CARDIOGENESIS CORP /CA
Form 10-Q
May 15, 2002

Table of Contents

SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

FORM 10-Q

Quarterly report pursuant to Section 13 or 15(d)
of the Securities Exchange Act of 1934

For the quarterly period ended March 31, 2002

Commission file number 0-28288

CARDIOGENESIS CORPORATION

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

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

26632 Towne Center Drive
Suite 320
Foothill Ranch, California 92610

(Address of principal executive offices)

(714) 649-5000

(Registrant s telephone number, including area code)

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

Yes [X] No [ ]

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

37,006,723 shares of Common Stock, no par value
As of April 30, 2002

TABLE OF CONTENTS

Table of Contents

CARDIOGENESIS CORPORATION
TABLE OF CONTENTS

PART 1
FINANCIAL INFORMATION

PART II
OTHER INFORMATION

Table of Contents

CARDIOGENESIS CORPORATION

CONSOLIDATED BALANCE SHEETS
(in thousands)

ASSETS

	March 31, 2002	December 31, 2001
	(unaudited)	
Current assets:		
Cash and cash equivalents	$ 1,879	$ 2,629
Accounts receivable, net of allowance for doubtful accounts of $1,314 and $1,114 at March 31, 2002 and December 31, 2001, respectively	1,444	2,330
Inventories, net of reserve of $1,200 and $1,246 at March 31, 2002 and December 31, 2001, respectively	2,733	3,215
Prepaids and other current assets	432	569
Total current assets	6,488	8,743
Property and equipment, net	755	863
Other assets	1,655	1,703
Total assets	$ 8,898	$ 11,309
LIABILITIES AND SHAREHOLDERS EQUITY		
Current liabilities:		
Accounts payable	$ 1,629	$ 1,548
Accrued liabilities	3,848	4,467
Customer deposits	50	54
Deferred revenue	698	931
Note payable	8	170
Current portion of capital lease obligation	30	30
Current portion of long-term liabilities	248	495
Total current liabilities	6,511	7,695
Capital lease obligation, less current portion	24	32
Total liabilities	6,535	7,727
Shareholders equity:		
Preferred stock:		
no par value; 6,600 shares authorized; none issued and outstanding		
Common stock:		
no par value; 50,000 shares authorized; 36,507 shares issued and outstanding at March 31, 2002 and December 31, 2001	167,750	167,750
Accumulated other comprehensive loss	(68)	(88)
Accumulated deficit	(165,319)	(164,080)
Total shareholders equity	2,363	3,582
Total liabilities and shareholders equity	$ 8,898	$ 11,309

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

Table of Contents

CARDIOGENESIS CORPORATION

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

	Three months ended March 31,	
	2002	**2001**
Net revenues	$ 3,158	$ 3,111
Cost of revenues	826	1,535
Gross profit	2,332	1,576
Operating expenses:		
Research and development	206	543
Sales, general and administrative	3,372	3,138
Total operating expenses	3,578	3,681
Operating loss	(1,246)	(2,105)
Interest, net	7	25
Equity in net loss of investee		(357)
Net loss	(1,239)	(2,437)
Other comprehensive income (loss):		
Unrealized holding gains on securities		3
Foreign currency translation adjustment	20	(27)
Other comprehensive income (loss)	20	(24)
Comprehensive loss	$ (1,219)	$ (2,461)
Net loss per share:		
Basic and diluted	$ (0.03)	$ (0.08)
Weighted average shares outstanding	36,507	30,837

