CARDIOGENESIS CORP /CA
Form 10-Q
November 09, 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 SEPTEMBER 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, CALIFORNIA 92610
(Address of principal executive offices)

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

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

Yes [X] No [ ]

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

34,209,065 shares of Common Stock, no par value
As of October 15, 2001

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PART 1
FINANCIAL INFORMATION

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

ASSETS

	SEPTEMBER 2001
	(unaudite
Current assets:	
Cash and cash equivalents	$ 98

Accounts receivable, net of allowance for doubtful accounts of $578 and $353 at September 30, 2001 and December 31, 2000, respectively	3,64
Inventories, net of reserves of $1,560 and $2,180 at September 30, 2001 and December 31, 2000, respectively	3,82
Prepaids and other current assets	87
Total current assets	9,33
Property and equipment, net	93
Accounts receivable over one year, net of allowance for doubtful accounts of $0 and $443 at September 30, 2001 and December 31, 2000, respectively	25
Other assets	1,76
Total assets	$ 12,28

LIABILITIES AND SHAREHOLDERS' EQUITY

Current liabilities:	
Accounts payable	$ 92
Accrued liabilities	5,53
Customer deposits	18
Deferred revenue	89
Note payable	29
Current portion of capital lease obligation	2
Current portion of long-term liabilities	49
Total current liabilities	8,34
Capital lease obligation, less current portion	4
Long-term liabilities, less current portion	-
Total liabilities	8,39
Shareholders' equity:	
Common stock:	
No par value; 50,000,000 shares authorized; 34,209,065 and 30,836,000 shares issued and outstanding at September 30, 2001 and December 31, 2000, respectively	165,72
Deferred compensation	(
Accumulated other comprehensive loss	(10
Accumulated deficit	(161,71
Total shareholders' equity	3,89
Total liabilities and shareholders' equity	$ 12,28

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

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

(UNAUDITED)

	THREE MONTHS ENDED SEPTEMBER 30,		NINE MO SEPTE
	2001	2000	2001
Net revenues	$ 4,221	$ 5,014	$ 11,362
Cost of revenues	1,627	2,460	4,745
Gross profit	2,594	2,554	6,617
Operating expenses:			
Research and development	337	1,183	1,586
Sales, general and administrative	4,309	5,171	11,203
Restructuring costs	442	--	1,132
Total operating expenses	5,088	6,354	13,921
Operating loss	(2,494)	(3,800)	(7,304)
Interest expense	(6)	(9)	(22)
Interest income	19	65	93
Equity in net loss of investee	--	--	(652)
Net loss	(2,481)	(3,744)	(7,885)
Other comprehensive income (loss):			
Unrealized holding gains arising during period	--	26	--
Foreign currency translation adjustment	(74)	(119)	(41)
Other comprehensive income (loss)	(74)	(93)	(41)
Comprehensive loss	$ (2,555)	$ (3,837)	$ (7,926)
Net loss per share:			
Basic and diluted	$ (0.07)	$ (0.12)	$ (0.24)
Weighted average shares outstanding	34,209	30,191	32,866

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

CARDIOGENESIS CORPORATION
CONSOLIDATED STATEMENTS OF CASH FLOWS
(IN THOUSANDS)
(UNAUDITED)

	NINE MONTHS SEPTEMBER
	2001
Cash flows from operating activities:	
Net loss	$ (7,885)
Adjustments to reconcile net loss to net cash used in operating activities:	
Depreciation	352
Loss from equity in investee	652
Provision for doubtful accounts	135
Inventory reserves	932
Amortization of deferred compensation	57
Amortization of intangible asset	156
Accretion of long-term liability	26
Changes in operating assets and liabilities:	
Accounts receivable - short term	(127)
Inventories	643
Prepaids and other current assets	49
Accounts receivable - long term	(138)
Other assets	(19)
Accounts payable	239
Accrued liabilities	(195)
Customer deposits	--
Deferred revenue	(414)
Current portion of long term liabilities	(10)
Long term liabilities	(365)
Net cash used in operating activities	(5,912)
Cash flows from investing activities:	
Purchase of marketable securities	--
Maturities of marketable securities	--
Acquisition of property and equipment	(302)
Net cash (used in) provided by investing activities	(302)
Cash flows from financing activities:	
Net proceeds from sales of common stock and from issuance of common stock from the exercise of options	3,697
Proceeds from short term borrowings	205
Repayments of capital lease obligations	(21)
Net cash provided by financing activities	3,881
Effects of exchange rate changes on cash and cash equivalents	(41)
Net decrease in cash and cash equivalents	(2,374)
Cash and cash equivalents at beginning of period	3,357
Cash and cash equivalents at end of period	$ 983
Supplemental schedule of cash flow information:	
Interest paid	$ 18
Taxes paid	$ 49

Supplemental schedule of noncash investing and financing activities:	
Change in unrealized loss on marketable securities	$ --
Deferred compensation	$ (4)
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 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 may require additional funding and may obtain debt financing or sell additional shares of its common stock or preferred stock through private placement or further public offerings.

