CARDIOGENESIS CORP /CA
Form 10-Q
May 15, 2003

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, 2003

Commission file number 0-28288

CARDIOGENESIS CORPORATION

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

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

26632 Towne Centre Drive
Suite 320
Foothill Ranch, California 92610
(Address of principal executive offices)

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

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

Yes x No o

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

Yes o No x

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

37,120,925 shares of Common Stock, no par value
As of April 30, 2003

TABLE OF CONTENTS

Table of Contents

CARDIOGENESIS CORPORATION
TABLE OF CONTENTS

Table of Contents

CARDIOGENESIS CORPORATION

CONSOLIDATED BALANCE SHEETS
(in thousands)
(unaudited)

	March 31, 2003	December 31, 2002
ASSETS		
Current assets:		
Cash and cash equivalents	$ 1,576	$ 1,490
Accounts receivable, net of allowance for doubtful accounts of $440 and $449 at March 31, 2003 and December 31, 2002, respectively	1,946	1,961
Inventories, net of reserves of $406 and $361 at March 31, 2003 and December 31, 2002, respectively	1,535	1,632
Prepaids and other current assets	529	574
Total current assets	5,586	5,657
Property and equipment, net	526	589
Other assets	1,460	1,509
Total assets	$ 7,572	$ 7,755
LIABILITIES AND SHAREHOLDERS EQUITY		
Current liabilities:		
Accounts payable	$ 1,388	$ 1,241
Accrued liabilities	1,638	2,101
Customer deposits	50	50
Deferred revenue	641	621
Current portion of capital lease obligation	23	30
Total current liabilities	3,740	4,043
Capital lease obligation, less current portion		1
Total liabilities	3,740	4,044
Shareholders equity:		
Preferred stock:		
no par value; 5,000 shares authorized; none issued and outstanding		
Common stock:		
no par value; 50,000 shares authorized; 37,121 shares issued and outstanding at March 31, 2003 and December 31, 2002	168,321	168,321
Accumulated deficit	(164,489)	(164,610)
Total shareholders equity	3,832	3,711
Total liabilities and shareholders equity	$ 7,572	$ 7,755

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

Table of Contents

CARDIOGENESIS CORPORATION

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

	Three months ended March 31,	
	2003	**2002**
Net revenues	$ 3,422	$ 3,158
Cost of revenues	622	826
Gross profit	2,800	2,332
Operating expenses:		
Research and development	383	206
Sales, general and administrative	2,298	3,372
Total operating expenses	2,681	3,578
Operating income (loss)	119	(1,246)
Interest income, net	2	7
Net income (loss)	121	(1,239)
Other comprehensive income:		
Foreign currency translation adjustment		20
Comprehensive income (loss)	$ 121	$ (1,219)
Net income (loss) per share:		
Basic and diluted	$ 0.00	$ (0.03)
Weighted average shares outstanding:		
Basic	37,121	36,507
Diluted	37,145	36,507

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,	
	2003	**2002**
Cash flows from operating activities:		
Net income (loss)	$ 121	$(1,239)
Adjustments to reconcile net income (loss) to net cash used in operating activities:		
Depreciation and amortization	65	85
Provision for doubtful accounts		200
Provision for inventory excess and obsolescence	121	291
Amortization of license fees	49	48
Loss on disposal of property and equipment		28
Changes in operating assets and liabilities:		
Accounts receivable	15	686
Inventories	(24)	191
Prepaids and other current assets	45	137
Accounts payable	147	81
Accrued liabilities	(463)	(619)
Customer deposits		(4)
Deferred revenue	20	(233)
Long term liabilities		(247)
Net cash provided by (used in) operating activities	96	(595)
Cash flows from investing activities:		
Acquisition of property and equipment	(2)	(5)
Net cash used in investing activities	(2)	(5)
Cash flows from financing activities:		
Payments on short term borrowings		(162)
Repayments of capital lease obligations	(8)	(8)
Net cash used in financing activities	(8)	(170)
Effects of exchange rate changes on cash and cash equivalents		20
Net increase (decrease) in cash and cash equivalents	86	(750)
Cash and cash equivalents at beginning of year	1,490	2,629
Cash and cash equivalents at end of period	$1,576	$ 1,879
Supplemental schedule of cash flow information:		
Interest paid	$ 1	$ 5
Taxes paid	$ 3	$ 2