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

Table of Contents

CARDIOGENESIS CORPORATION

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

	Three months ended March 31,	
	2002	**2001**
Cash flows from operating activities:		
Net loss	$(1,239)	$(2,437)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation and amortization	85	121
Equity in net loss of investee		357
Provision for doubtful accounts	200	91
Inventory reserves	291	230
Amortization of deferred compensation		28
Amortization of license fees	48	48
Loss on disposal of property and equipment	28	
Changes in operating assets and liabilities:		
Accounts receivable	686	1,256
Inventories	191	163
Prepaids and other current assets	137	428
Accounts payable	81	(266)
Accrued liabilities	(619)	(809)
Customer deposits	(4)	
Deferred revenue	(233)	(156)
Long term liabilities	(247)	(115)
Net cash used in operating activities	(595)	(1,061)
Cash flows from investing activities:		
Acquisition of property and equipment	(5)	(39)
Net cash used in investing activities	(5)	(39)
Cash flows from financing activities:		
Net proceeds from issuance of common stock from exercise of options		1
Net proceeds from sale of common stock		1,000
Payments on short term borrowings	(162)	(86)
Repayments of capital lease obligations	(8)	(6)
Net cash (used in) provided by financing activities	(170)	909
Effects of exchange rate changes on cash and cash equivalents	20	(24)
Net decrease in cash and cash equivalents	(750)	(215)
Cash and cash equivalents at beginning of year	2,629	3,357
Cash and cash equivalents at end of period	$ 1,879	$ 3,142
Supplemental schedule of cash flow information:		
Interest paid	$ 5	$ 5
Taxes paid	$ 2	$ 13

Supplemental schedule of noncash investing and financing activities:		
Change in unrealized gain on marketable securities	$	$ 3
Deferred compensation	$	$ 19

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

Table of Contents

CARDIOGENESIS CORPORATION

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

1. Summary of Significant Accounting Policies:

Interim Financial Information (unaudited):

The interim financial statements in this report reflect all adjustments, consisting of normal recurring adjustments, that are, in the opinion of management, necessary for a fair presentation of the results of operations and cash flows for the interim periods covered and of the financial position of the Company at the interim balance sheet date. Results for interim periods are not necessarily indicative of results to be expected for the full fiscal year. The year-end balance sheet information was derived from audited financial statements but does not include all disclosures required by generally accepted accounting principles. These financial statements should be read in conjunction with CardioGenesis audited financial statements and notes thereto for the year ended December 31, 2001, contained in the Company s Annual Report on Form 10-K as filed with the U.S. Securities and Exchange Commission (SEC).

These financial statements contemplate the realization of assets and the satisfaction of liabilities in the normal course of business. CardioGenesis has sustained significant losses for the last several years and expects to continue to incur losses through 2002. Management believes its cash balance as of March 31, 2002 is not sufficient to meet the Company s capital and operating requirements through the end of the fiscal year ending December 31, 2002. CardioGenesis obtained additional funding through the sale of an investment and the sale of common stock through a private placement in April 2002 (See Note 3 Subsequent Events).

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

Net Loss Per Share:

Basic earnings per share (EPS) is computed by dividing the net loss by the weighted average number of common shares outstanding for the period. Dilutive EPS is computed giving effect to all dilutive potential common shares that were outstanding during the period. Dilutive potential common shares consist of incremental shares issuable upon the exercise of stock options and warrants using the treasury stock method.

Options to purchase 2,972,673 and 4,004,834 shares of common stock were outstanding at March 31, 2002 and 2001, respectively. Warrants to purchase 75,000 shares of common stock at $1.63 per share were outstanding as of March 31, 2002. No warrants were outstanding as of March 31, 2001. Both the options and warrants were not included in the calculation of diluted EPS because their inclusion would have been anti-dilutive.

2. Inventories:

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

	March 31, 2002	December 31, 2001
	(unaudited)	
Raw materials	$ 811	$ 917
Work-in-process	281	323
Finished goods	1,641	1,975
	$2,733	$3,215

Table of Contents

3. Subsequent Events:

In April 2002, the Company sold its ownership interest in Microheart, Inc. for $2,285,150 and will recognize a gain of an equal amount in the second quarter of 2002. The Company did not incur any costs in conjunction with the sale of this investment.

