CARDIOGENESIS CORP /CA
Form 10-Q
August 14, 2001

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U.S. 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, 2001

Commission file number 0-28288

CARDIOGENESIS CORPORATION
(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, CA 92610
(Address of principal executive offices)

(714) 649-5000
(Registrant's telephone number, including area code)

ECLIPSE SURGICAL TECHNOLOGIES, INC.
1049 KIEL COURT, SUNNYVALE, CA 94089
(Registrant's Former Name and Former Address)

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.

34,209,065 shares of Common Stock, no par value
As of July 31, 2001

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CARDIOGENESIS CORPORATION
CONSOLIDATED BALANCE SHEETS
(IN THOUSANDS, EXCEPT SHARE AMOUNTS)

ASSETS

Current assets:
Cash and cash equivalents .....
Accounts receivable, net of allowance for doubtful accounts of $557 and $353 at June 30, 2001 and December 31, 2000, respectively .....
Inventories, net of reserves of $1,518 and $2,180 at June 30, 2001 and

December 31, 2000, respectively .....
Prepaids and other current assets .....

Total current assets .....
Property and equipment, net .....
Accounts receivable over one year, net of allowance for doubtful accounts of $0 and $443 at June 30, 2001 and December 31, 2000, respectively .....
Other assets .....

Total assets .....

LIABILITIES AND SHAREHOLDERS' EQUITY

Current liabilities:
Accounts payable .....
Accrued liabilities .....
Customer deposits .....
Deferred revenue .....
Note payable .....
Current portion of capital lease obligation .....
Current portion of long-term liabilities .....

Total current liabilities .....
Capital lease obligation, less current portion .....
Long-term liabilities, less current portion .....

Total liabilities .....

Shareholders' equity:
Common stock:
No par value; 50,000,000 shares authorized; 34,209,000 and 30,836,000 shares issued and outstanding at June 30, 2001 and December 31, 2000, respectively .....
Deferred compensation .....
Accumulated other comprehensive loss .....
Accumulated deficit .....

Total shareholders' equity .....

Total liabilities and shareholders' equity .....

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

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CARDIOGENESIS CORPORATION
CONSOLIDATED STATEMENTS OF OPERATIONS & COMPREHENSIVE LOSS
(IN THOUSANDS, EXCEPT PER SHARE AMOUNTS)
(UNAUDITED)

	THREE MONTHS ENDED JUNE 30,	
	2001	2000

Net revenues	$ 4,030	$ 6,608
Cost of revenues	1,583	2,698
Gross profit	2,447	3,910
Operating expenses:		
Research and development	706	1,308
Sales and marketing	2,396	4,345
General and administrative	1,360	1,655
Restructuring costs	690	--
Total operating expenses	5,152	7,308
Operating loss	(2,705)	(3,398)
Interest expense	(2)	(8)
Interest income	35	144
Equity in net loss of investee	(295)	--
Net loss	(2,967)	(3,262)
Other comprehensive income (loss):		
Unrealized holding gains (losses) arising during period	(3)	(9)
Less: reclassification adjustment for gains included in net income	--	--
Foreign currency translation adjustment	60	--
Other comprehensive income (loss)	57	(9)
Comprehensive loss	$ (2,910)	$ (3,271)
Net loss per share:		
Basic and diluted	$ (0.09)	$ (0.11)
Weighted average shares outstanding	33,631	30,064

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,	
	2001	2000

Cash flows from operating activities:		
Net loss	$(5,404)	$(7,7
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation and amortization	246	4
Loss from equity in investee	652	
Provision for doubtful accounts	109	3
Inventory reserves	670	9
Amortization of deferred compensation	56	4
Accretion of long-term liability	19	
Amortization of license fees	98	
Changes in operating assets and liabilities:		
Accounts receivable - short term	497	2,0
Inventories	127	(9
Prepaids and other current assets	(249)	(1
Accounts receivable - long term	(138)	8
Accounts payable	(109)	(5
Accrued liabilities	(100)	(2,6
Current portion of long term liabilities	--	(4
Long term liabilities	(250)	(1
Customer deposits	--	
Deferred revenue	(249)	(
Net cash used in operating activities	(4,025)	(7,5
Cash flows from investing activities:		
Purchase of marketable securities	--	(4,6
Maturities of marketable securities	--	8,0
Acquisition of property and equipment	(19)	(1
Net cash (used in) provided by investing activities	(19)	3,2
Cash flows from financing activities:		
Net proceeds from sales of common stock and from issuance of common stock from exercise of options	3,709	1,2
Proceeds from short term borrowings	305	4
Repayments of capital lease obligations	(14)	(
Net cash provided by financing activities	4,000	1,6
Effects of exchange rate changes on cash and cash equivalents	33	
Net (decrease) increase in cash and cash equivalents	(11)	(2,6
Cash and cash equivalents at beginning of period	3,357	5,5
Cash and cash equivalents at end of period	$ 3,346	$ 2,9
Supplemental schedule of cash flow information:		
Interest paid	$ 2	$
Taxes paid	$ 26	$
Supplemental schedule of noncash investing and financing activities:		
Change in unrealized gain (loss) on marketable securities	$ --	$ (
Deferred compensation	$ 11	$ 1
Issuance of warrants	$ 94	$

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

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 Corporation's (formerly known as Eclipse Surgical Technologies, Inc.) audited financial statements and notes thereto for the year ended December 31, 2000, 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 Corporation ("CardioGenesis") has sustained significant losses for the last several years. CardioGenesis will require additional funding and may sell additional shares of its common stock or preferred stock through private placement or further public offerings. (See Note 5).