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, 2002, 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. Although the Company has achieved profitability in the quarter ended March 31, 2003, CardioGenesis has had significant losses for the last several years and may incur losses in the future. Management believes its cash balance as of March 31, 2003 is sufficient to meet the Company s capital and operating requirements for the next 12 months. CardioGenesis has additional funding available through a $2,000,000 revolving convertible note credit facility.

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

Net Income (Loss) Per Share:

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

Options to purchase 4,556,285 and 2,972,673 shares of common stock were outstanding at March 31, 2003 and 2002, respectively. Warrants to purchase 75,000 shares of common stock at $1.63 per share were outstanding as of March 31, 2003 and 2002. For the three months ended March 31, 2003, potentially dilutive securities resulted in potential common shares of approximately 24,000 shares. For the three months ended March 31, 2002, no potential common shares were included in the diluted per share amount as the effect would have been anti-dilutive.

Table of Contents

2. Inventories:

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

	March 31, 2003	December 31, 2002
	(unaudited)	
Raw materials	$1,120	$1,121
Work-in-process	191	136
Finished goods	630	736
	1,941	1,993
Less reserves	(406)	(361)
	$1,535	$1,632

3. Stock-Based Compensation:

The Company has adopted the disclosure only provisions of SFAS 123 as amended by SFAS 148 Accounting for Stock-Based Compensation, Transition and Disclosure . CardioGenesis, however, continues to apply APB 25 and related interpretations in accounting for its plans. Had compensation cost for the Stock Option Plan, the Director s Stock Option Plan and the Employee Stock Purchase Plan been determined based on the fair value of the options at the grant date for awards in the quarter ended March 31, 2003 and 2002 consistent with the provisions of SFAS 123, CardioGenesis net income (loss) and net income (loss) per share would have changed to the pro forma amounts indicated below *(in thousands, except per share amounts):*

	Three Months Ended March 31,	
	2003	2002
Net income (loss) as reported	$ 121	$(1,219)
Stock-based employee compensation	$ (309)	$ (354)
Pro forma net loss	$ (188)	$(1,573)
Basic and diluted net income (loss) per share as reported	$ 0.00	$ (0.03)
Pro forma basic and diluted net loss per share	$(0.01)	$ (0.04)

The above pro-forma disclosures are not necessarily representative of the effects on reported net income (loss) for future years. The aggregate fair value and weighted average fair value per share of options granted in the three months ended March 31, 2003 and 2002 were $241,000 and $158,000 and $0.20 and $0.53, respectively. The fair value of each option grant is estimated on the date of grant using the Black-Scholes option pricing model.

4. Recently Issued Accounting Standards

In December 2002, the FASB issued Statement of Financial Accounting Standards, or SFAS, No. 148, Accounting for Stock-Based Compensation, Transition and Disclosure. SFAS No. 148 provides alternative methods of transition for a voluntary change to the fair value based method of accounting for stock-based employee compensation. SFAS No. 148 also requires that disclosures of the pro forma effect of using the fair value method of accounting for stock-based employee compensation be displayed more prominently and in a tabular format. Additionally, SFAS No. 148 requires disclosure of the pro forma effect in interim financial statements. The transition and annual disclosure requirements of SFAS No. 148 are effective immediately. The interim disclosure requirements became effective for the first quarter of 2003. The adoption of SFAS No. 148 did not have a material effect on our results of operations or financial condition.

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

Table of Contents

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 expres 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. In July 2001, the FDA Advisory Panel recommended against approval of PMR for public sale and use in the United States. In February 2003, the FDA granted an independent panel review of our pending PMA application for PMR by the Medical Devices Dispute Resolution Panel. We currently expect the Dispute Resolution Panel to convene in the third quarter of 2003. There can be no assurance, however, that we will receive a favorable decision from the FDA.