In April 2002, the Company sold 500,000 shares of common stock to a governmental entity at a negotiated purchase price of $1.00 per share. These securities carry registration rights. If a registration statement is not declared effective by the SEC on or before July 10, 2002, the Company will be required to pay liquidated damages in the amount of 0.25% of the total purchase price of the shares for each week after July 10, 2002 that the registration statement is not declared effective.

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

This Management s Discussion and Analysis of Financial Condition and Results of Operations contains descriptions of our expectations regarding future trends affecting our business. These forward-looking statements and other forward-looking statements made elsewhere in this document are made in reliance upon the safe harbor provisions of the Private Securities Litigation Reform Act of 1995. Please read the section below titled Factors Affecting Future Results to review conditions which we believe could cause actual results to differ materially from those contemplated by the forward-looking statements. Forward-looking statements are identified by words such as believes, anticipates, expects, intends, plans, will, may and similar expressions. In addition, any statements that refer to our plans, expectations, strategies or other characterizations of future events or circumstances are forward-looking statements. Our business may have changed since the date hereof and we undertake no obligation to update these forward looking statements.

The following discussion should be read in conjunction with financial statements and notes thereto included in this Quarterly Report on Form 10-Q.

Overview

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

On February 11, 1999, we received final approval from the FDA for our TMR products for certain indications, and we are now able to sell those products in the U.S. on a commercial basis. We have also received the European Conforming Mark (CE Mark) allowing the commercial sale of our TMR laser systems and our PMR catheter system to customers in the European Community. Effective July 1, 1999, Health Care Financial Administration began providing Medicare coverage for TMR. Hospitals and physicians are now eligible to receive Medicare reimbursement for TMR equipment and procedures.

We have completed pivotal clinical trials involving PMR, and study results were submitted to the FDA in a Pre Market Approval (PMA) application in December of 1999 along with subsequent amendments. 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. However, we are continuing to pursue FDA approval for PMR. There can be no assurance, however, that we will receive a favorable decision from the agency.

As of March 31, 2002, we had an accumulated deficit of $165,319,000. We expect to continue to incur operating losses through 2002. The timing and amounts of our expenditures will depend upon a number of factors, including the efforts required to develop our sales and marketing organization, the timing of market acceptance of our products and the status and timing of regulatory approvals.

Table of Contents

Results of Operations

Net Revenues

Net revenues of $3,158,000 for the quarter ended March 31, 2002 increased $47,000, or 2%, when compared to net revenues of $3,111,000 for the quarter ended March 31, 2001.

For the quarter ended March 31, 2002, domestic laser revenue increased by $497,000 and domestic disposable handpiece revenue decreased by $421,000 compared to the quarter ended March 31, 2001. In the first quarter of 2002, domestic handpiece revenue consisted of $556,000 in sales of product to customers operating under the loaned laser program, of which $68,000 was attributed to premiums associated with such sales. In the first quarter of 2001, domestic handpiece revenue consisted of $815,000 in sales of product to customers operating under the loaned laser program, of which $341,000 was attributed to premiums associated with such sales. In the first quarter of 2002 and 2001, sales of product to customers not operating under the loaned laser program were $1,209,000 and $1,371,000, respectively. International sales, accounting for approximately 10% of net revenues for the quarter ended March 31, 2002, increased $36,000 from the prior year when international sales accounted for 9% of total sales. We define international sales as sales to customers located outside of the United States. In addition, service revenue of $257,000 decreased $65,000 or 20% for the quarter ended March 31, 2002 when compared to $322,000 for the quarter ended March 31, 2001.

Gross Profit

Gross profit increased to 74% of net revenues for the quarter ended March 31, 2002 as compared to 51% of net revenues for the quarter ended March 31, 2001. Gross profit in absolute dollars increased by $756,000 to $2,332,000 for the quarter ended March 31, 2002, as compared to $1,576,000 for the quarter ended March 31, 2001. The increase in gross profit resulted from improved margins on lasers and disposables partially as a result of the outsourcing of manufacturing of disposables which occurred in the second half of 2001.