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 equity or debt financing may involve substantial dilution to CardioGenesis' stockholders, restrictive covenants or high interest costs. The failure to raise needed funds on sufficiently favorable terms could have a material adverse effect on CardioGenesis' business, operating results and financial condition.

CardioGenesis' long-term liquidity also depends upon its ability to increase revenues from the sale of its products and achieve profitability. The failure to achieve these goals could have a material adverse effect on the business, operating results and financial condition.

Net Loss Per Share:

Basic earnings per share is the weighted-average number of common shares outstanding during the period, and diluted earnings per share is computed by dividing net loss by the weighted-average common shares outstanding and all dilutive potential common shares outstanding. For the three and six months ended June 30, 2001 and 2000 dilutive potential common shares outstanding reflects shares issuable under the Company's stock option plans and warrants. There are no reconciling items in the numerator or denominator of the earnings per share calculation for the periods presented.

Options and warrants to purchase 3,186,412 and 3,469,303 shares of common stock were outstanding at June 30, 2001 and 2000 respectively, but were not included in the calculation of diluted EPS because their inclusion would have been antidilutive.

2. Inventories:

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

	JUNE 30, 2001 (UNAUDITED)	DECEMBER 31, 2000
Raw materials .	$1,425	$2,045
Work in process	770	715
Finished goods	2,408	2,640
	$4,603	$5,400

3. Restructuring Costs:

In the second quarter of 2001, the Company recognized one-time restructuring charges of $690,000 related to a company-wide restructuring which included a reduction in headcount, outsourcing of manufacturing and the move to a new, less costly facility located in Foothill Ranch, CA. In addition, progress was made towards completing the close of the CardioGenesis B.V. office located in the Netherlands.

The following table summarizes the restructuring costs (in thousands).

DESCRIPTION	AMOUNT (unaudited)
Personnel severance	$140
Employee relocation	100
Penalty for early termination of Sunnyvale facility lease ...	210
Closing of Netherlands office	135
Other costs including fixed asset write-offs and moving costs	105
Total	$690

The following table summarizes the Company's restructuring reserve balances (in thousands):

RESTRUCTURING ACTIVITY FOR THE THREE MONTH PERIOD ENDED JUNE 30, 2001	AMOUNT
	(unaudited)
Original balance	$690
Less:	
Non-cash charges	58
Cash payments	98
Restructuring Reserve balance at June 30, 2001	534

The restructuring reserve balance is included in accrued liabilities.

4. Recently Issued Accounting Standards:

In July 2001, the Financial Accounting Standards Board (FASB) issued Statement of Financial Accounting Standards (SFAS) No. 141 "Business Combinations," and SFAS No. 142 "Goodwill and Other Intangible Assets," which change the accounting for business combinations and goodwill. SFAS No. 141 requires that the purchase

method of accounting be used for business combinations initiated after June 30, 2001. Use of the pooling-of-interests method will be prohibited. SFAS No. 142 changes the accounting for goodwill from an amortization method to an impairment-only approach. Amortization of goodwill, including goodwill recorded in past business combinations, will therefore cease upon adoption of the Statement, which for the Company will be January 1, 2002. The Company is currently evaluating SFAS No. 141 and SFAS No. 142, but does not expect that they will have a material effect on its financial statements.

5. Subsequent Events:

In August 2001, the Company established a $2 million asset-based line of credit with Pacific Business Funding, a division of Cupertino National Bank. As of August 2001, the Company has access to the entire $2 million credit line based on qualifying assets. The agreement expires in August of 2002 and provides the Company with the option of borrowing at an annual rate of 12% plus an administrative fee of 0.50%.

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, formerly Eclipse Surgical Technologies, Inc., 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 transmyocardial revascularization ("PMR").

On February 11, 1999, we received final approval from the Food and Drug Administration ("FDA") for our TMR products for certain indications, and we are now able to sell those products in the U.S. on a commercial basis. We have also received the European Conforming Mark ("CE Mark") allowing the commercial sale of our TMR laser systems and our PMR catheter system to customers in the European Community. Effective July 1, 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 completed pivotal clinical trials involving PMR, and study results were submitted to the FDA in a Pre-Market Approval ("PMA") application in December of 1999. On July 9, 2001, the Food and Drug Administration's Circulatory Devices Panel recommended against approval by the Food and Drug Administration of 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 clinical trials. The Advisory Panel cited a concern about complications reported in the treated patients. While these individual events were not statistically significant between the treated group and the control group, they were still a concern for the Advisory Panel. We expect to be able to provide additional follow up data and analysis to address these safety concerns.