As of March 31, 2003, we had an accumulated deficit of $164,489,000. We may incur operating losses in the future. The timing and amounts of our expenditures will depend upon a number of factors, including the efforts required to develop our sales and marketing organization, the timing of market acceptance of our products and the status and timing of regulatory approvals.

Results of Operations

Net Revenues

Net revenues of $3,422,000 for the quarter ended March 31, 2003 increased $264,000, or 8%, when compared to net revenues of $3,158,000 for the quarter ended March 31, 2002. The increase in net revenues is primarily attributed to an increase in disposable handpiece revenue.

For the quarter ended March 31, 2003, domestic disposable handpiece revenue increased by $314,000 and domestic laser revenue decreased by $12,000 compared to the quarter ended March 31, 2002. In the first quarter of 2003, domestic handpiece revenue consisted of $567,000 in sales of product to customers operating under the loaned laser program, of which $138,000 was attributed to premiums associated with such sales. In the first quarter of 2002, domestic handpiece revenue consisted of $562,000 in sales of product to customers operating under the loaned laser program, of which $90,000 was attributed to premiums associated with such sales. In the first quarter of 2003 and 2002, sales of handpieces to customers not operating under the loaned laser program were $1,513,000 and $1,204,000, respectively. International sales, accounting for approximately 8% of net revenues for the quarter ended March 31, 2003, decreased $47,000 from the prior year when international sales accounted for 10% of total sales. We define international sales as sales to customers located outside of the United States. In addition, service revenue

Table of Contents

of $267,000 increased $10,000 for the quarter ended March 31, 2003 when compared to $257,000 for the quarter ended March 31, 2002.

Gross Profit

Gross profit increased to 82% of net revenues for the quarter ended March 31, 2003 as compared to 74% of net revenues for the quarter ended March 31, 2002. Gross profit in absolute dollars increased by $468,000 to $2,800,000 for the quarter ended March 31, 2003, as compared to $2,332,000 for the quarter ended March 31, 2002. The increase in gross profit, as a percentage of sales and in absolute terms, resulted from improved margins on lasers sold as well as improved margins on disposable handpieces.

Research and Development

Research and development expenditures of $383,000 increased $177,000 or 86% for the quarter ended March 31, 2003 when compared to $206,000 for the quarter ended March 31, 2002. The increase in overall research and development expense was primarily attributed to expenses related to our pursuit of PMR approval.

Sales, General and Administrative

Sales, general and administrative expenditures of $2,298,000 decreased $1,074,000 or 32% for the quarter ended March 31, 2003 when compared to $3,372,000 for the quarter ended March 31, 2002. The decrease in expenses resulted primarily from decreases in employee headcount and related expenses and outside services of $613,000 and $150,000, respectively, as well as lower expenses in other areas.

Liquidity and Capital Resources

At March 31, 2003, we had cash and cash equivalents of $1,576,000 compared to $1,490,000 at December 31, 2002, an increase of $86,000. During the three months ended March 31, 2003, we had net income of $121,000 which provided cash of $96,000 to support operating activities.

On March 27, 2003, we entered into a Purchase and Security Agreement with a private equity fund and entered into a revolving Convertible Note credit facility (the Note) that matures on March 26, 2006. The Note, which is collateralized by our assets, provides for borrowings of up to $2,000,000 based upon eligible accounts receivable. Advances under the Note will bear interest at prime plus 3.35%. The Note includes a right of conversion into common stock at a fixed conversion price of $.30 per share, subject to adjustment. In conjunction with this transaction, we issued 275,000 five year warrants. The warrants are exercisable for common stock at exercise prices ranging from $.35 to $.44 per share. As of March 31, 2003, our borrowing capacity was approximately $1,400,000 based on eligible accounts receivable and we had no outstanding borrowings on the Note.

We have incurred significant losses for the last several years and at March 31, 2003 have an accumulated deficit of $164,489,000. Our ability to maintain current operations is dependent upon sustaining 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 sales, general and administrative expenses. We ve significantly reduced our cost of revenues, primarily due to the outsourcing of a significant portion of our manufacturing which allows us to purchase products at lower costs. To reduce operating expenses, we have focused our efforts on reducing headcount and overall expenses in functions that are not essential to core and critical activities.