Research and Development

Research and development expenditures of $206,000 decreased $337,000 or 62% for the quarter ended March 31, 2002 when compared to $543,000 for the quarter ended March 31, 2001. The decrease in overall research and development expense was primarily attributed to a decrease in employee expenses of $288,000 related to reductions in force.

Sales, General and Administrative

Sales, general and administrative expenditures of $3,372,000 increased $234,000 or 7% for the quarter ended March 31, 2002 when compared to $3,138,000 for the quarter ended March 31, 2001. The increase in expenses resulted primarily from increases in employee expenses and legal expenses of $110,000 and $175,000, respectively, partially offset by lower expenses in other areas.

Non-Operating Expenses

Equity in net loss of investee of $357,000 in the quarter ended March 31, 2001 represented our share of the net loss of Microheart, Inc., a privately-held company, of which our ownership at the time was approximately 30%. There was no net loss recorded in the quarter ended March 31, 2002 for this investment because we carried no investment balance for Microheart, Inc. in the current period.

Liquidity and Capital Resources

Cash and cash equivalents were $1,879,000 at March 31, 2002 compared to $2,629,000 at December 31, 2001, a decrease of $750,000. We used $595,000 of cash for operating activities, including funding our operating loss and changes in accounts receivable, inventories and accrued liabilities. Accounts receivable decreased by $886,000 or 38% to $1,444,000 at March 31, 2002 from $2,330,000 at December 31, 2001. The decrease in accounts receivable is attributed to collections on receivables during the first three months of the year and an increase in bad debt reserve of $200,000. Inventories decreased by $482,000 or 15% to $2,733,000 at March 31, 2002 from

Table of Contents

$3,215,000 at December 31, 2001 due to product sales in the first three months of the year and laser depreciation on our loaned lasers. Accrued liabilities decreased by $619,000 or 14% to $3,848,000 at March 31, 2002 compared to $4,467,000 at December 31, 2001, primarily due to payments on obligations.

In the quarter ended March 31, 2002, investing and financing activities used cash of $5,000 and $170,000, respectively. Cash used in financing activities was primarily related to payments on short term borrowings.

Since our inception, we have satisfied our capital requirements through sales of our equity securities. In addition, our operations have been funded through sales of our products. In April 2002, we sold our ownership interest in Microheart, Inc. for $2,285,150. In April 2002, we sold 500,000 shares of common stock to a governmental entity at a negotiated purchase price of $1.00 per share. We have incurred significant losses for the last several years and at March 31, 2002 have an accumulated deficit of $165,319,000. The accompanying consolidated financial statements have been prepared assuming we will continue as a going concern. Our ability to continue as a going concern is dependent upon achieving profitable operations in the future. Our plans include increasing sales through increased direct sales and marketing efforts on existing products and achieving timely regulatory approval for certain other products.

We 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 completed the outsourcing of a significant portion of our manufacturing, which allows us to purchase products at lower 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 operations followed by profitability. Our actions have been guided by this imperative, and the resulting cost containment measures have helped to conserve our cash. Our focus is upon core and critical activities, thus operating expenses that are nonessential to our core operations have been eliminated.

We believe our cash balance as of March 31, 2002, the borrowing capacity of approximately $750,000 available under our receivable financing arrangement and the infusions to our cash balance in April 2002 will be sufficient to meet our capital and operating requirements through the end of 2002. We believe that if revenues from sales or new funds from debt or equity instruments is insufficient to maintain the current expenditure rate, it will be necessary to significantly reduce our operations until an appropriate solution is implemented.

Table of Contents

Factors Affecting Future Results

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

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

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

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 the future, the Food and Drug Administration could restrict the current uses of our TMR product.