RESULTS OF OPERATIONS

Net Revenues

Net revenues of $4,030,000 for the quarter ended June 30, 2001 decreased $2,578,000 or 39% from $6,608,000 for the quarter ended June 30, 2000. Net revenues of $7,141,000 for the six months ended June 30, 2001 decreased $5,144,000 or 42% from $12,285,000 for the six months ended June 30, 2000. The decrease on both the three month and six month comparisons is due to a decline in the unit sales of both lasers and disposables related to a sales force transition during the six month period ending June 30, 2001.

At year-end, a sales force transition plan was initiated and was completed in the second quarter of 2001. New sales representatives were hired to fill territories resulting from general attrition and the release of sales

representatives who did not meet company sales objectives. As a result of the transitioning sales force, disposable sales fell 13% in units domestically from the quarter ended June 30, 2000 to the same period in 2001. Disposable sales fell 18% in units domestically from the six-month period ended June 30, 2000 to the same period in 2001.

Gross Profit

Gross profit was $2,447,000 or 61% of net revenues for the quarter ended June 30, 2001 compared to $3,910,000 or 59% of net revenues for the quarter ended June 30, 2000. Gross profit decreased to $4,023,000 or 56% of net revenues for the six months ended June 30, 2001 compared to $7,256,000 or 59% of net revenues for the six months ended June 30, 2000. The decline in gross profit resulted from lower net revenues. The improvement in gross margin for the three months ended June 30, 2001 from the three months ended June 30, 2000 resulted from an increase in production during the period. With increased production, the fixed cost component of cost of goods sold was spread over more units and thus, lowering the costs of goods sold on a per unit basis.

Research and Development

Research and development expenditures of $706,000 decreased $602,000 or 46% for the quarter ended June 30, 2001 from $1,308,000 for the quarter ended June 30, 2000. The decrease in expenses from the three month period ended June 30, 2000 to the same period in 2001 resulted from a decrease in employee expenses of $440,000 related to the December 2000 reduction in force, a decrease in clinical trials expenses of $70,000 related to the conclusion of several of our major clinical trials, a decrease in consulting expenses of $90,000 and a decrease in development project expenses of $70,000. These decreases were offset by an increase in consulting expenses of $160,000 related to the preparation for the July 9, 2001 FDA panel meeting.

Research and development expenditures of $1,249,000 decreased $1,846,000 or 60% for the six months ended June 30, 2001 from $3,095,000 for the six months ended June 30, 2000. The decrease in expenses from the six-month period ended June 30, 2000 to the same period in 2001 resulted from a reduction in employee expenses of $690,000 related to the December 2000 reduction in force and a reduction in clinical trials expenses of $690,000 related to the conclusion of several of our major clinical trials. Additionally, expenditures for engineering have decreased due to a reduction in development activities.

Sales and Marketing

Sales and marketing expenditures of $2,396,000 decreased $1,949,000 or 45% for the quarter ended June 30, 2001 from $4,345,000 for the quarter ended June 30, 2000. The decrease resulted from a reduction in employee expenses of $1,570,000 related to the elimination of 15 clinical sales positions coupled with a major transition in the sales force, which began at the end of 2000 and was concluded in the second quarter of 2001. Additionally, expenses for physician training decreased by $200,000 and general marketing expenses decreased by $150,000.

Sales and marketing expenditures of $4,348,000 decreased $4,546,000 or 51% for the six months ended June 30, 2001 from $8,894,000 for the six months ended June 30, 2000. The decrease resulted from a reduction in employee expenses of $2,740,000 related to the elimination of 15 clinical sales positions coupled with a major transition in the sales force, which began at the end of 2000 and was concluded in the second quarter of 2001.

Additionally, expenses for physician training decreased by $350,000, the cost of materials used by the service department decreased by $170,000 and general marketing expenses decreased by $250,000.

General and Administrative

General and administrative expenses of $1,360,000 decreased $295,000 or 18% for the quarter ended June 30, 2001 from $1,655,000 for the quarter ended June 30, 2000. The decrease is mainly due to a $140,000 reduction in deferred compensation expense for stock options granted to consultants and a decrease in consulting expenses of $140,000.

General and administrative expenses of $2,546,000 decreased $665,000 or 21% for the six months ended June 30, 2001, compared to $3,211,000 for the six months ended June 30, 2000. The decrease is mainly due to a $360,000 reduction in deferred compensation expense for stock options granted to consultants and a decrease of $350,000 in consulting expenses.

Restructuring Costs

In the second quarter of 2001, we recognized one-time restructuring charges of $690,000 related to a company-wide restructuring which included a reduction in headcount, outsourcing of manufacturing and the move to a new, less costly facility located in Foothill Ranch, CA. In addition, progress was made towards completing the close of the CardioGenesis B.V. office located in the Netherlands.

The following table summarizes the restructuring costs (in thousands).