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 computed by dividing the net loss by 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 during the period. For the three and nine months ended September 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 4,110,728 and 3,518,436 shares of common stock were outstanding at September 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):

	SEPTEMBER 30, 2001	DECEMBER 31, 2000
	(UNAUDITED)	
Raw materials	$1,889	$2,045
Work in process	128	715
Finished goods	1,808	2,640
	$3,825	$5,400

3. Restructuring Costs:

In the third quarter of 2001, the Company recognized restructuring charges of $442,000 related to the company-wide restructuring which began in the second quarter of 2001. The restructuring included a reduction in headcount, the closing of the Company's facilities in Sunnyvale, California and the move to a new facility located in Foothill Ranch, California. As a result of the restructuring, 48 employees were identified in the original plan and have since been terminated, primarily from the Finance and Manufacturing departments.

The following table summarizes the restructuring activity and the remaining restructuring reserve balance (in thousands):

	Personnel and Severance Costs	Lease and Other Contractual Commitments	Other Miscellaneous Costs	Total
Balance at March 31, 2001	$ --	$ --	$ --	$ --

Provisions	304	248	138	690
Payments	(98)	--	--	(98
Non-cash charges	--	--	(58)	(58
Balance as of June 30, 2001	206	248	80	534
Provisions	304	82	56	442
Payments	(407)	(238)	(112)	(757
Non-cash charges	--	(52)	--	(52
Balance as of September 30, 2001	$ 103	$ 40	$ 24	$ 167

The restructuring reserve balance is included in accrued liabilities.

Personnel and severance costs are comprised of severance, retention and relocation costs. Certain employees were offered a retention incentive to stay employed through a certain date while the Company was going through the restructuring phase. Severance costs were accrued in the quarter in which the restructuring event occurred. Employee retention costs and relocation costs were accrued when incurred.

Lease and other contractual commitments are comprised of the termination penalties associated with the early lease termination on the Company's manufacturing and office facilities. At the end of the second quarter, the Company had a reasonable estimate as to what the penalties would be on the manufacturing facility, however, no such estimate was available on the office facility. In the third quarter, the Company arrived at a settlement amount on the office facility and these charges were expensed in the current quarter.

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 is now 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.

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, incorporated in California in 1989, is a medical device company which specializes in the treatment of cardiovascular disease. We design, develop, and distribute laser-based surgical products and disposable fiber-optic accessories for the treatment of advanced cardiovascular disease. Our laser system and disposable fiber-optic accessories are used in two medical procedures known as transmyocardial revascularization ("TMR") and percutaneous transmyocardial revascularization ("PMR") to treat patients suffering from angina.

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 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 $4,221,000 for the quarter ended September 30, 2001 decreased $793,000 or 16% from $5,014,000 for the quarter ended September 30, 2000. Net revenues of $11,362,000 for the nine months ended September 30, 2001 decreased $5,937,000 or 34% from $17,299,000 for the nine months ended September 30, 2000. The decrease on both the three month and nine month comparisons is due to a decline in the unit sales of both lasers and disposables. The decline in laser and disposable revenues in both the three and nine months ending September 30, 2001 from the same periods in 2000 are related to a sales force transition during the six month period ending June 30, 2001. Since the transition ended in the second quarter of 2001, the third quarter of 2001 was the first full quarter with a new sales force.

In the fourth quarter of 2000, a sales force transition 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.

Gross Profit

Gross profit was $2,594,000 or 61% of net revenues for the quarter ended September 30, 2001 compared to $2,554,000 or 51% of net revenues for the quarter ended September 30, 2000. The improvement in gross margin resulted from an improved margin on lasers and disposables sold partially as a result of outsourcing of the manufacturing process during the quarter ended September 30, 2001.

Gross profit decreased to $6,617,000 or 58% of net revenues for the nine months ended September 30, 2001 compared to $9,810,000 or 57% of net revenues for the nine months ended September 30, 2000. The decline in gross profit resulted primarily from lower net revenues partially offset by an improvement in gross margin on lasers and disposables sold partially as a result of outsourcing of the manufacturing process during the quarter ended September 30, 2001.