The Food and Drug Administration has approved our TMR product for sale and use by physicians in the United States. At the request of the Food and Drug Administration, we are currently conducting post-market surveillance of our TMR product. We received a letter from the Food and Drug Administration in January of 2001 expressing concern about the progress of our post-market surveillance study for our TMR product. We have submitted a plan to the Food and Drug Administration to enable the timely completion of our post-market surveillance study. However, if we should fail to meet the requirements mandated by the Food and Drug Administration or fail to complete our post-market surveillance study in an acceptable time period, the Food and Drug Administration could withdraw its approval for the sale and use of our TMR product by physicians in the United States. Additionally, though we are not aware of any safety concerns during our on-going post-market surveillance of our TMR product, if concerns over the safety of our TMR product were to arise, the Food and Drug Administration could possibly restrict the currently approved uses of our TMR product. In the future, if the Food and Drug Administration were to withdraw its approval or restrict the range of uses for which our TMR product can be used by physicians, such as restricting TMR s use with the coronary artery bypass grafting procedure which occurs in more than half the procedures in which TMR is used, either outcome could lead to reduced or no sales of our TMR product in the United States and our business could be adversely affected.

Table of Contents

The Circulatory Devices Panel of the Food and Drug Administration in July 2001 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 recommended in July 2001 that the Food and Drug Administration not approve our PMR device for public sale and use in the United States based on concerns related to the safety of the device and the data regarding adverse events in the clinical trials. Although we do not expect to conduct further clinical trials of our PMR device, this recommendation has necessitated the further investment of additional resources toward obtaining the Food and Drug Administration s approval of our PMR device. We will not be able to derive any revenue from the sale of that device in the United States until such time, if any, that the Food and Drug Administration approves the device. Such inability to realize revenue from sales of our PMR device in the United States may have an adverse effect on our results of operations. Additionally, the trading price of our common stock on the NASDAQ National Market fell substantially after the panel s recommendation became public.

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

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

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

Positive endorsements, by physicians, are essential for clinical adoption of our TMR and PMR laser systems. 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 PMR with the targeted patient population.

Patient acceptance of the procedure will depend on:

physician recommendations;

the degree of invasiveness;

the effectiveness of the procedure; and

the rate and severity of complications associated with the procedure as compared to other procedures.

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

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

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.

Table of Contents

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

The growth in our business may place a significant strain on our limited personnel, management, financial systems and other resources. The evolving growth of our business presents numerous risks and challenges, including:

- the dependence on the growth of the market for our TMR and PMR systems;
- our ability to successfully and rapidly expand sales to potential customers in response to potentially increasing clinical adoption of the TMR procedure;
- the costs associated with such growth, which are difficult to quantify, but could be significant;
- domestic and international regulatory developments;
- rapid technological change;
- the highly competitive nature of the medical devices industry; and
- the risk of entering emerging markets in which we have limited or no direct experience.

To accommodate any such growth and compete effectively, we may need to obtain additional funding to improve information systems, procedures and controls and expand, train, motivate and manage our employees, and such funding may not be available in sufficient quantities, if at all. If we are not able to manage these activities and implement these strategies successfully to expand to meet any increased demand, our operating results could suffer.

Our operating results are expected to fluctuate and quarter-to-quarter comparisons of our results may not indicate future performance.

Our operating results have fluctuated significantly from quarter-to-quarter and are expected to fluctuate significantly from quarter-to-quarter 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.

Table of Contents

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. The Health Care Financing Administration has not approved reimbursement for PMR. If it does not in the future provide reimbursement, our ability to successfully market and sell our PMR products will be harmed.

Currently there are over 2,000 private health insurers and managed care organizations in the United States. Even though Medicare beneficiaries appear to account for approximately 52% of all patients treated with the TMR procedure, the remaining 48% are beneficiaries of private insurance and private health plans. We have limited data on the reimbursement of our TMR procedures by private insurance and private health plans. If they do not provide reimbursement, our business will suffer.