DESCRIPTION	AMOUNT
Personnel severance	$140
Employee relocation	100
Penalty for early termination of Sunnyvale facility lease	210
Closing of Netherlands office	135
Other costs including fixed asset write-offs and moving costs	105
Total	$690

In addition, the relocation of our corporate headquarters resulted in one-time charges that were not classified as restructuring charges but are a component of operating expenses in the quarter ended June 30, 2001. These one-time charges resulted from the termination of almost 50 positions of which approximately 10 of the positions were replaced. As a result, we incurred one-time charges of $150,000 related to duplicate salaries for positions where a replacement employee was hired and a Sunnyvale employee was retained through a short transition period. We also incurred $50,000 in travel costs for employees who traveled to the Sunnyvale office until the new Foothill Ranch office opened in June 2001.

Non-Operating Expenses

Equity in net loss of investee of $295,000 in the quarter ended June 30, 2001 and $652,000 for the six months ended June 30, 2001 represents our share of

the net loss of Microheart Holdings, Inc., a privately held company of which our ownership is 31.1%.

Interest income of $35,000 in the quarter ended June 30, 2001 declined 76% or $109,000 compared to $144,000 in the quarter ended June 30, 2000. Interest income of $65,000 in the six months ended June 30, 2001 declined 75% or $195,000 compared to $260,000 in the six months ended June 30, 2000. The reduction in interest income was a result of lower investments in marketable securities, cash and cash equivalents.

LIQUIDITY AND CAPITAL RESOURCES

Cash and cash equivalents were $3,346,000 at June 30, 2001 compared to $3,357,000 at December 31, 2000. We used $4,025,000 of cash for operating activities in the six-month period ended June 30, 2001 which was used primarily to fund our operating losses. In addition, a decrease in accounts receivable provided $500,000 in cash offset by a decrease in long-term liabilities of $230,000. Investing activities provided cash of $19,000 in the first six months of 2001. Financing activities provided cash of $4,000,000 in the first six months of 2001, primarily from the issuance of common stock and the exercise of employee stock options.

Since our inception, we have satisfied our capital requirements primarily through sales of our equity securities. In addition, our operations have been funded in part through sales of our products.

In March 2001, we sold 898,202 shares of common stock to Acqua Wellington North American Equities Fund, Ltd. at a negotiated purchase price of $1.1133 per share. We did not pay any other compensation in conjunction with the sale of our common stock. In April 2001, the Board adopted an amendment to our Bylaws which precludes the Company from entering into or exercising any rights under any equity line agreement, including the Acqua Wellington equity line agreement, unless approval from the shareholders holding a majority of the shares is obtained.

In April 2001, we sold 2,000,000 shares of common stock to a governmental entity at a negotiated purchase price of $1.00 per share. We did not pay any other compensation in conjunction with the sale of our common stock.

In August 2001, the Company established a $2 million asset based line of credit with Pacific Business Funding, a division of Cupertino National Bank. As of August 2001, the Company has access to the entire $2 million credit line based on qualifying assets. The agreement expires in August of 2002 and provides the Company with the option of borrowing at an annual rate of 12% plus an administrative fee of 0.50%.

We have incurred significant losses for the last several years and as of June 30, 2001 we had an accumulated deficit of $159,237,000. The accompanying 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 direct sales and marketing efforts of existing products and pursuing regulatory approval for certain other products for which clinical trials have been completed. We also plan to continue our cost containment efforts that are focused both on reducing cost of revenues and on bringing operating expenses in line with revenues. With regard to reducing cost of revenues, we are in the process of outsourcing our manufacturing which allows us to produce at lower levels of costs. With regard to reducing operating expenses, we have focused our

efforts on reducing headcount and overall expenses in functions that are not essential to critical activities.

Currently, one of the primary goals of the Company is to achieve break-even followed by profitability within a relatively short span of time. In many respects, the Company's actions have been guided by this imperative, and the resulting cost containment measures have helped to conserve our cash. The focus of the Company is upon critical activities, thus production activities and operating expenses that are nonessential to our core operations have been or are in the process of being eliminated.

We believe our cash balance as of June 30, 2001 and borrowings available under our new asset-based line of credit will be sufficient to meet our capital and operating requirements through the end of 2001. In September 2000, March 2001 and April 2001, we raised approximately $1,873,000, $1,000,000 and $1,895,000, respectively, net of offering costs, from the sale of shares of common stock. We believe that if revenue from sales or new funds from debt or equity instruments is insufficient to maintain the current expenditure rate, it will be necessary to significantly reduce our operations until an appropriate solution is implemented.

RECENTLY ISSUED ACCOUNTING STANDARDS

In July 2001, the Financial Accounting Standards Board (FASB) issued Statement of Financial Accounting Standards (SFAS) No. 141 "Business Combinations," and SFAS No. 142 "Goodwill and Other Intangible Assets," which change the accounting for business combinations and goodwill. SFAS No. 141 requires that the purchase method of accounting be used for business combinations initiated after June 30, 2001. Use of the pooling-of-interests method will be prohibited. SFAS No. 142 changes the accounting for goodwill from an amortization method to an impairment-only approach. Amortization of goodwill, including goodwill recorded in past business combinations, will therefore cease upon adoption of the Statement, which for the Company will be January 1, 2002. The Company is currently evaluating SFAS No. 141 and SFAS No. 142, but does not expect that they will have a material effect on its financial statements.

