CARDIOGENESIS CORP /CA
Form 10-Q
May 16, 2005

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, 2005

Commission file number 0-28288

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CARDIOGENESIS CORPORATION

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

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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 þ No o

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

Yes o No þ

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

42,447,757 shares of Common Stock, no par value
As of May 2, 2005

CARDIOGENESIS CORPORATION
TABLE OF CONTENTS

Table of Contents

Item 1. Financial Statements (unaudited)

CARDIOGENESIS CORPORATION

CONDENSED CONSOLIDATED BALANCE SHEETS
(in thousands)
(unaudited)

	March 31, 2005	December 31, 2004
ASSETS		
Current assets:		
Cash and cash equivalents	$ 4,214	$ 4,740
Accounts receivable, net of allowance for doubtful accounts of $11 and $11 at March 31, 2005 and December 31, 2004, respectively	2,143	3,578
Inventories, net of reserves of $401 and $402 at March 31, 2005 and December 31, 2004, respectively	2,338	1,782
Prepaids and other current assets	579	513
Total current assets	9,274	10,613
Property and equipment, net	636	601
Restricted cash	2,567	2,884
Other assets	1,466	1,585
Total assets	$ 13,943	$ 15,683
LIABILITIES AND SHAREHOLDERS EQUITY		
Current liabilities:		
Accounts payable	$ 1,377	$ 893
Accrued liabilities	827	1,263
Deferred revenue	604	658
Notes payable	184	
Current portion of capital lease obligation	5	5
Current portion of Convertible Term Note	1,100	800
Total current liabilities	4,097	3,619
Capital lease obligation, less current portion	16	18
Other long term liability	465	496
Convertible Term Note and related obligations	6,881	6,815
Total liabilities	11,459	10,948
Shareholders equity:		
Preferred stock:		
no par value; 5,000 shares authorized; none issued and outstanding		
Common stock:		
	171,572	171,012

no par value; 75,000 shares authorized; 42,331 and 41,500 shares issued and outstanding at March 31, 2005 and December 31, 2004, respectively		
Accumulated deficit	(169,088)	(166,277)
Total shareholders equity	2,484	4,735
Total liabilities and shareholders equity	$ 13,943	$ 15,683

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

Table of Contents

CARDIOGENESIS CORPORATION

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

	Three months ended March 31,	
	2005	**2004**
Net revenues	$ 2,991	$ 4,041
Cost of revenues	605	553
Gross profit	2,386	3,488
Operating expenses:		
Research and development	350	291
Sales, general and administrative	3,744	2,928
Total operating expenses	4,094	3,219
Operating (loss) income	(1,708)	269
Interest expense	(185)	(7)
Interest income	42	5
Non-cash interest expense	(636)	
Other non-cash expense	(324)	
Net (loss) income	(2,811)	267
Net (loss) income per share:		
Basic and diluted	$ (0.07)	$ 0.01
Weighted average shares outstanding:		
Basic	41,899	40,490
Diluted	41,899	41,204

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,	
	2005	**2004**
Cash flows from operating activities:		
Net (loss) income	$ (2,811)	$ 267
Adjustments to reconcile net (loss) income to net cash used in operating activities:		
Derivative and warrant fair value adjustments	460	
Accretion related to discount on notes payable	201	
Depreciation and amortization	71	60
Inventory reserves	20	6
Interest expense accrued on note payable	108	
Amortization of other assets	48	49
Amortization of debt issuance costs	49	6
Gain on debt extinguishment	(307)	
Reduction of clinical trial accrual		(117)
Changes in operating assets and liabilities:		
Accounts receivable	1,435	(671)
Inventories	(576)	39
Prepaids and other current assets	118	124
Other assets	(15)	5
Accounts payable	484	90
Accrued liabilities	(504)	(267)
Current portion of long term liabilities	300	
Long term liabilities	(337)	
Deferred revenue	(54)	(16)
Net cash used in operating activities	(1,310)	(425)
Cash flows from investing activities:		
Increase in restricted cash	332	
Acquisition of property and equipment	(106)	(128)
Net cash provided by (used in) investing activities	226	(128)
Cash flows from financing activities:		
Net proceeds from issuance of common stock from exercise of options	560	159
Net proceeds from sale of common stock		2,433
Payments on capital lease obligations	(2)	(1)
Net cash provided by financing activities	558	2,591
Net (decrease) increase in cash and cash equivalents	(526)	2,038
Cash and cash equivalents at beginning of year	4,740	1,013

Cash and cash equivalents at end of period	$ 4,214	$ 3,051
Supplemental schedule of cash flow information:		
Interest paid	$ 5	$ 7
Taxes paid	$ 1	$ 3

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

Table of Contents

CARDIOGENESIS CORPORATION

NOTES TO UNAUDITED CONDENSED 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 statement 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 accounting principles generally accepted in the United States of America. These financial statements should be read in conjunction with Cardiogenesis audited financial statements and notes thereto for the year ended December 31, 2004, 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 operating losses for the last several years and may continue to incur losses in the future. Management believes its cash balance as of March 31, 2005 is sufficient to meet the Company s capital and operating requirements for the next 12 months.

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

Options to purchase 4,903,999 and 4,240,102 shares of common stock were outstanding at March 31, 2005 and 2004, respectively. The range of per share exercise prices for these options was $0.32-$12.6875 for 2005 and 2004. Warrants to purchase 75,000 shares of common stock at $1.63 per share were outstanding as of March 31, 2005 and 2004. Warrants to purchase 275,000 shares of common stock at prices ranging from $0.35 to $0.44 per share were outstanding as of March 31, 2005 and 2004. For the three months ended March 31, 2004, potentially dilutive securities resulted in potential common shares of approximately 714,000 shares. Warrants to purchase 3,100,000 and 2,640,000 shares of common stock at $1.37 and $0.50, respectively, per share were also outstanding at March 31, 2005. A Secured Convertible Term Note, convertible at $0.50 per share subject to certain downward adjustments due to decreases in the Company s stock price, was outstanding at March 31, 2005 and December 31, 2004. The balance as

of March 31, 2005 and December 31, 2004 was $5,668,000 and $6,000,000, respectively. None of the options, warrants or convertible notes were included in the calculation of diluted EPS for the 3 months ended March 31, 2005 because their inclusion 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, 2005 (unaudited)	December 31, 2004
Raw materials	$ 1,064	$ 1,085
Work-in-process	159	210
Finished goods	1,516	889
	2,739	2,184
Less reserves	(401)	(402)
	$ 2,338	$ 1,782