Based on physician feedback, we know that private insurers are reimbursing hospitals and physicians when the procedure is performed on non-Medicare patients. In May 2001, Blue Cross/Blue Shield s Technology Evaluation Center (TEC) assessed our therapy and confirmed that both TMR and TMR used as an adjunct to bypass surgery, improves net health outcomes. While TEC decisions are not binding, many Blue Cross/Blue Shield plans and other third-party payors use the Center as a benchmark and adopt into policy those therapies that meet the TEC assessment.

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 that Edwards Life Sciences has exercised its option to assume full sales and marketing responsibility in the U.S. for PLC s TMR Heart Laser 2 System and associated kits pursuant to a co-marketing agreement between the two companies that was signed in January 2001.

Table of Contents

If we obtain the Food and Drug Administration s approval for our PMR laser system, we will face competition for market acceptance and market share for that product. Our ability to compete may depend in significant part on the timing of introduction of competitive products into the market, and will be affected by the pace, relative to competitors, at which we are able to:

develop products;

complete clinical testing and regulatory approval processes;

obtain third party reimbursement acceptance; and

supply adequate quantities of the product to the market.

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.

Table of Contents

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

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

obtain patent protection for our products and processes;

preserve our trade secrets and proprietary technology; and

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

The medical device industry has been characterized by extensive litigation regarding patents and other intellectual property rights. Companies in the medical device industry have employed intellectual property litigation to gain a competitive advantage. Certain competitors and potential competitors of ours have obtained United States patents covering technology that could be used for certain TMR and PMR procedures. We do not know if such competitors, potential competitors or others have filed and hold international patents covering other TMR or PMR technology. In addition, international patents may not be interpreted the same as any counterpart United States patents.

While we periodically review the scope of our patents and other relevant patents of which we are aware, the question of patent infringement involves complex legal and factual issues. Any conclusion regarding infringement may not be consistent with the resolution of any such issues by a court.

Costly litigation may be necessary to protect intellectual property rights.

We may have to engage in time consuming and costly litigation to protect our intellectual property rights or to determine the proprietary rights of others. In addition, we may become subject to patent infringement claims or litigation, or interference proceedings declared by the United States Patent and Trademark Office to determine the priority of inventions.

Defending and prosecuting intellectual property suits, United States Patent and Trademark Office interference proceedings and related legal and administrative proceedings are both costly and time-consuming. We may be required to litigate further to:

enforce our issued patents;

protect our trade secrets or know-how; or

determine the enforceability, scope and validity of the proprietary rights of others.

Any litigation or interference proceedings will result in substantial expense and significant diversion of effort by technical and management personnel. If the results of such litigation or interference proceedings are adverse to us, then the results may:

subject us to significant liabilities to third parties;

require us to seek licenses from third parties;

prevent us from selling our products in certain markets or at all; or

require us to modify our products.

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

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

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

Table of Contents

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

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

Furthermore, we cannot assure you that our competitors:

- have not developed or will not develop similar products;
- will not duplicate our products; or
- will not design around any patents issued to or licensed by us.

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

- others did not first file applications for inventions covered by our pending patent applications; or
- we will not infringe any patents that may issue to others on such applications.

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

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

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

Table of Contents

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

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

fines, injunctions, and civil penalties;

recalls or seizures of products;

total or partial suspensions of production; and

criminal prosecutions.

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

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

We are exposed to potential product liability claims and product recalls. These risks are inherent in the design, development, manufacture and marketing of medical devices. We could be subject to product liability claims if the use of our TMR or PMR laser systems is alleged to have caused adverse effects on a patient or such products are believed to be defective. Our products are designed to be used in life-threatening situations where there is a high risk of serious injury or death. We are not aware of any material side effects or adverse events arising from the use of our TMR product. Though we are in the process of responding to the Food and Drug Administration s Circulatory Devices Panel s recent recommendation against approval of our PMR product because of concerns over the safety of the device and the data regarding adverse events in the clinical trials, we believe there are no material side effects or adverse events arising from the use of our PMR product. When being clinically investigated, it is not uncommon for new surgical or interventional procedures to result in a higher rate of complications in the treated population of patients as opposed to those reported in the control group. In light of this, we believe that the difference in the rates of complications between the treated groups and the control groups in the clinical trials for our PMR product are not statistically significant, which is why we believe that there are no material side effects or material adverse events arising from the use of our PMR product.