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 timely regulatory approval for other products under clinical trials. If we are unable to increase our sales or achieve timely 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. This would raise substantial doubt about our ability to continue as a going concern. We may be required to seek additional sources of financing, which could include short-term debt, long-term debt or equity. There is a risk that we may be unsuccessful in obtaining such

financing and will not have sufficient cash to fund our operations.

WE MAY FAIL TO OBTAIN REQUIRED REGULATORY APPROVALS TO MARKET OUR PRODUCTS INCLUDING OUR PMR LASER SYSTEM IN THE UNITED STATES.

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 PMR study compares PMR to conventional medical therapy in patients with no option for other treatment. The Food and Drug Administration may not accept the study as safe and effective, and PMR may not be approved for commercial use in the United States. Responding to Food and Drug Administration requests for additional information could require substantial financial and management resources and take several years.

In October 2000, preliminary results from a competitor's clinical trial of a catheter-based device employing Direct Myocardial Revascularization also known as DMR were presented at a medical conference in Washington D.C. The trial's principal investigator concluded that this catheter-based device did not show significant evidence of clinical benefit with regard to angina class reduction or exercise tolerance, and questioned the efficacy of other devices and procedures relying on TMR. We believe that the preliminary results of that catheter-based device study should not call the results of our PMR study into question because the devices and procedures are substantially different. We cannot predict, however, how those preliminary results of that catheter-based device study will impact the Food and Drug Administration's decision on our PMR system.

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. Though we are not aware of any safety concerns during our on-going postmarket 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 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, it could lead to reduced sales of our TMR product and our business could be adversely affected.

THE CIRCULATORY DEVICES PANEL OF THE FOOD AND DRUG ADMINISTRATION RECENTLY RECOMMENDED AGAINST APPROVAL OF OUR PMR DEVICE FOR PUBLIC SALE AND USE IN THE UNITED STATES, WHICH HAS EFFECTIVELY DELAYED POTENTIAL REVENUE, IF ANY, THAT MAY HAVE BEEN DERIVED IN THE FUTURE FROM THE SALE OF THAT DEVICE IN THE UNITED STATES AND WHICH MAY HAVE OTHER ADVERSE EFFECTS.

The Circulatory Devices Panel of the Food and Drug Administration recently recommended 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. If the Food and Drug Administration accepts the recommendation of the Advisory Panel and does not approve our PMR device for public sale and use in the United States, 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 will have an adverse effect on our results of operations. Additionally, the trading price of our common stock on the NASDAQ National Market fell substantially after the panel's recommendation became public. If our common stock were to trade under $1.00 for 30 consecutive days on the NASDAQ National Market, our common stock could be subject to certain consequences established by the NASDAQ National Market, such as being delisted. If our common stock were delisted, then we could apply for listing on the Nasdaq SmallCap Market, subject to Nasdaq's approval. If our common stock is not approved for trading on the Nasdaq SmallCap Market, then our common stock would trade only in the secondary markets in the so-called "pink sheets" or Nasdaq's "OTC Bulletin Board." Delisting from the Nasdaq National Market could adversely affect the liquidity and price of our common stock and it could have a long-term adverse impact on our ability to raise capital in the future.

THE MEDICAL COMMUNITY HAS NOT BROADLY ADOPTED OUR PRODUCTS, AND UNLESS OUR PRODUCTS ARE BROADLY ADOPTED, OUR BUSINESS WILL SUFFER.

Our TMR products have not yet achieved broad commercial adoption, and our PMR products are experimental and have not yet achieved broad 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. Even if the clinical efficacy of TMR and PMR laser systems is established, physicians may elect not to recommend TMR and PMR laser systems for any number of reasons.

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 then 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 for investigational use only. We have been expanding our operations by hiring additional sales and marketing personnel. This has required and will continue to require substantial management effort and financial resources.

IF OUR SALES FORCE IS NOT SUCCESSFUL IN INCREASING MARKET SHARE AND SELLING OUR DISPOSABLE HANDPIECES, OUR BUSINESS WILL SUFFER.

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. In the fourth quarter of 1999, we changed our U.S. sales strategy to include both selling lasers to hospitals outright, as well as loaning lasers to hospitals in return for the hospital purchasing a minimum number of disposable handpieces at a higher price. During the current year, the majority of lasers shipped have been under this loan program. The purpose of this strategy is to focus our sales force on increasing market penetration and selling disposable handpieces used in connection with our TMR procedure.

THE 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 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;
- completing the clinical trials that are currently in progress as well as developing and preparing additional products for clinical trials;
- the highly competitive nature of the medical devices industry; and

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

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To accommodate any such growth and compete effectively, we must 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 due to a number of events and factors, including:

- the level of product demand and the timing of customer orders;
- changes in strategy;
- delays associated with the Food and Drug Administration and other regulatory approval processes;
- personnel changes including our ability to continue to attract, train and motivate additional qualified personnel in all areas;
- the level of international sales;
- changes in competitive pricing policies;
- the ability to develop, introduce and market new and enhanced versions of products on a timely basis;
- deferrals in customer orders in anticipation of new or enhanced products;
- product quality problems; and
- the enactment of health care reform legislation and any changes in third party reimbursement policies.