3. Stock-Based Compensation:

Cardiogenesis accounts for its stock-based compensation in accordance with Accounting Principles Board Opinion No. 25, Accounting for Stock Issued to Employees (APB 25). Cardiogenesis has elected to adopt the disclosure only provisions of Statement of Financial Accounting Standards No. 123, Accounting for Stock-Based Compensation (SFAS 123), which requires pro forma disclosures in the financial statements as if the measurement provisions of SFAS 123 had been adopted. In addition, the Company has made the appropriate disclosures as required under the Statement of Financial Accounting Standards No. 148, Accounting for Stock-Based Compensation Transition and Disclosure.

Had compensation cost for the Stock Option Plan, the Director s Stock Option Plan and the ESPP been determined based on the fair value of the options at the grant date for awards in the quarter ended March 31, 2005 and 2004, consistent with the provisions of SFAS 123, Cardiogenesis net (loss) income and net (loss) income per share would have increased to the pro forma amounts indicated below *(in thousands, except per share amounts):*

	Three Months Ended March 31,	
	2005	2004
Net (loss) income as reported	$ (2,811)	$ 267
Stock-based employee compensation	$ (282)	$ (118)
Pro forma net (loss) income	$ (3,093)	$ 149
Basic and diluted net (loss) income per share as reported	$ (0.07)	$ 0.01
Pro forma basic and diluted net (loss) income per share	$ (0.07)	$ 0.00

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, 2005 and 2004 were $261,000 and $406,000 and $0.32 and $0.74, 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 September 2004, the Emerging Issues Task Force finalized its consensus on EITF Issue No. 04-8, The Effect of Contingently Convertible Debt on Diluted Earnings Per Share (EITF 04-8). EITF 04-8 addresses when the dilutive effect of contingently convertible debt with a market price trigger should be included in diluted earnings per share (EPS). Under EITF 04-8, the market price contingency should be ignored and these securities should be treated as non-contingent, convertible securities and always included in the diluted EPS computation unless their inclusion would be anti-dilutive. EITF 04-8 requires these securities be included in diluted EPS using either the if-converted method or the net share settlement method, depending on the conversion terms of the security. EITF 04-8 is effective for all periods ending after December 15, 2004 and is to be applied by retrospectively restating previously reported EPS. The adoption of EITF 04-8 will have an effect on our diluted EPS computation if, in future periods, the inclusion of contingently convertible debt becomes dilutive.

In November 2004, the FASB issued SFAS No. 151, *Inventory Costs An Amendment of ARB No. 43, Chapter 4* (SFAS No. 151). SFAS No. 151 amends the guidance in ARB No. 43, Chapter 4, Inventory Pricing, to clarify the accounting for abnormal amounts of idle facility expense, freight, handling costs, and wasted material (spoilage). Among other provisions, the new rule requires that items such as idle facility expense, excessive spoilage, double freight, and rehandling costs be recognized as current-period charges regardless of whether they meet the criterion of so abnormal as stated in ARB No. 43. Additionally, SFAS No. 151 requires that the allocation of fixed production overheads to the costs of conversion be based on the normal capacity of the production facilities. SFAS No. 151 is effective for inventory costs incurred during fiscal years beginning after June 15, 2005. We are currently evaluating the effect that the adoption of SFAS No. 151 will have on our consolidated results of operations and financial position, but we do not expect the adoption of this Statement to have a material impact.

In December 2004, the FASB issued SFAS No. 123 (revised 2004), *Share-Based Payment* (SFAS No. 123R), which replaces SFAS No. 123 and supersedes APB Opinion No. 25. SFAS No. 123R addresses the accounting for transactions in which an enterprise receives employee services in exchange for (a) equity instruments of the enterprise or (b) liabilities that are based on the fair value of the enterprise s equity instruments or that may be settled by the issuance of such equity instruments. SFAS No. 123R requires all share-based payments to employees, including grants of employee stock options and restrictive stock grants and units, to be recognized as a compensation cost based on their fair values. The pro forma disclosures previously permitted under SFAS No. 123 no longer will be an alternative to financial statement recognition. We are required to adopt SFAS No. 123R no later than July 3, 2005. Under SFAS No. 123R, we must determine the appropriate fair value model to be used for valuing share-based payments, the amortization method for compensation cost and the transition method to be used at the date of adoption. The transition methods include prospective and retroactive adoption options. Under the retroactive option, prior periods may be restated either as of the beginning of the year of adoption or for all periods presented. The prospective method requires that compensation expense be recorded for all unvested stock options and restricted stock at the beginning of the first quarter of adoption of SFAS No. 123R, while the retroactive methods would record compensation expense for all unvested stock options and restricted stock beginning with the first period restated. We are currently assessing the impact that adoption of this Standard will have on our consolidated result of operations, financial position and cash flows. However, we believe that adoption of this standard will result in a charge to reported earnings.

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

This Management s Discussion and Analysis of Financial Condition and Results of Operations contains descriptions of our expectations regarding future trends affecting our business. These forward-looking statements and other forward-looking statements made elsewhere in this document are made in reliance upon the safe harbor provisions of the Private Securities Litigation Reform Act of 1995. Please read the section below titled Factors Affecting Future Results to review conditions which we believe could cause actual results to differ materially from

those contemplated by the forward-looking statements. Forward-looking statements are identified by words such as believes, anticipates, expects, intends, plans, will, may and similar expressions. In addition, any statement to our plans, expectations, strategies or other characterizations of future events or circumstances are forward-looking statements. Our business may have changed since the date hereof and we undertake no obligation to update these forward looking statements.

Table of Contents

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., incorporated in California in 1989, designs, develops and distributes laser-based surgical products and disposable fiber-optic accessories for the treatment of advanced cardiovascular disease through transmyocardial revascularization (TMR) and percutaneous myocardial channeling (PMC). PMC was formerly referred to as percutaneous myocardial revascularization (PMR). The new name PMC more literally depicts the immediate physiologic tissue effect of the Cardiogenesis PMC system to ablate precise, partial thickness channels into the heart muscle from the inside of the left ventricle.

