are established, when necessary, to reduce deferred tax assets to the amounts expected to be realized.

Risk Factors

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

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Our ability to maintain current operations is dependent upon sustaining profitable operations or obtaining financing in the future.

We have incurred significant losses since inception. For example, for the fiscal years 2003, 2002 and 2001 we incurred net losses of $348,000, $530,000 and $10,247,000 respectively. We will have a continuing need for new infusions of cash if we continue to incur losses in the future. We plan to increase our revenues through increased direct sales and marketing efforts on existing products and achieving regulatory approval for other products. If our direct sales and marketing efforts are unsuccessful or we are unable to achieve regulatory approval for our products, we will be unable to significantly increase our revenues. We believe that if we are unable to generate sufficient funds from sales or from debt or equity issuances to maintain our current expenditure rate, it will be necessary to significantly reduce our operations, including our sales and marketing efforts and research and development. If we are required to significantly reduce our operations, our business will be harmed.

We may be required to seek additional sources of financing, which could include short-term debt, long-term debt or equity. Although in the past we have been successful in obtaining financing, most recently through the private placement of equity securities in January 2004, there is a risk that we may be unsuccessful in obtaining financing in the future on terms acceptable to us and that we will not have sufficient cash to fund our continued operations.

Our revenues and operating income may be constrained:

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

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

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

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

The FDA has not approved our PMR laser system for any application in the United States. 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 (MDDRP). In July 2003, the FDA agreed to an alternative process in which additional data in support of our PMA supplement for PMR could be submitted and reviewed by the FDA in an interactive review process. The data was submitted in August 2003 and the independent panel review by the MDDRP was cancelled. The FDA agreed to reschedule the MDDRP hearing in the future if the dispute cannot be resolved. The FDA has informed us that they believe the data submitted in August 2003 in connection with the interactive review process is still not adequate to support approval by the FDA of our PMR system.

In March 2004, the FDA decided not to overturn their previous non-approvable recommendation. The FDA has agreed to meet with us to clarify the pathway for approval of PMR. After meeting with the FDA, we will be in position to determine the next steps for PMR which may include a partnership to complete any necessary additional clinical trials with PMR or pursuit of a hearing with the Medical Device Dispute Resolution Panel. We are currently working with the FDA to establish a meeting date in the near term. There can be no assurance, however, that a suitable partner will be identified on favorable terms that we will receive an approvable determination from the FDA.

We will not be able to derive any revenue from the sale of our PMR system in the United States until such time, if any, that the FDA approves the device. Such inability to realize revenue from sales of our 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 and thereby restrict our ability to generate revenues.

We currently derive approximately 99% of our revenues from our TMR product. The FDA has approved this product for sale and use by physicians in the United States. At the request of the FDA, we are currently conducting post-market surveillance of our TMR product. If we should fail to meet the requirements mandated by the FDA or fail to complete our post-market surveillance study in an acceptable time period, the FDA could withdraw its approval for the sale and use of our TMR product by physicians in the United States. Additionally, although we are

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not aware of any safety concerns during our on-going post-market surveillance of our TMR product, if concerns over the safety of our TMR product were to arise, the FDA could possibly restrict the currently approved uses of our TMR product. In the future, if the FDA were to withdraw its approval or restrict the range of uses for which our TMR product can be used by physicians in the United States, such as restricting TMR s use with the coronary artery bypass grafting procedure, either outcome could lead to reduced or no sales of our TMR product in the United States and our business could be materially and adversely affected.

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

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

fines, injunctions, and civil penalties;

recalls or seizures of products;

total or partial suspensions of production; and

criminal prosecutions.

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

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

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

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

the loss of previously obtained approvals or clearances; or

the failure to comply with existing or future regulatory requirements.

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

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

would significantly reduce international revenue.

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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. If CMS were to materially reduce or terminate Medicare coverage of TMR procedures, our business and results of operation would be harmed.

As PMR has not been approved by the FDA, the CMS has not approved reimbursement for PMR. If we obtain FDA approval for PMR in the future and CMS does not in the 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. We have limited experience to date with the acceptability of our TMR procedures for reimbursement by private insurance and private health plans. If private insurance and private health plans do not provide reimbursement, our business will suffer.

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

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

We purchase certain critical products and components for lasers and disposable handpieces from single sources. Moreover, we are currently exploring manufacturing outsourcing options for the TMR 2000 laser. In addition, we are vulnerable to delays and interruptions, for reasons out of our control, because we outsource the manufacturing of our products to third parties. We may experience harm to our business if we cannot timely provide lasers to our customers or if our outsourcing suppliers have difficulties supplying our needs for products and components.