Currently, our primary goal is to sustain 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, 2003 and the borrowing capacity available under our $2,000,000 revolving convertible note credit facility, will be sufficient to meet our capital and operating

Table of Contents

requirements through the next 12 months. 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.

Recently Issued Accounting Standards

In December 2002, the FASB issued Statement of Financial Accounting Standards, or SFAS, No. 148, Accounting for Stock-Based Compensation, Transition and Disclosure. SFAS No. 148 provides alternative methods of transition for a voluntary change to the fair value based method of accounting for stock-based employee compensation. SFAS No. 148 also requires that disclosures of the pro forma effect of using the fair value method of accounting for stock-based employee compensation be displayed more prominently and in a tabular format. Additionally, SFAS No. 148 requires disclosure of the pro forma effect in interim financial statements. The transition and annual disclosure requirements of SFAS No. 148 are effective immediately. The interim disclosure requirements became effective for the first quarter of 2003. The adoption of SFAS No. 148 did not have a material effect on our results of operations or financial condition.

Risk Factors

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

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

We will have a continuing need for new infusions of cash if we incur losses in the future. We plan to increase our sales through increased direct sales and marketing efforts on existing products and achieving regulatory approval for other products. If our direct sales and marketing efforts are unsuccessful or we are unable to achieve regulatory approval for our products, we will be unable to significantly increase our revenues. We believe that if we are unable to generate sufficient funds from sales 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 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 FDA and other regulatory approvals for our PMR laser systems; and

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

We may not sustain profitability in the future.

Our common stock has been delisted by the Nasdaq SmallCap Market which may have an unfavorable impact on our stock price and liquidity.

The stock market has experienced significant price and volume fluctuations that have particularly affected the trading prices of equity securities of many high technology companies. These fluctuations have often been unrelated or disproportionate to the operating performance of many of these companies. Any negative change in the public s perception of medical device companies could depress our stock price regardless of our operating results. The delisting of our common stock from the Nasdaq SmallCap 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. Our common stock is currently listed on the OTC Bulletin Board.

Table of Contents

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

The market price of our common stock has been and may continue to be volatile. For example, during the 52-week period ended March 31, 2003, the closing prices of our common stock as reported on Nasdaq ranged from a high of $1.20 to a low of $0.22. 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.

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

Our business could be harmed if any of the following events, circumstances or occurrences related to the regulatory process occurred thereby causing a reduction in our revenues:

- the failure to obtain regulatory approvals for our PMR system;
- any significant limitations in the indicated uses for which our products may be marketed; and
- substantial costs incurred in obtaining regulatory approvals.

The FDA has not approved our PMR laser system for any application in the United States. In February 2003, the FDA granted an independent panel review of our pending PMA application for PMR by the Medical Devices Dispute Resolution Panel. We currently expect the Dispute Resolution Panel to convene in the third quarter of 2003. There is no assurance, however, that we will receive a favorable decision from the FDA. 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 FDA approves the device. Such inability to realize revenue from sales of our PMR device in the United States may have an adverse effect on our results of operations.

In the future, the FDA could restrict the current uses of our TMR product.

The FDA has approved our TMR product for sale and use by physicians in the United States. At the request of the FDA, we are currently conducting post-market surveillance of our TMR product. However, if we should fail to meet the requirements mandated by the FDA or fail to complete our post-market surveillance study in an acceptable time period, the FDA could withdraw its approval for the sale and use of our TMR product by physicians in the United States. Additionally, 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 FDA could possibly restrict the currently approved uses of our TMR product. In the future, if the FDA were to withdraw its approval or restrict the range of uses for which our TMR product can be used by physicians, such as restricting TMR s use with the coronary artery bypass grafting procedure, either outcome could lead to reduced or no sales of our TMR product in the United States and our business could be adversely affected.

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

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

- fines, injunctions, and civil penalties;

Table of Contents

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

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

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

the loss of previously obtained approvals or clearances; or

the failure to comply with existing or future regulatory requirements.

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