In February 1999, we received final approval from the FDA for our TMR products for certain indications, and we are permitted to sell those products in the U.S. on a commercial basis. We have also received the European Conforming Mark (CE Mark) allowing the commercial sale of our TMR laser systems and our PMC catheter system to customers in the European Community. Effective July 1999, the Centers for Medicare and Medicaid Services (CMS) began providing Medicare coverage for TMR. As a result, hospitals and physicians are now eligible to receive Medicare reimbursement for TMR equipment and procedures performed on Medicare recipients.

We have completed pivotal clinical trials involving PMC, and study results were submitted to the FDA in a Pre Market Approval (PMA application) in December 1999 along with subsequent amendments. In July 2001, the FDA Advisory Panel recommended against approval of PMC 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 PMC by the Medical Devices Dispute Resolution Panel (MDDRP). In July 2003, the FDA agreed to review additional data in support of our PMA supplement for PMC under the structure of an interactive review process between us and the FDA review team The independent panel review by the MDDRP was cancelled in lieu of the interactive review, but the FDA has agreed to reschedule the MDDRP hearing in the future, if the dispute cannot be resolved. In August 2004, we met with the FDA and agreed on the steps needed to design and initiate a new clinical trial to confirm the safety and efficacy of PMC. In January 2005, we again met with the agency and agreed on major trial parameters. We are working closely with the FDA in finalizing the clinical trial protocol to be formally agreed upon. Once the agreement is achieved and the related costs are clearly understood, we expect to move forward, either on our own or with a corporate partner in the interventional cardiology arena. There can be no assurance, however, that we will receive a favorable determination from the FDA.

As of March 31, 2005, we had an accumulated deficit of $169,088,000. We may continue to incur operating losses in the future. The timing and amounts of our expenditures will depend upon a number of factors, including the efforts required to develop our sales and marketing organization, the timing of market acceptance of our products and the status and timing of regulatory approvals.

Results of Operations

Net Revenues

We generate our revenues primarily through the sale of our TMR laser systems, fiber optic handpiece delivery systems, and related services. Net revenues of $2,991,000 for the quarter ended March 31, 2005 decreased $1,050,000, or 26%, when compared to net revenues of $4,041,000 for the quarter ended March 31, 2004. The decrease in net revenues is primarily attributed to a decrease in laser revenue. Laser revenue decreased as a result of a fewer number of laser units sold this quarter. The decrease in laser sales is partially attributed to the realignment of sales territories to provide more efficient geographic coverage. This realignment, coupled with a sales force expansion of 30%, resulted

in a decrease in laser sales since some territories had new region managers. Our new expanded sales force provides us with wider, focused coverage that will assist us in reaching our sales objectives for this coming year.

Table of Contents

For the quarter ended March 31, 2005, domestic disposable handpiece revenue increased by $25,000 and domestic laser revenue decreased by $815,000 compared to the quarter ended March 31, 2004. In the first quarter of 2005, domestic handpiece revenue included $426,000 in sales of product to customers operating under the loaned laser program, of which $146,000 was attributed to premiums associated with such sales. In the first quarter of 2004, domestic handpiece revenue included $604,000 in sales of product to customers operating under the loaned laser program, of which $201,000 was attributed to premiums associated with such sales. In the first quarter of 2005 and 2004, sales of handpieces to customers not operating under the loaned laser program were $2,115,000 and $1,912,000, respectively. International sales, accounting for approximately 4% of net revenues for the quarter ended March 31, 2005, decreased $232,000 from the prior year. We define international sales as sales to customers located outside of the United States. In addition, service revenue of $206,000 decreased $28,000 for the quarter ended March 31, 2005 when compared to $234,000 for the quarter ended March 31, 2004.

Gross Profit

Gross profit decreased to 80% of net revenues for the quarter ended March 31, 2005 as compared to 86% of net revenues for the quarter ended March 31, 2004. Gross profit in absolute dollars decreased by $1,102,000 to $2,386,000 for the quarter ended March 31, 2005, as compared to $3,488,000 for the quarter ended March 31, 2004. The decrease in gross profit, as a percentage of sales and in absolute terms, resulted from a decrease in sales of our higher margin lasers resulting in lower profit margins.

Research and Development

Research and development expenditures of $350,000 increased $59,000 or 20% for the quarter ended March 31, 2005 when compared to $291,000 for the quarter ended March 31, 2004. The increase in overall research and development expense was primarily attributed to increased spending on research and development activity for our minimally invasive TMR platform.

Sales, General and Administrative

Sales, general and administrative expenditures of $3,744,000 increased $816,000 or 28% for the quarter ended March 31, 2005 when compared to $2,928,000 for the quarter ended March 31, 2004. The increase in expenses resulted primarily from increases in employee headcount and related expenses, legal and patent expenses, and marketing expenses of $600,000, $133,000 and $95,000, respectively. In addition, the company incurred increased costs attributed to trade shows and increased marketing expenses due to the introduction of the new minimally invasive platform and Cellerator platelet-rich plasma product line.

Liquidity and Capital Resources

At March 31, 2005, we had cash and cash equivalents of $4,214,000 compared to $4,740,000 at December 31, 2004, a decrease of $526,000. During the three months ended March 31, 2005, we had a net loss of $2,811,000 and used cash of $1,310,000 in operating activities primarily to fund our operating loss, pay accrued liabilities, and purchase inventory. Accounts receivable decreased by $1,435,000 from $3,578,000 at December 31, 2004 to $2,143,000 at March 31, 2005, primarily due to decreased sales revenue in the first three months of 2005.