In addition, we do not have long-term supply contracts. As a result, our sources are not obligated to continue to provide these critical products or components to us. Although we have identified alternative suppliers and manufacturers, a lengthy process would be required to qualify them as additional or replacement suppliers or manufacturers. Also, it is possible some of our suppliers or manufacturers could have difficulty meeting our needs if demand for our TMR and PMR laser systems were to increase rapidly or significantly. We believe that we have an adequate supply of lasers to meet our expected demand for the next twelve months and currently expect to have production capacity for our TMR 2000 laser by the fourth quarter of 2004. However, if demand for our TMR 2000 laser is greater than we currently anticipate and there is a delay in obtaining production capacity, unless we are able to obtain lasers originally placed through our loaned laser program and no longer utilized by a hospital, we may not be

able to meet the demand for our TMR 2000 laser. In addition, any defect or malfunction in the laser or other products provided by our suppliers and manufacturers could cause delays in regulatory approvals or adversely affect product acceptance. Further, we cannot predict:

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

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

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

In 2001 we began a restructuring of our business in order, in part, to bring our cost structure more in line with our revenues. As part of this restructuring we significantly reduced our workforce. Growth in our business may place a significant strain on our limited personnel, management, financial systems and other resources. The evolving growth of our business presents numerous risks and challenges, including:

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

Our common stock is listed on the OTC Bulletin Board which may have an unfavorable impact on our stock price and liquidity.

Effective April 3, 2003 our common stock was delisted from The Nasdaq SmallCap Market and became quoted on the OTC Bulletin Board on the same day. The OTC Bulletin Board is a significantly more limited market in comparison to the Nasdaq system. The listing of our shares on the OTC Bulletin Board may result in a less liquid market available for existing and potential stockholders to trade shares of our common stock, could ultimately further depress the trading price of our common stock and could have a long-term adverse impact on our ability to raise capital in the future.

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

The stock market has experienced significant price and volume fluctuations that have particularly affected the trading prices of equity securities of many high technology companies. These fluctuations have often been unrelated or disproportionate to the

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operating performance of many of these companies. Any negative change in the public s perception of medical device companies could depress our stock price regardless of our operating results.

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

The market price of our common stock has been and may continue to be volatile. For example, during the 52-week period ended May 6, 2004, the closing prices of our common stock as reported on the OTC Bulletin Board ranged from a high of $1.92 per share to a low of $0.59 per share. We expect our stock price to be subject to fluctuations as a result of a variety of factors, including factors beyond our control. These factors include:

actual or anticipated variations in our quarterly operating results;

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

announcements relating to strategic relationships or acquisitions;

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

statements by securities analysts regarding us or our industry;

conditions or trends in the medical device industry; and

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

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

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

The market for TMR laser systems is competitive. We currently compete with PLC Systems, a publicly traded company which uses a CO2 laser and an articulated mechanical arm in its TMR products. Edwards Lifesciences, a well known, publicly traded provider of products and technologies to treat cardiovascular disease, has assumed full sales and marketing responsibility in the U.S. for PLC s TMR Heart Laser 2 System and associated kits pursuant to a co-marketing agreement between the two companies executed in January 2001. Through its significantly greater financial and human resources, including a well-established and extensive sales representative network, we believe Edwards has the potential to market to a greater number of hospitals and doctors that we currently can. If PLC, or any new competitor, is more effective than we are in developing new products and procedures and marketing existing and future products similar to ours, our business will suffer.

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

are more effective than our products;

are more effectively marketed than our products; or

may render our products or technology obsolete.

If we obtain the FDA s approval for our 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;

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obtain third party reimbursement acceptance; and

supply adequate quantities of the product to the market.

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

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

obtain patent protection for our products and processes;

preserve our trade secrets and proprietary technology; and

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

The medical device industry has been characterized by extensive litigation regarding patents and other intellectual property rights. Companies in the medical device industry have employed intellectual property litigation to gain a competitive advantage. Certain competitors and potential competitors of ours have obtained United States patents covering technology that could be used for certain TMR and 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.

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

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

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

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

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

Furthermore, we cannot assure you that our competitors:

have not developed or will not develop similar products;

will not duplicate our products; or

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

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

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

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

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

We are exposed to potential product liability claims and product recalls. These risks are inherent in the design, development, manufacture and marketing of medical devices. We could be subject to product liability claims if the use of our TMR or 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.

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

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

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

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

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

Our future business and results of operations depend in significant part upon the continued contributions of our key technical and senior management personnel. They also depend in significant part upon our ability to attract and retain additional qualified management, technical, marketing and sales and support personnel for our operations. If we lose a key employee or if a key employee fails to perform in his or her current position, or if we are not able to attract and retain skilled employees as needed, our business could suffer. Significant turnover in our senior management could significantly deplete our institutional knowledge held by our existing senior management team. For example, in November 2003, our employment relationship with Darrell Eckstein, our former President, Chief Operating Officer, Acting Chief Financial Officer, Chief Accounting Officer, Treasurer and Secretary was terminated. We depend on the skills and abilities of these key employees in managing the manufacturing, technical, marketing and sales aspects of our business, any part of which could be harmed by further turnover.