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.

GROWTH IN OUR FUTURE OPERATING RESULTS IS HIGHLY CONTINGENT AND SUBJECT TO SIGNIFICANT RISKS.

Our future operating results will be significantly affected by our ability to:

- successfully and rapidly expand sales to potential customers;
- implement operating, manufacturing and financial procedures and controls;
- improve coordination among different operating functions; and
- achieve manufacturing efficiencies as production volume increases.

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 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 and equipment. The Health Care Financing Administration may not approve reimbursement for PMR. If it does not provide reimbursement, our ability to successfully market and sell our PMR products will be harmed. We have limited experience to date with the acceptability of our TMR procedures for reimbursement by private insurance and private health plans and thus do not have reliable data as to the success of our patients in obtaining reimbursement for the costs of our TMR products outside of the Medicare system. Private insurance and private health plans may not approve reimbursement TMR or PMR procedures. If they do not provide reimbursement, our business will suffer.

Potential purchasers must determine whether the clinical benefits of our TMR and PMR laser systems justify:

- the additional cost or the additional effort required to obtain prior authorization or coverage; and
- the uncertainty of actually obtaining such authorization or coverage.

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. 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.

We currently compete with PLC Systems. PLC recently announced a co-marketing agreement with Edwards Life Sciences to distribute their lasers and disposables which is expected to add another 18 direct domestic sales representatives involved in promoting the PLC technology.

Even with the Food and Drug Administration approval for our TMR 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.

OUR PRODUCTS DEPEND ON TMR TECHNOLOGY THAT IS RAPIDLY CHANGING WHICH MAY REQUIRE US TO INCUR SUBSTANTIAL PRODUCT DEVELOPMENT EXPENDITURES TO PREVENT OUR PRODUCTS FROM BECOMING OBSOLETE.

The medical device industry is characterized by rapid and significant technological change. Our future success will depend in large part on our ability to respond to such changes through further product research and development. In addition, we must expand the indications and applications for our products by developing and introducing enhanced and new versions of our TMR and PMR laser systems. Product research and development requires substantial expenditures and is inherently risky. We may not be able to:

- identify products for which demand exists; or
- develop products that have the characteristics necessary to treat particular indications.

OVERALL INCREASES IN MEDICAL COSTS COULD ADVERSELY AFFECT OUR BUSINESS.

We believe that the overall escalating cost of medical products and services has led, and will continue to lead, to increased pressures on the health care industry, both foreign and domestic, to reduce the cost of products and services, including products offered by them. We cannot assure you that in either United States or international markets that:

- third party reimbursement and coverage will be available or adequate;
- current reimbursement amounts will not be decreased in the future; or
- future legislation, regulation or reimbursement policies of third party payors will not otherwise adversely affect the demand for our products or our ability to profitably sell our products.

Fundamental reforms in the healthcare industry in the United States and Europe continue to be considered. We cannot predict whether or when any

healthcare reform proposals will be adopted and what effect such proposals might have on our business.

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.

In September 1995, one of our competitors sent us a notice of potential infringement of their patent regarding a method for TMR utilizing synchronization of laser pulses to the electrical signals from the heart. After discussion with patent counsel, we concluded that we did not utilize the process and/or apparatus that was the subject

of the patent at issue, and we provided a response to the competitor to that effect. We have not received any additional correspondence from this competitor on these matters.

In 1996, prior to the merger with us, the company formerly known as CardioGenesis Corporation initiated a suit in the United States against PLC seeking a judgment that the PLC patent is invalid and unenforceable. In 1997, PLC counterclaimed in that suit alleging infringement by the former CardioGenesis Corporation of the PLC patent. Also in 1997, PLC initiated suit in

Germany against the former CardioGenesis Corporation and the former CardioGenesis Corporation's former German sales agent alleging infringement of a European counterpart to the PLC patent. In 1997, the former CardioGenesis Corporation filed an Opposition in the European Patent Office to a European counterpart to the PLC patent, seeking to have the European patent declared invalid.

On January 5, 1999, before trial on the United States suit commenced, the company formerly known as CardioGenesis Corporation and PLC settled all litigation between them, both in the United States and in Germany, with respect to the PLC patent and the European patents. Under the Settlement and License Agreement signed by the parties, the former CardioGenesis Corporation stipulated to the validity of the PLC patents and PLC granted the former CardioGenesis Corporation a non-exclusive worldwide license to the PLC patents. The former CardioGenesis Corporation agreed to pay PLC a license fee, and minimum royalties, totaling $2.5 million in equal monthly installments over an approximately forty-month period, with a running royalty credited against the minimums.

The Settlement and License Agreement applies only to those products or that technology covered by the PLC patents, and the agreement does not provide PLC any rights to any former CardioGenesis Corporation intellectual property. Our TMR 2000 laser system does not use the technology associated with the PLC 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, until recently, maintained in secrecy until patents issue, 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 DEPEND ON SINGLE SOURCE SUPPLIERS FOR KEY COMPONENTS AND PRODUCTION COULD BE INTERRUPTED IF A KEY SUPPLIER HAD TO BE REPLACED.