In October 2004, we completed a financing transaction with Laurus Master Fund, Ltd, a Cayman Islands corporation (Laurus), pursuant to which we issued a Secured Convertible Term Note (the Note) in the aggregate principal amount of $6.0 million and a warrant to purchase an aggregate of 2,640,000 shares of our common stock at a price of $0.50 per share to Laurus in a private offering. Net proceeds to us from the financing, after payment of fees and expenses to Laurus and its affiliates, were $5,752,500. Of this amount, $2,877,000 was deposited in a restricted

cash account and was not available for use in our operations. Cash provided by investing activities during the three months ended March 31, 2005 was $226,000 due to the Laurus conversion of $332,000 in principal into shares of common stock, which allowed for a corresponding amount to be released from restricted cash as available for use by the Company, and an offsetting decrease of $106,000 associated to the acquisition of property and equipment. As of March 31, 2005, there was $2,567,000 in the restricted cash account, which included $22,000 of interest income. Funds deposited in the restricted cash account will only be released to us, if at all, upon satisfaction of certain conditions, such as: 1) voluntary conversion of the restricted funds by Laurus, and 2) conversion rights of the restricted funds by us subject to certain stock price levels and trading volume limitations.

Table of Contents

The Note matures in October 2007, absent earlier redemption by us or earlier conversion by Laurus. Annual interest on the Note is equal to the prime rate published in The Wall Street Journal from time to time, plus two percent (2.0%), provided that such annual rate of interest may not be less than six and one-half percent (6.5%), subject to certain downward adjustments resulting from certain increases in the market price of our common stock. Interest on the Note is payable monthly in arrears on the first day of each month during the term of the Note, commencing November 2004. In addition, commencing May 2005, we are required to make monthly principal payments of $100,000 per month. To the extent that funds are released from the restricted cash account prior to repayment in full of the unrestricted portion of the Note proceeds, the monthly payment amount may be increased by an amount equal to the amount released from the restricted cash account divided by the remaining number of monthly principal payments due on or prior to the maturity date. The Note is convertible into shares of our common stock at the option of Laurus and, in certain circumstances, at our option.

The $6,000,000 Note includes embedded derivative financial instruments. In conjunction with the Note, we issued a warrant to purchase 2,640,000 shares of common stock. The accounting treatment of the derivatives and warrant requires that we record the derivatives and warrant at their relative fair value as of the inception date of the agreement, and at fair value as of each subsequent balance sheet date. Any change in fair value will be recorded as non-operating, non-cash income or expense at each reporting date. If the fair value of the derivatives and warrant is higher at the subsequent balance sheet date, we will record a non-operating, non-cash charge. If the fair value of the derivatives and warrant is lower at the subsequent balance sheet date, we will record non-operating, non-cash income. As of March 31, 2005 and December 31, 2004, the derivatives were valued at $2,723,309 and $2,337,777, respectively. Conversion related derivatives were valued using the Binomial Option Pricing Model with the following assumptions as of March 31, 2005 and December 31, 2004, respectively: dividend yield of 0% and 0%; annual volatility of 70.5% and 70.5%; and risk free interest rate of 3.96% and 3.25% as well as probability analysis related to trading volume restrictions. The remaining derivatives were valued using discounted cash flows and probability analysis. The warrant was valued at $871,200 and $766,020 at March 31, 2005 and December 31, 2004, respectively, using the Binomial Option Pricing model with the following assumptions: dividend yield of 0% and 0%; annual volatility of 70.5 % and 70.5%; risk-free interest rate of 4.33% and 3.94%; and exercise factor of 2 and 2. Both the derivatives and warrant were classified as long-term liabilities on the balance sheet line Convertible Term Note and related obligations.

We have incurred significant losses for the last several years and at March 31, 2005 we have an accumulated deficit of $169,088,000. Our ability to maintain current operations is dependent upon maintaining our sales at least at the same levels achieved in prior years, increasing our sales through direct sales channels and marketing efforts on existing products and achieving timely regulatory approval for certain other products.

Currently, our primary goal is to achieve consistent profitability at the operating level. Our actions have been guided by this initiative, and as a result, cost containment measures have been implemented to help 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, 2005 will be sufficient to meet our capital, debt and operating requirements through the next 12 months. We believe that if revenues from sales or new funds from debt or equity instruments are insufficient to maintain the current expenditure rate, it will be necessary to significantly reduce our operations until an appropriate solution is implemented.

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 that we will not have sufficient cash to fund our operations.

Table of Contents

Contractual Obligations

		Payments Due by Period			
Contractual Obligations	**Total**	**Less than 1 Year**	**1-3 Years**	**3-5 Years**	**More than 5 Years**
		(In thousands)			
Secured Convertible Term Note, net of restricted cash	$ 3,000	$ 1,100	$ 1,900	$	$
Secured Convertible Term Note Interest(1)	524	203	321		
Capital Lease Obligations	21	5	12	4	
Operating Leases	594	366	228		
Total	$ 4,139	$ 1,674	$ 2,461	$ 4	$

(1) Assumes 6.75% effective interest rate.

Critical Accounting Policies and Estimates

The preparation of financial statements in conformity with generally accepted accounting principles requires our management to make estimates and assumptions that affect the reported amounts of assets and liabilities and disclosure of contingent assets and liabilities at the date of the financial statements and the reported amounts of revenues and expenses during the reporting period. Actual results could differ from those estimates.

The following presents a summary of our critical accounting policies and estimates, defined as those policies and estimates we believe are: (i) the most important to the portrayal of our financial condition and results of operations, and (ii) that require our most difficult, subjective or complex judgments, often as a result of the need to make estimates about the effects of matters that are inherently uncertain. Our most significant estimates relate to the determination of the allowance for bad debt, inventory reserves, valuation allowance relating to deferred tax asset, warranty reserve, the assessment of future cash flows in evaluating intangible assets for impairment and assumptions used in fair value determination of warrants and derivatives.

Revenue Recognition:

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

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

We frequently loan lasers to hospitals in return for the hospital purchasing a minimum number of handpieces at a premium over the list price. The loaned lasers are depreciated to cost of revenues over a useful life of 24 months. The revenue on the handpieces is recognized upon shipment at an amount equal to the list price. The premium over the list price represents revenue related to the use of the laser unit and is recognized ratably, generally over the 24-month useful life of the placed lasers.