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

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

foreign currency fluctuations;

economic or political instability;

foreign tax laws;

shipping delays;

various tariffs and trade regulations;

restrictions and foreign medical regulations;

customs duties, export quotas or other trade restrictions; and

difficulty in protecting intellectual property rights.

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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.

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, 2004 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	2004	2005	2006	2007	2008	Total Fair Value
Assets						
Cash, cash equivalents	$3,051	$	$	$	$	$3,051
Weighted average interest rate	0.2%					0.2%
Liabilities						
Fixed Rate Debt						
Lease obligation	$ 21	$	$	$	$	$ 21
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.

Currency Rate Risk. 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.

Item 4. Controls and Procedures

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

files with the SEC within the required time periods.

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

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Part II Other Information

Item 1. Legal Proceedings

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

Item 2. Changes in Securities and Use of Proceeds

On January 22, 2004, we entered into a Securities Purchase Agreement with certain institutional investors pursuant to which the Company issued in a private placement 3,139,535 shares of its common stock. In addition, the Company issued to the investors two sets of warrants to acquire common stock. The first set of warrants are immediately exercisable for a period of five years for up to an aggregate of 3,139,535 shares of common stock at an exercise price of $1.37 per share. The second set of warrants are exercisable for up to an aggregate of 1,569,768 shares of common stock at an exercise price of $1.00 per share for a period ending September 30, 2004. There were no underwriters involved in the issuance and sale of these securities. Commissions of $162,000 were paid to a placement agent. We relied on the exemption from registration provided by Section 4(2) of the Securities Act.

Item 3. Defaults Upon Senior Securities

None.

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

None.

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

Exhibit 3.2(2)	Certificate of Amendment of Restated Articles of Incorporation, as filed with California Secretary of State on July 18, 2001
Exhibit 3.3(3)	Certificate of Determination of Preferences of Series A Preferred Stock, as filed with the California Secretary of State on August 23, 2001
Exhibit 3.4(4)	Certificate of Amendment of Restated Articles of Incorporation, as filed with the California Secretary of State on January 23, 2004
Exhibit 3.5(5)	Amended and Restated Bylaws
Exhibit 4.1(6)	Form of Common Stock Purchase Warrant issued in connection with Facilities Lease for 26632 Towne Center Drive, Suite 320, Foothill Ranch, California
Exhibit 4.2(7)	Second Amendment to Rights Agreement, dated as of January 21, 2004, between CardioGenesis Corporation and EquiServe Trust Company, N.A., as Rights Agent

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(1) Incorporated by reference to Exhibit 3.1 to the Registrant s Registration Statement on Form S-1/A (File No. 33-03770), filed on May 21, 1996
(2) Incorporated by reference to Exhibit 3.2 to the Registrant s Quarterly Report on Form 10-Q filed on August 14, 2001

(3) Incorporated by reference to Exhibit 4.2 to the Registrant s Current Report on Form 8-K filed on August 14, 2001

(4) Incorporated by reference to Exhibit 3.1.4 to the Registrant s Annual Report on Form 10-K filed on March 10, 2004

(5) Incorporated by reference to Exhibit 3.2 to the Registrant s Annual Report on Form 10-K filed on March 10, 2004

(6) Incorporated by reference to Exhibit 10.1 to the Registrant s Quarterly Report on Form 10-Q/A filed on August 16, 2001

(7) Incorporated by reference to Exhibit 4.1 to the Registrant s Current Report on Form 8-K filed January 22, 2004

(8) Incorporated by reference to Exhibit 4.1 to the Registrant s Current Report on Form 8-K filed January 18, 2002

(9) Incorporated by reference to Exhibit 4.1 to the Registrant s Current Report on Form 8-K filed August 20, 2001

(10) Incorporated by reference to Exhibit 4.2 to the Registrant s Current Report on Form 8-K filed April 12, 2002

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(11) Incorporated by reference to Exhibit 4.4 to the Registrant s Current Report on Form 8-K filed January 22, 2004

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

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

(14) Incorporated by reference to Exhibit 4.7 to the Registrant s Current Report on Form 8-K filed January 22, 2004

b) Reports on Form 8-K

1. The Registrant filed Form 8-K on January 26, 2004, announcing the completion of a private placement of common stock and warrants by the Registrant and certain related transactions. .

2. The Registrant filed Form 8-K on February 26, 2004, announcing Registrant s 2003 fourth quarter and year end financial results.

3. The Registrant filed Form 8-K on March 25, 2004, announcing that the U.S. Food and Drug Administration was unable to reach a favorable outcome with respect to the Company s supplemental premarket approval application for Percutaneous Myocardial Revascularization (PMR).

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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 17, 2004

/s/ Michael J. Quinn

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

Date: May 17, 2004

/s/ Christine Ocampo

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