Any regulatory clearance for commercial sale of these products will not remove these risks. Any failure to comply with the Food and Drug Administration s good manufacturing practices or other regulations could hurt our ability to defend against product liability lawsuits.

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

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

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.

Table of Contents

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

Our future business and results of operations depend in significant part upon the continued contributions of our key technical and senior management personnel. They also depend in significant part upon our ability to attract and retain additional qualified management, technical, marketing and sales and support personnel for our operations. If we lose a key employee or if a key employee fails to perform in his or her current position, or if we are not able to attract and retain skilled employees as needed, our business could suffer.

During the last two years, we have had significant change in our senior management team. 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 former Chief Financial Officer, J. Stephen Wilkins, was hired in May 2001. In January 2002, our former Chief Financial Officer, J. Stephen Wilkins, resigned and was replaced by Darrell Eckstein who was originally hired in December 2000 as our Vice President of Operations, originally replacing Bill Picht, who resigned earlier in 2000. Additionally, Richard Lanigan moved from Vice President of Sales to Vice President of Government Affairs and Business Development in March 2001 and Michael A. Tuckerman was promoted to Vice President, U.S. Sales, after Thomas Kinder, our former Vice President of Worldwide Sales resigned in January 2002. In addition, Christopher M. Owens was hired as Vice President of Marketing in March 2001. William Von Brendel, who was hired in August 2001 as Vice President and General Manager of the International Business Unit, resigned in January 2002 and is currently providing international sales support under a consulting agreement with us.

Our future business could be harmed by our turnover in senior management if we have difficulty familiarizing and training our new management with respect to our business. Further significant turnover in our senior management could significantly deplete our institutional knowledge held by our existing senior management team. We depend on the skills and abilities of these key employees in managing the manufacturing, technical, marketing and sales aspects of our business, any part of which could be harmed by further turnover.

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

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

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

the loss of previously obtained approvals or clearances; or

the failure to comply with existing or future regulatory requirements.

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

We have completed CE mark registration for all of our products in accordance with the implementation of various medical device directives in the European Union. Failure to maintain the right to affix the CE Marking or other requisite approvals could prohibit us from selling our products in member countries of the European Union or elsewhere. Any enforcement action by international regulatory authorities with respect to past or future regulatory noncompliance could cause our business to suffer. Noncompliance with international regulatory requirements could result in enforcement action such as not being allowed to market our product in the European Union, which would significantly reduce international revenue.

Table of Contents

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

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

- foreign currency fluctuations;
- economic or political instability;
- foreign tax laws;
- shipping delays;
- various tariffs and trade regulations;
- restrictions and foreign medical regulations;
- customs duties, export quotas or other trade restrictions; and
- difficulty in protecting intellectual property rights.

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

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

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 of our common stock has been and may continue to be volatile. For example, during 52-week period ended May 10, 2002, 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 $0.60. 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;

Table of Contents

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. Our common stock could be subject to certain consequences in the future established by the NASDAQ National Market such as being delisted if we do not meet the Nasdaq s continued listing standards. For instance, if our common stock were to trade under $1.00 for 30 consecutive days on the NASDAQ National Market, or our current net tangible assets fell below $4 million, or if we do not in the future meet the Nasdaq s $10 million in stockholder s equity test starting November 1, 2002, we would be in violation of the Nasdaq s continued listing standards. If our common stock were delisted from the NASDAQ National Market, then we could apply for listing on the Nasdaq SmallCap Market or explore becoming listed on an alternative market. 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 and currency risk. These risks arise from transactions and operations entered into in the normal course of business. The Company does not use derivatives to alter the interest characteristics of its marketable securities or its debt instruments. The Company has no holdings of derivative or commodity instruments.