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

Accounts Receivable:

Accounts receivable consist of trade receivables recorded upon recognition of revenue for product sales, reduced by reserves for the estimated amount deemed uncollectible due to bad debt. The allowance for doubtful accounts is our best estimate of the amount of probable credit losses in our existing accounts receivable. We review the allowance for doubtful accounts quarterly with the corresponding provision included in general and administrative expenses. Past due balances over 90 days and over a specified amount are reviewed individually for collectibility. All other balances are reviewed on a pooled basis by type of receivable. Account balances are charged off against the allowance when we feel it is probable the receivable will not be recovered. We do not have any off-balance-sheet credit exposure related to our customers.

Table of Contents

Inventories:

Inventories are stated at the lower of cost (principally standard cost, which approximates actual cost on a first-in, first-out basis) or market value. We regularly monitor potential excess, or obsolete, inventory by analyzing the usage for parts on hand and comparing the market value to cost. When necessary, we reduce the carrying amount of our inventory to its market value.

Valuation of Long-lived Assets:

We assess potential impairment of our finite lived, intangible assets and other long-lived assets when there is evidence that recent events or changes in circumstances indicate that their carrying value may not be recoverable. Reviews are performed to determine whether the carrying value of assets is impaired based on comparison to the undiscounted estimated future cash flows. If the comparison indicates that there is impairment, the impaired asset is written down to fair value, which is typically calculated using discounted estimated future cash flows. The amount of impairment would be recognized as the excess of the assets carrying value over its fair value. Events or changes in circumstances which may cause impairment include: significant changes in the manner of use of the acquired asset, negative industry or economic trends, and underperformance relative to historic or projected future operating results.

Income Taxes:

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

Risk Factors

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

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

We have incurred significant losses since inception. For example, for the fiscal years 2004, 2003 and 2002 we incurred net losses of $1,319,000, $348,000 and $530,000 respectively. We will have a continuing need for new infusions of cash if we continue to incur losses in the future. We plan to increase our revenues through increased direct sales and marketing efforts on existing products and achieving regulatory approval for other products. If our direct sales and marketing efforts are unsuccessful or we are unable to achieve regulatory approval for our products, we will be unable to significantly increase our revenues. We believe that if we are unable to generate sufficient funds from sales or from debt or equity issuances to maintain our current expenditure rate, it will be necessary to significantly reduce our operations, including our sales and marketing efforts and research and development. If we are required to significantly reduce our operations, our business will be harmed.

In October 2004, we obtained $6.0 million of convertible debt financing which we believe will be sufficient to satisfy our capital needs for at least the next 12 months. However, changes in our business, financial performance or the market for our products may require us to seek additional sources of financing, which could include short-term debt, long-term debt or equity. Although in the past we have been successful in obtaining financing, there is a risk that we may be unsuccessful in obtaining financing in the future on terms acceptable to us and that we will not have sufficient cash to fund our continued operations.

Table of Contents

Our revenues and operating income may be constrained:

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

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

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

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

The FDA has not approved our PMC laser system for any application in the United States. In July 2001, the FDA Advisory Panel recommended against approval of PMC 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 PMC by the Medical Devices Dispute Resolution Panel (MDDRP). In July 2003, the FDA agreed to an alternative process in which additional data in support of our PMA supplement for PMC could be submitted and reviewed by the FDA in an interactive review process. The data was submitted in August 2003 and the panel review by the MDDRP was cancelled. The FDA agreed to reschedule the MDDRP hearing in the future if the dispute cannot be resolved.

In March 2004, the FDA informed us that the data submitted in August 2003 was not adequate to support approval by the FDA of our PMC system. In August 2004, we met with the FDA and agreed on the steps needed to design and initiate a new clinical trial to confirm the safety and efficacy of PMC. In January 2005, we again met with the agency and agreed on major trial parameters. We are working closely with the FDA in finalizing the clinical trial protocol to be formally agreed upon. Once the agreement is achieved and the related costs are clearly understood, we expect to move forward, either on our own or with a corporate partner in the interventional cardiology arena. There can be no assurance, however, that we will receive a favorable determination from the FDA.

In August 2004, we decided to rename the PMC platform to Percutaneous Myocardial Channeling (PMC). The new name more literally depicts the immediate physiologic tissue effect of the percutaneous procedure.

We will not be able to derive any revenue from the sale of our PMC system in the United States until such time, if any, that the FDA approves the device. Such inability to realize revenue from sales of our PMC device in the United States may have an adverse effect on our results of operations.

We may incur impairment charges on long-lived assets if future events indicate asset values my not be recoverable.

In January 1999, we entered into an agreement with PLC Systems, Inc., which granted us non-exclusive worldwide use of certain PLC patents. In return, we paid PLC a license fee totaling $2,500,000 over a forty-month period. The present value of the payments of $2,300,000 was recorded as an asset and is included in other assets. The PLC patents are valuable to our PMC product line. The PMC product line is not approved for sale in the United States but is sold internationally. If PMC product sales decline in the future, we may suffer an impairment of the asset s value on our balance sheet.

We may fail to obtain required regulatory approvals in the United States to market our new minimally invasive and robotically assisted handpieces.

The Pearl 5.0 mm and 8.0 mm minimally invasive handpieces have been included in applications to the FDA and to international health authorities, and we are currently working with these respective agencies toward approvals. We will not be able to derive any revenue from the sale of our new minimally invasive and robotically assisted handpieces in the United States until such time, if any, that the FDA approves these devices. Such inability to realize revenue from sales of these devices in the United States may have an adverse effect on our results of operations.

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

Table of Contents

payors, such as Medicare, to reimburse all or part of the cost of the procedure in which the medical device is being used. Effective July 1, 1999, the Centers for Medicare and Medicaid Services (CMS), formerly the Health Care Financing Administration, commenced Medicare coverage for TMR systems for any manufacturer s TMR procedures. Hospitals and physicians are eligible to receive Medicare reimbursement covering 100% of the costs for TMR procedures. If CMS were to materially reduce or terminate Medicare coverage of TMR procedures, our business and results of operation would be harmed.

In July 2004, CMS convened the Medicare Advisory Committee (MCAC) to review the clinical evidence regarding laser myocardial revascularization as a treatment option for Medicare patients. The MCAC meeting was a non-binding public hearing to consider the body of scientific evidence concerning the safety and efficacy of laser myocardial revascularization and to provide advice and recommendations to the CMS on clinical issues. The MCAC reviewed more than six years of clinical evidence on laser myocardial revascularization and heard testimony from a group of leading physicians regarding TMR. CMS does not have a pending National Coverage Determination relating to laser myocardial revascularization. In September 2004, we confirmed that CMS does not intend to commence any action on TMR coverage at this time.