Research and Development

Research and development expenditures of $337,000 decreased $846,000 or 72% for the quarter ended September 30, 2001 from $1,183,000 for the quarter ended September 30, 2000. The decrease in expenses resulted from a decrease in employee expenses of $450,000 related to the December 2000 and second quarter of 2001 reductions in force. Facilities and office expenses decreased $220,000 as a result of the move to Foothill Ranch, California and reduction in staff. Additionally, clinical trials expenses of $140,000 decreased related to the conclusion of clinical trials.

Research and development expenditures of $1,586,000 decreased $2,692,000 or 63% for the nine months ended September 30, 2001 from $4,278,000 for the nine months ended September 30, 2000. The decrease in expenses resulted from a decrease in employee expenses of $1,260,000 related to the December 2000 and second quarter of 2001 reductions in force and a reduction in clinical trials expenses of $785,000 related to the conclusion of several of our major clinical trials. Additionally, expenditures for engineering have decreased by $540,000 due to a reduction in development activities.

Sales, General and Administrative

Sales, general and administrative expenditures of $4,309,000 decreased $862,000 or 17% for the quarter ended September 30, 2001 from $5,171,000 for the quarter ended September 30, 2000. The decrease resulted from a reduction in employee expenses of $240,000 primarily related to the elimination of 15 clinical marketing positions that were occupied in the third quarter of 2000. Additionally, general marketing expenses decreased by $245,000 as a result of efforts to curtail costs, costs of materials used by the service department decreased by $95,000 and expenses incurred for the use of outside services and consultants decreased by $200,000.

Sales, general and administrative expenditures of $11,203,000 decreased $6,073,000 or 35% for the nine months ended September 30, 2001 from $17,276,000 for the nine months ended September 30, 2000. The decrease in expenses resulted primarily from a decrease in employee expenses of $3,340,000 related to the December 2000 and second quarter of 2001 reductions in force and a decrease in travel expenses of $1,005,000. Additionally, facilities and office expenses decreased by $830,000, expenses for physician training decreased by $700,000 and

the cost of materials used by the service department decreased by $200,000.

Restructuring Costs

In the third quarter of 2001, we recognized restructuring charges of $442,000 related to the company-wide restructuring which began in the second quarter of 2001. The restructuring included a reduction in headcount, the closing of the Company's facilities in Sunnyvale, California and the move to a new facility located in Foothill Ranch, California. As a result of the restructuring, 48 employees were identified in the original plan and have since

been terminated, primarily from the Finance and Manufacturing departments.

The following table summarizes the restructuring activity and the remaining restructuring reserve balance (in thousands):

	Personnel and Severance Costs	Lease and Other Contractual Commitments	Other Miscellaneous Costs	Total
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The restructuring reserve balance is included in accrued liabilities.

Personnel and severance costs are comprised of severance, retention and relocation costs. Certain employees were offered a retention incentive to stay employed through a certain date while we were going through the restructuring phase. Severance costs were accrued in the quarter in which the restructuring event occurred. Employee retention costs and relocation costs were accrued when incurred.

Lease and other contractual commitments are comprised of the termination penalties associated with the early lease termination on our manufacturing and office facilities. At the end of the second quarter, we had a reasonable estimate as to what the penalties would be on the manufacturing facility, however, no such estimate was available on the office facility. In the third quarter, we arrived at a settlement amount on the office facility and these charges were expensed in the current quarter.

In addition, the relocation of our corporate headquarters resulted in incremental charges of $25,000 that were not classified as restructuring charges but are a component of sales, general and administrative expenses in the quarter ended September 30, 2001. These incremental charges resulted from the

elimination of approximately 40 positions. As a result, we incurred charges of $25,000 related to duplicate salaries for positions where a replacement employee was hired and a Sunnyvale employee was retained through a short transition period.

Non-Operating Income and Expenses

Interest income of $19,000 in the quarter ended September 30, 2001 declined 71% or $46,000 compared to $65,000 in the quarter ended September 30, 2000. Interest income of $93,000 in the nine months ended September 30, 2001 declined 71% or $233,000 compared to $326,000 in the nine months ended September 30, 2000. The reduction in interest income was a result of lower investments in marketable securities.

Equity in net loss of $652,000 for the nine months ended September 30, 2001, respectively, represents our share of the net loss of Microheart Holdings, Inc., a privately-held company of which our ownership is 30.3%. As of September 30, 2001, we carry no investment balance on our financial statements for Microheart Holdings, Inc.