Interest Rate Risk. The Company is subject to interest rate risks on cash and cash equivalents and any future financing requirements. The long-term debt at March 31, 2002 consists of an outstanding balance on a lease obligation.

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

In Thousands	2002	2003	2004	2005	2006	Total Fair Value
Assets						
Cash, cash equivalents	$1,879	$	$	$	$	$ 1,879
Weighted average interest rate	1.0%					1.0%
Liabilities						
Fixed Rate Debt						
Lease obligation	$ 30	$ 24	$	$	$	$ 54
Weighted average interest rate	6.8%	6.8%				6.8%

Table of Contents

Qualitative Disclosures

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

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

The Company does not hedge any balance sheet exposures and intercompany balances against future movements in foreign exchange rates. The exposure related to currency rate movements would not have a material impact on future net income or cash flows.

Part II Other Information

Item 1. Legal Proceedings

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

a) Pursuant to the Share Purchase Agreement, dated December 21, 2001, between the Registrant and the State of Wisconsin Investment Board (the Agreement), the Registrant issued and sold 2,222,225 shares of its common stock to the State of Wisconsin Investment Board in a transaction exempt from the registration requirements of the Securities Act of 1933, as amended. In connection with the closing of the transaction contemplated by the Agreement, and pursuant to Section 7.7 thereof, the Board of Directors of the Registrant on January 16, 2002 approved and amended the Rights Agreement, dated as of August 17, 2001 between the Registrant and EquiServe Trust Company, N.A., as Rights Agent (the Rights Agreement), to insert the following provision at the end of the definition of Acquiring Person in the Rights Agreement:

> The foregoing shall only apply in its entirety to the State of Wisconsin Investment Board (**SWIB**) as to when SWIB Beneficially Owns 21% or more of the Voting Shares of the Company then outstanding.

For additional information regarding the amendment to our Rights Agreement, please see our First Amendment to Rights Agreement, dated January 17, 2002, attached hereto as Exhibit 4.1 and our Agreement, attached hereto as Exhibit 4.2, each incorporated herein by reference.

Item 3. Defaults Upon Senior Securities

None.

Item 4. Submission of Matter 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	First Amendment to Rights Agreement, dated as of January 17, 2002, between CardioGenesis Corporation and EquiServe Trust Company, N.A., as Rights Agent (incorporated by reference to CardioGenesis Form 8-K, filed January 18, 2002).
4.2	Share Purchase Agreement, dated as of December 21, 2001, by and between CardioGenesis Corporation and the State of Wisconsin Investment Board (incorporated by reference to CardioGenesis Form 8-K, filed January 18, 2002).

b) Reports on Form 8-K

A report was filed on January 18, 2002, to announce preliminary financial results for the fourth quarter ended December 31, 2001 and to announce the organizational restructuring which occurred in January 2002. The report also disclosed the approval of an amendment to the Shareholder Rights Agreement pursuant to the Share Purchase Agreement between CardioGenesis Corporation and the State of Wisconsin Investment Board dated December 21, 2001.

Table of Contents

CARDIOGENESIS CORPORATION

SIGNATURES

Pursuant to the requirements of the Securities Exchange Act of 1934, the Registrant has duly caused this report to be signed on its behalf by the undersigned thereunto duly authorized.

CARDIOGENESIS CORPORATION
Registrant

Date: May 15, 2002

/s/ Michael J. Quinn

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

Date: May 15, 2002

/s/ Darrell F. Eckstein

Darrell F. Eckstein
Vice President and Interim Chief Financial Officer
(Principal Accounting and Financial Officer)