As PMC has not been approved by the FDA, the CMS has not approved reimbursement for PMC. If we obtain FDA approval for PMC in the future and CMS does not provide reimbursement, our ability to successfully market and sell our PMC products may be affected.

Even though Medicare beneficiaries appear to account for a majority of all patients treated with the TMR procedure, the remaining patients are beneficiaries of private insurance and private health plans. We have limited experience to date with the acceptability of our TMR procedures for reimbursement by private insurance and private health plans. If private insurance and private health plans do not provide reimbursement, our business will suffer.

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

In the future, the FDA could restrict the current uses of our TMR product and thereby restrict our ability to generate revenues.

We currently derive approximately 99% of our revenues from our TMR product. The FDA has approved this product for sale and use by physicians in the United States. At the request of the FDA, we are currently conducting post-market surveillance of our TMR product. If we should fail to meet the requirements mandated by the FDA or fail to complete our post-market surveillance study in an acceptable time period, the FDA could withdraw its approval for the sale and use of our TMR product by physicians in the United States. Additionally, although we are not aware of any safety concerns during our on-going post-market surveillance of our TMR product, if concerns over the safety of our TMR product were to arise, the FDA could possibly restrict the currently approved uses of our TMR product. In the future, if the FDA were to withdraw its approval or restrict the range of uses for which our TMR product can be used by physicians in the United States, such as restricting TMR s use with the coronary artery bypass grafting procedure, either outcome could lead to reduced or no sales of our TMR product in the United States and our business could be materially and adversely affected.

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

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

Table of Contents

other regulatory requirements, we can be subject to:

fines, injunctions, and civil penalties;

recalls or seizures of products;

total or partial suspensions of production; and

criminal prosecutions.

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

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

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

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

the loss of previously obtained approvals or clearances; or

the failure to comply with existing or future regulatory requirements.

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

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

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

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

In addition, we do not have long-term supply contracts. As a result, our sources are not obligated to continue to provide these critical products or components to us. Although we have identified alternative suppliers and

manufacturers, a lengthy process would be required to qualify them as additional or replacement suppliers or manufacturers. Also, it is possible some of our suppliers or manufacturers could have difficulty meeting our needs if demand for our TMR and PMC laser systems were to increase rapidly or significantly. We believe that we have an adequate supply of lasers to meet our expected demand for the next twelve months. However, if demand for our TMR laser is greater than we currently anticipate and there is a delay in obtaining production capacity, unless we are

Table of Contents

able to obtain lasers originally placed through our loaned laser program and no longer utilized by a hospital, we may not be able to meet the demand for our TMR laser. In addition, any defect or malfunction in the laser or other products provided by our suppliers and manufacturers could cause delays in regulatory approvals or adversely affect product acceptance. Further, we cannot predict:

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

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

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

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

- the dependence on the growth of the market for our TMR and PMC systems;

- our ability to successfully and rapidly expand sales to potential customers in response to potentially increasing clinical adoption of the TMR procedure;

- the costs associated with such growth, which are difficult to quantify, but could be significant;

- domestic and international regulatory developments;

- rapid technological change;

- the highly competitive nature of the medical devices industry; and

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

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

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

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

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

Effective April 3, 2003 our common stock was delisted from The Nasdaq SmallCap Market and became quoted on the OTC Bulletin Board on the same day. The OTC Bulletin Board is a significantly more limited market in

Table of Contents

comparison to the Nasdaq system. The listing of our shares on the OTC Bulletin Board may result in a less liquid market available for existing and potential stockholders to trade shares of our common stock, could ultimately further depress the trading price of our common stock and could have a long-term adverse impact on our ability to raise capital in the future.

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

The stock market has experienced significant price and volume fluctuations that have particularly affected the trading prices of equity securities of many high technology companies. These fluctuations have often been unrelated or disproportionate to the operating performance of many of these companies. Any negative change in the public s perception of medical device companies could depress our stock price regardless of our operating results.

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

The market price of our common stock has been and may continue to be volatile. For example, during the 52-week period ended May 5, 2005, the closing prices of our common stock as reported on the OTC Bulletin Board ranged from a high of $0.79 per share to a low of $0.35 per share. We expect our stock price to be subject to fluctuations as a result of a variety of factors, including factors beyond our control. These factors include:

actual or anticipated variations in our quarterly operating results;

the timing and amount of conversions and subsequent sales of common stock issuable upon conversion of outstanding convertible promissory notes and warrants;

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

announcements relating to strategic relationships or acquisitions;

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

statements by securities analysts regarding us or our industry;

conditions or trends in the medical device industry; and

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

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

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

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

new competitor, is more effective than we are in developing new products and procedures and marketing existing and future products similar to ours, our business will suffer.

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

Table of Contents

are more effective than our products;

are more effectively marketed than our products; or

may render our products or technology obsolete.

If we obtain the FDA s approval for our PMC 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.

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

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

obtain patent protection for our products and processes;

preserve our trade secrets and proprietary technology; and

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

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

Table of Contents

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

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

subject us to significant liabilities to third parties;

require us to seek licenses from third parties;

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

require us to modify our products.

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

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

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

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

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

Furthermore, we cannot assure you that our competitors:

have not developed or will not develop similar products;

will not duplicate our products; or

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

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

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

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

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

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

Table of Contents

TMR product. Though we are in the process of responding to the FDA s Circulatory Devices Panel s recent recommendation against approval of our PMC 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 PMC 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 PMC 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 PMC product.

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

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

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

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

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

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

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

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

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

- foreign currency fluctuations;

economic or political instability;

foreign tax laws;

shipping delays;

Table of Contents

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.

If an Event of Default Occurs Under the Convertible Note Issued to Laurus, It Could Seriously Harm Our Operations.