LIQUIDITY AND CAPITAL RESOURCES

Cash and cash equivalents were $983,000 at September 30, 2001 compared to $3,357,000 at December 31, 2000. We used $5,912,000 of cash for operating activities in the nine month period ended September 30, 2001, which was used primarily to fund our operating losses. In addition, a decrease in inventories provided $643,000 in cash offset by uses of cash resulting from an increase in accounts receivable of $265,000, a decrease in deferred revenue of $414,000 and a decrease in long-term liabilities of $365,000. Investing activities used cash of $302,000 in the nine month period ended September 30, 2001. Financing activities provided cash of $3,881,000 in the nine month period ended September 30, 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. 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. In August 2001, we established a $2 million asset based line of credit with Pacific Business Funding, a division of Cupertino National Bank. As of September 30, 2001, we have access to the entire $2 million credit line based on qualifying assets and have borrowed a total of $57,000 against the line. The agreement expires in August of 2002 and provides us 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 September 30, 2001 we had an accumulated deficit of $161,718,000. 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 by focusing on reducing cost of revenues and on reducing sales, general and administrative expenses. With regard to reducing cost of revenues, we are in the process of completing the outsourcing of our manufacturing which allows us to purchase products 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 core and critical activities.

Currently, one of our primary goals is to achieve break-even followed by profitability within a relatively short span of time. Our actions have been guided by this imperative, and the resulting cost containment measures have helped to conserve our cash. Our focus is upon core and critical activities, thus 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 September 30, 2001 and borrowings available under our 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 is now 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 regulatory approval for other products under clinical trials. If we are unable to increase our sales or achieve regulatory approval for our products, we will be unable to significantly increase our revenues. We believe that if we are unable to generate sufficient funds from sales or from debt or equity issuances to maintain our current expenditure rate, it will be necessary

to significantly reduce our operations. We may be required to seek additional sources of financing, which could include short-term debt, long-term debt or equity. There is a risk that we may be unsuccessful in obtaining such financing and will not have sufficient cash to fund our operations.

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.

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 MAY NOT BE ABLE TO MEET FUTURE PRODUCT DEMAND INCREASES 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 currently purchase critical laser products and components from single sources. In addition, we are vulnerable to delays and interruptions, for reasons out of our control, because we outsource the manufacturing of some of these products to third parties. We may experience harm to our business if these sources have difficulties supplying our needs for these products and components. In addition, we do not have long term supply contracts. As a result, these sources are not obligated to continue to provide these critical products or components to us. Although we have identified alternative suppliers and manufacturers, a lengthy process would be required to qualify them as additional or replacement suppliers or manufacturers. Also, it is possible some of our suppliers or manufacturers could have difficulty meeting our needs if demand for our TMR and PMR laser systems were to increase rapidly or significantly. In addition, any defect or malfunction in the laser or other products provided by such suppliers and manufacturers could cause a delay in regulatory approvals or adversely affect product acceptance. Further, we cannot predict:

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

OUR PRODUCTS COULD 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 impairment/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 October 19, 2001, the closing prices of our common stock as reported on the NASDAQ National Market ranged from a high of $3.12 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.....	$983,000
Average interest rate.....	1.2%

PART II OTHER INFORMATION

ITEM 1. LEGAL PROCEEDINGS

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

ITEM 2. CHANGES IN SECURITIES AND USE OF PROCEEDS.

On June 15, 2001, the Board of Directors of CardioGenesis approved the adoption of a Shareholder Rights Plan. The Shareholder Rights Plan, effective at the close of business on August 17, 20001, authorized a dividend of one preferred share purchase right for each share of common stock, no par value per share, of CardioGenesis which was distributed to shareholders of record at the close of business on August 30, 2001. The preferred stock purchase rights are not exercisable until any person becomes or attempts to become a 15% or more shareholder.

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 NUMBER	DESCRIPTION
4.1	Form of Rights Agreement, dated as of August 17, 2001, between CardioGenesis Corporation and Equiserve Trust Company, N.A., as Rights Agent, which includes as Exhibit A the Form of Right Certificate, Form of Assignment and Form of Election to Purchase (incorporated by reference to the Registrant's Form 8-K filed August 20, 2001).
4.2	Form of Certificate of Determination of Series A Preferred Stock (incorporated by reference to the Registrant's Form 8-K filed August 20, 2001).

b) Reports on Form 8-K

(i) A report on Form 8-K was filed on July 26, 2001, to report under Item 5, Other Events, CardioGenesis' issuance of a press release of the same date announcing its second 2001 financial results.

(ii) A report on Form 8-K was filed on August 20, 2001, to report under Item 5, Other Events, the adoption and execution of a Shareholder Rights Plan by CardioGenesis.

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: November 9, 2001

/s/ Michael J. Quinn

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

Date: November 9, 2001

/s/ J. Stephen Wilkins

J. Stephen Wilkins
Vice President and Chief Financial Officer (Principal Accounting and Financial Officer)