We currently purchase critical laser and fiber-optic components from single sources. These sources may have difficulties supplying our needs for these 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 components to us. Although we have identified alternative suppliers, a lengthy process would be required to qualify them as additional or replacement suppliers. Any significant interruption in the supply of critical materials or components could delay our ability to manufacture our products and could disrupt our manufacturing operations and harm our business.

LEAD TIMES FOR MATERIALS AND COMPONENTS VARY SIGNIFICANTLY WHICH COULD LEAD TO EXCESS INVENTORY LEVELS AS WELL AS SHORTAGES OF CRITICAL COMPONENTS IF OUR SUPPLY FORECASTS ARE INACCURATE.

We anticipate that products will be manufactured based on forecasted demand and will seek to purchase subassemblies and components in anticipation of the actual receipt of purchase orders from customers. Lead times for materials and components vary significantly and depend on factors such as the business practices of each specific supplier and the terms of particular contracts, as well as the overall market demand for such materials and components at any given time. If the forecasts are inaccurate, we could experience fluctuations in inventory levels, resulting in excess inventory, or shortages of critical components, either of which could cause our business to suffer.

WE MAY NOT BE ABLE TO MEET FUTURE DEMAND INCREASES ON A TIMELY BASIS BECAUSE SOME OF OUR SUPPLIERS COULD HAVE DIFFICULTY MEETING SIGNIFICANT OR RAPIDLY INCREASING ORDER AMOUNTS.

Some of our suppliers could have difficulty expanding their manufacturing capacity to meet 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 could cause a delay in regulatory approvals or adversely affect product acceptance. We cannot predict if:

- materials obtained from outside suppliers will be available in adequate quantities to meet our future needs; or
- replacement suppliers can be qualified on a timely basis if our current suppliers are unable to meet our needs.

WE HAVE LIMITED MANUFACTURING EXPERIENCE WHICH COULD PREVENT US FROM SUCCESSFULLY INCREASING CAPACITY IN RESPONSE TO MARKET DEMAND.

We have limited experience in manufacturing products. In the course of manufacturing our products, we may encounter difficulties in increasing production, including problems involving:

- production yields;
- adequate supplies of components;
- achieving manufacturing efficiencies as production volume increases;
- quality control and assurance (including failure to comply with good manufacturing practices regulations, international quality standards and other regulatory requirements); and
- shortages of qualified personnel.

OUR PRODUCTS CONTAIN DEFECTS WHICH COULD DELAY REGULATORY APPROVAL OR MARKET ACCEPTANCE OF OUR PRODUCTS.

We may experience future product defects, malfunctions, manufacturing difficulties or recalls related to the lasers or other components used in our TMR and PMR laser systems. Any such occurrence could cause a delay in regulatory

approvals or adversely affect the commercial acceptance of our products. We are unable to quantify the likelihood or costs of any such occurrences, but they could potentially be significant. Our business could be harmed because we may be unable to sufficiently remedy a significant product recall while still maintaining our daily manufacturing quotas.

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. Although we have not experienced any product liability claims to date, any such claims could cause our business to suffer.

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, manufacturing, 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 two years, we have had significant change in our senior management team. Our former Chief Executive Officer, Allen Hill, resigned from the company in December 1999. One of our current Directors, Alan Kaganov, acted as interim Chief Executive Officer until we hired our current Chief Executive Officer, Michael Quinn, in October of 2000. Our former Chief Financial Officer, Dick Powers, resigned from the company in July 2000. Ian Johnston, our then Vice President of Finance who resigned in June 2001, acted as interim Chief Financial Officer until our current Chief Financial Officer, J. Stephen Wilkins, was hired in May 2001. Richard Lanigan moved from Vice President of Sales to Vice President of Government Affairs and Business Development in March 2001 and Thomas Kinder was hired in March 2001 as our new Vice President of Worldwide Sales. Darrell Eckstein was hired in December 2000 as our Vice President of Operations, replacing Bill Picht, who resigned earlier in 2000.

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 achieved International Standards Organization and European Union certification for our manufacturing facility. In addition, 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 TMR 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 according to our plan. 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 TMR products in the international markets in which such approvals are sought, which would significantly reduce international revenue.

WE MAY ENGAGE IN FUTURE ACQUISITIONS THAT COULD DISTRACT OUR MANAGEMENT, CAUSE US TO INCUR DEBT, OR DILUTE OUR SHAREHOLDERS.

We may, from time to time, acquire or invest in other complementary businesses, products or technologies. While there are currently no commitments with respect to any particular acquisition or investment, our management frequently evaluates the strategic opportunities available in complementary businesses, products or technologies. The process of integrating an acquired company's business into our operations may result in unforeseen operating difficulties and expenditures and may absorb significant management attention that would otherwise be available for the ongoing development of our business. Moreover, the anticipated benefits of any acquisition or investment may not be realized. Any future acquisitions or investments by us could result in potentially dilutive issuances of equity securities, the incurrence of debt and contingent liabilities and amortization expenses related to goodwill and other intangible assets, any of which could materially harm our operating results.