On October 26, 2004, we issued a $6,000,000 secured convertible term note to Laurus. The note and related agreements contain numerous events of default which include:

A failure to pay interest and principal payments when due;

a breach by us of any material covenant or term or condition of the note or any agreement made in connection therewith;

a breach by us of any material representation or warranty made in the note or in any agreement made in connection therewith;

if we make an assignment for the benefit of our creditors, or a receiver or trustee is appointed for us;

any form of bankruptcy or insolvency proceeding is instituted by or against us and is not dismissed within 60 days;

any money judgment entered or filed against us for more than $50,000 and remains unresolved for 30 days;

our failure to timely deliver shares of common stock when due upon conversions of the note;

our common stock is suspended for 5 consecutive days or 5 days during any 10 consecutive days from a principal market;

we experience an event of default under any other debt obligations; and

we experience a loss, damage or encumbrance upon collateral securing the Laurus debt which is valued at more than $100,000 and is not timely mitigated.

If we default on the note and the holder demands all payments due and payable, the cash required to pay such amounts would most likely come out of working capital and non current assets, which may not be sufficient to repay the amounts due. In addition, since we rely on our working capital for our day to day operations, such a default on the note could materially adversely effect our business, operating results or financial condition to such extent that we are forced to restructure, file for bankruptcy, sell assets or cease operations. Further, our obligations under the note are secured by all of our assets. Failure to fulfill our obligations under the note and related agreements could lead to loss of these assets, which would be detrimental to our operations.

We may incur significant non-operating, non-cash charges resulting from changes in the fair value of warrants and derivatives.

In October 2004, we entered into a Secured Convertible Term Note agreement with Laurus Funds. Pursuant to the Note agreement, a warrant to purchase 2.6 million shares of our common stock was issued to Laurus. This warrant, along with multiple embedded derivatives in the agreement, have been recorded at their relative fair value at the inception date of the agreement, October 27, 2004, and will be recorded at fair value at each subsequent balance

Table of Contents

sheet date. Any change in value between reporting periods will be recorded as a non-operating, non-cash charge at each reporting date. The impact of these non-operating, non-cash charges could have an adverse effect on our stock price in the future.

The fair value of the warrant and derivatives is tied in large part to our stock price. If our stock price increases between reporting periods, the warrant and derivatives become more valuable. As such, there is no way to forecast what the non-operating, non-cash charges will be in the future or what the future impact will be on our financial statements.

The restrictions on our activities contained in the Laurus financing documents could negatively impact our ability to obtain financing from other sources.

The Laurus financing documents restrict us from obtaining additional debt financing, subject to certain specified exceptions. To the extent that Laurus declined to approve a debt financing that does not otherwise qualify for an exception to the consent requirement, we would be unable to obtain such debt financing. In addition, subject to certain exceptions, we have granted to Laurus a right of first refusal to provide additional financing to us in the event that we propose to engage in additional debt financing or to sell any of our equity securities. Laurus s right of first refusal could act as a deterrent to third parties which may be interested in providing us with debt financing or purchasing our equity securities. To the extent that such a financing is required for us to conduct our operations, these restrictions could materially adversely impact our ability to achieve our operational objectives.

Low market prices for our common stock would result in greater dilution to our shareholders, and could negatively impact our ability to convert the Laurus debt into equity

The market price of our common stock significantly impacts the extent to which we are permitted to convert the unrestricted and restricted portions of the Laurus debt into shares of our common stock. The lower the market price of our common stock as of the respective times of conversion, the more shares we will need to issue to Laurus to convert the principal and interest payments then due on the unrestricted portion of the debt. If the market price of our common stock falls below certain thresholds, we will be unable to convert any such repayments of principal and interest into equity, and we will be forced to make such repayments in cash, which we currently forecast will be required to sustain our operations. Our operations could be materially adversely impacted if we are forced to make repeated cash payments on the unrestricted portion of the Laurus debt. Further, prior to the full repayment of the unrestricted portion of the Laurus debt, we will only be able to require conversions of the $3,000,000 restricted cash amount to the extent the market price of our common stock exceeds certain levels. To the extent that the market price of our common stock does not reach such specified levels, we will be not be entitled to take possession of any of the restricted cash during the term of the Laurus note. Our inability to access such cash could limit our ability to achieve our operational objectives. The restricted portion of the debt will continue to accrue interest during the entire period that we are unable to require conversion. In addition, to the extent that conversions of the restricted portion of the debt are not effected during the term of the note, we have only a limited ability to convert a specified amount of the restricted debt (subject to meeting certain minimum market price thresholds and volume requirements), and we will be required to repay the remaining restricted principal and interest in cash. The cash required to pay such amounts would most likely come out of working capital and restricted cash, which may not be sufficient to repay the amounts due.

Future sales of our common stock could lower our stock price.

The sale of our common stock by the holders of the Laurus debt upon conversion of all or any portion of the Laurus debt could cause the market price of our common stock to decline. In addition, if our shareholders sell substantial amounts of our common stock, including shares issuable upon exercise of options or warrants or shares issued in previous financings, in the public market, the market price of our common stock could decline. If these sales

were to occur, we may also find it more difficult to sell equity or equity-related securities in the future at a time and price that we deem appropriate and desirable.

In the future, we may issue additional shares in public or private offerings. We cannot predict the size of future issuances of our common stock or the effect, if any, that future issuances and sales of our common stock would have on the market price of our common stock. We expect that Laurus will generally promptly sell any shares into which the Laurus indebtedness is converted, and that the market price of our common stock could decline as a result of such sales.

Table of Contents

Provisions of our certificate of incorporation as well as our rights agreement could discourage potential acquisition proposals and could deter or prevent a change of control.