THE PRICE OF OUR COMMON STOCK MAY FLUCTUATE SIGNIFICANTLY, WHICH MAY RESULT IN LOSSES FOR INVESTORS.

The market price for our common stock has been and may continue to be volatile. For example, during the 52-week period ended August 13, 2001, the closing prices of our common stock as reported on the NASDAQ National Market ranged from a high of $4.68 to a low of $0.50. We expect our stock price to be subject to fluctuations as a result of a variety of factors, including factors beyond our control. These factors include:

- actual or anticipated variations in our quarterly operating results;
- announcements of technological innovations or new products or services by us or our competitors;
- announcements relating to strategic relationships or acquisitions;
- changes in financial estimates by securities analysts;
- statements by securities analysts regarding us or our industry;
- conditions or trends in the medical device industry; and
- changes in the economic performance and/or market valuations of other medical device companies.

Because of this volatility, we may fail to meet the expectations of our shareholders or of securities analysts at some time in the future, and our stock price could decline as a result.

In addition, 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 these companies. Any negative change in the public's perception of medical device companies could depress our stock price regardless of our operating results. If our common stock were to trade under $1.00 for 30 consecutive days on the NASDAQ National

Market, our common stock could be subject to certain consequences established by the NASDAQ National Market such as being delisted. If our common stock were delisted, then we could apply for listing on the Nasdaq SmallCap Market, subject to Nasdaq's approval. If our common stock is not approved for trading on the Nasdaq SmallCap Market, then our common stock would trade only in the secondary markets in the so-called "pink sheets" or Nasdaq's "OTC Bulletin Board." Delisting from the Nasdaq National Market could adversely affect the liquidity and price of our common stock and it could have a long-term adverse impact on our ability to raise capital in the future.

Recently, when the market price of a stock has been volatile, holders of that stock have often instituted securities class action litigation against the company that issued the stock. If any of our shareholders brought such a lawsuit against us, we could incur substantial costs defending the lawsuit. The lawsuit could also divert the time and attention of our management.

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. 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 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, existing long-term debts and any future financing requirements. The long-term debt at June 30, 2001 consists of outstanding balances on lease obligations.

Assets

Cash and cash equivalents.....	$3,346,000
Average interest rate.....	4.0%

PART II OTHER INFORMATION

ITEM 1. LEGAL PROCEEDINGS

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

ITEM 4. SUBMISSION OF MATTERS TO A VOTE OF SECURITY HOLDERS

At CardioGenesis Corporation's Annual Meeting of Shareholders held on June 15, 2001, 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 successors are elected and qualified.

	Number of Shares Voted:	
	For	Withheld
Michael J. Quinn	26,945,345	3,497,500
Jack M. Gill, Ph.D.	26,666,186	3,776,659
Alan L. Kaganov, Sc.D.	29,372,067	1,070,778
Robert L. Mortensen	29,377,235	1,065,610
Robert C. Strauss	29,379,935	1,062,910

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2. To approve an amendment to Eclipse Surgical Technologies, Inc.'s Restated Articles of Incorporation to change the name of Eclipse Surgical Technologies, Inc. to Cardiogenesis Corporation.

Number of Shares Voted:

For	Against	Abstain
28,837,797	413,637	1,191,411

3. To ratify the appointment of PricewaterhouseCoopers LLP as the independent auditors of Eclipse Surgical Technologies, Inc. for the fiscal year ending December 31, 2001.

Number of Shares Voted:

For	Against	Abstain
30,352,767	38,848	51,230

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

Number of Shares Voted:

For	Against	Abstain
26,217,555	4,130,975	94,314

5. To approve an amendment to the Employee Stock Purchase Plan to increase the number of shares of Common Stock reserved for issuance thereunder by 300,000 shares.

Number of Shares Voted:

For	Against	Abstain
29,644,747	715,685	82,413

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
3.1	Amended and Restated Bylaws of CardioGenesis Corporation adopted as of April 11, 2001 herein incorporated by reference from CardioGenesis' Form 8-K filed on April 23, 2001.
3.2	Certificate of Amendment to Articles of Incorporation of CardioGenesis Corporation filed with the Secretary of State of California on June 18, 2001.

b) Reports on Form 8-K

(i) A report on Form 8-K was filed on April 23, 2001, to report under Item 5, Other Events, CardioGenesis' sale of common stock to the State of Wisconsin Investment Board and amendment to CardioGenesis' Bylaws.

(ii) A report on Form 8-K was filed on June 20, 2001, to report under Item 5, Other Events, the change of CardioGenesis' name from its former name of Eclipse Surgical Technologies, Inc. (Nasdaq: ESTI) to CardioGensis Corporation (Nasdaq: CGCP).

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, 2001

/s/ Michael J. Quinn

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

Date: August 14, 2001

/s/ J. Stephen Wilkins

J. Stephen Wilkins
Vice President and Chief

Financial Officer
(Principal Accounting and
Financial Officer)

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EXHIBIT INDEX

EXHIBIT NUMBER	DESCRIPTION
3.2	Certificate of Amendment to Articles of Incorporation of CardioGenesis Corporation filed with the Secretary of State of California on June 18, 2001.