Our articles of incorporation authorize our board of directors, subject to any limitations prescribed by law, to issue shares of preferred stock in one or more series without shareholder approval. On August 17, 2001 we adopted a shareholder rights plan, as amended, and under the rights plan, our board of directors declared a dividend distribution of one right for each outstanding share of common stock to shareholders of record at the close of business on August 30, 2001. Pursuant to the Rights Agreement, in the event (a) any person or group acquires 15% or more of our then outstanding shares of voting stock (or 21% or more of our then outstanding shares of voting stock in the case of State of Wisconsin Investment Board), (b) a tender offer or exchange offer is commenced that would result in a person or group acquiring 15% or more of our then outstanding voting stock, (c) we are acquired in a merger or other business combination in which we are not the surviving corporation or (d) 50% or more of our consolidated assets or earning power are sold, then the holders of our common stock are entitled to exercise the rights under the Rights Plan, which include, based on the type of event which has occurred, (i) rights to purchase preferred shares from us, (ii) rights to purchase common shares from us having a value twice that of the underlying exercise price, and (iii) rights to acquire common stock of the surviving corporation or purchaser having a market value of twice that of the exercise price. The rights expire on August 17, 2011, and may be redeemed prior thereto at $.001 per right under certain circumstances. The Board s ability to issue preferred stock without shareholder approval while providing desirable flexibility in connection with financings, acquisitions and other corporate purposes, and the existence of the rights plan might discourage, delay or prevent a change in the ownership of our company or a change in our management. In addition, these provisions could limit the price that investors would be willing to pay in the future for shares of our common stock.

Changes in, or interpretations of, accounting rules and regulations could result in unfavorable accounting charges.

We prepare our consolidated financial statements in conformity with generally accepted accounting principles. These principles are subject to interpretation by the SEC and various bodies formed to interpret and create appropriate accounting policies. A change in these policies can have a significant effect on our reported results and may even retroactively affect previously reported transactions. To the extent that such interpretations or changes in policies negatively impact our reported financial results, our results of stock price could be adversely affected.

Recent rulemaking by the Financial Accounting Standards Board will require us to expense equity compensation given to our employees and could significantly harm our operating results and may reduce our ability to effectively utilize equity compensation to attract and retain employees.

We historically have used stock options as a component of our employee compensation program in order to align employees interests with the interests of our stockholders, encourage employee retention, and provide competitive compensation packages. The Financial Accounting Standards Board has adopted changes that will require companies to record a charge to earnings for employee stock option grants and other equity incentives beginning July 1, 2005, which is effective for the Company on January 1, 2006. This accounting change will reduce our reported earnings and may require us to reduce the availability and amount of equity incentives provided to employees, which may make it more difficult for us to attract, retain and motivate key personnel. Each of these results could materially and adversely affect our business.

While we believe that we currently have adequate internal controls over financial reporting, we are exposed to risks from recent legislation requiring companies to evaluate those internal controls.

Section 404 of the Sarbanes-Oxley Act of 2002 requires our management to report on, and our independent registered public accounting firm to attest to, the effectiveness of our internal control structure and procedures for financial reporting. We are developing a program to perform the system and process evaluation and testing necessary to comply with these requirements on a sustained basis. Companies do not have significant experience in complying with these requirements on an ongoing and sustained basis. As a result, we expect to continue to incur increased expense and to devote management resources to Section 404 compliance. In the event that our chief executive

Table of Contents

officer, chief financial officer or our independent registered public accounting firm determine that our internal control over financial reporting is not effective as defined under Section 404, investor perceptions of CardioGenesis may be adversely affected and could cause a decline in the market price of our stock.

Item 3. Quantitative and Qualitative Disclosures About Market Risk

Quantitative Disclosures

We are exposed to market risks inherent in our 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. We do not use derivatives to alter the interest characteristics of our marketable securities. However, we do have multiple embedded derivatives included in the Secured Convertible Term Note (the Note) entered into with Laurus Master Fund in October 2004. Pursuant to the Note agreement, a warrant to purchase 2.6 million shares of our common stock was issued to Laurus. This warrant, along with multiple embedded derivatives in the agreement, have been recorded at their relative fair value at the inception date of the agreement, October 27, 2004, and will be recorded at fair value at each subsequent balance sheet date. Any change in value between reporting periods will be recorded as a non-operating, non-cash charge at each reporting date. The impact of these non-operating, non-cash charges could have an adverse effect on our stock price in the future.

The fair value of the warrant and derivatives is tied in a large part to our stock price. If our stock price increases between reporting periods, the warrant and derivatives become more valuable. As such, there is no way to forecast what the non-operating, non-cash charges will be in the future or what the future impact will be on our financial statements.

We are subject to interest rate risks on cash and cash equivalents and any future financing requirements. Our primary interest rate risk exposures relate to the impact of interest rate movements on our ability to obtain adequate financing to fund future operations. We are also exposed to interest rate risk on our note payable obligation resulting from the Secured Convertible Term Note. This Note bears an interest rate of prime plus 2%, and as such, is exposed to variability. In the future, the interest rate could be increased to levels that would have a material affect on our financial statements.

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

	2005	2006	2007	2008	2009	Total Fair Value
			In Thousands			
Assets						
Cash, cash equivalents	$ 4,214	$	$	$	$	$ 4,214
Weighted average interest rate	3.8%					3.8%
Liabilities						
Fixed rate debt lease obligation	$ 5	$ 6	$ 6	$ 6	$	$ 23
Weighted average interest rate	6.8%	6.8%	6.8%	6.8%		6.8%
Variable rate note payable, net of restricted cash	$ 800	$ 1,200	$ 1,000	$	$	$ 3,000
Weighted average effective interest rate(1)	36%	36%	36%			36%

(1) Includes interest expense at 6.75%, accretion of the debt discount, and amortization of debt issuance costs relating to the Secured Convertible Term Note.

Qualitative Disclosures

Interest Rate Risk. We do not hedge any balance sheet exposures and intercompany balances against future movements in foreign exchange rates. Given the relatively small number of foreign currency transactions, we do not believe that our potential exposure related to currency rate movements would have a material impact on future net income or cash flows.

Table of Contents

Item 4. Controls and Procedures

Under the supervision and with the participation of our management, including our Chief Executive Officer and Chief Financial Officer, we have evaluated the effectiveness of our disclosure controls and procedures (as such term is defined in Rules 13a-15(e) and 15d-15(e) under the Securities Exchange Act of 1934, as amended) as of the end of the period covered by this report, which we refer to as the Evaluation Date . Based on such evaluation, our Chief Executive Officer and Chief Financial Officer have concluded that, as of the Evaluation Date, our disclosure controls and procedures are effective to provide reasonable assurance that information required to be disclosed by us in our periodic reports under the Exchange Act is recorded, processed, summarized and reported within the time periods specified by the Securities and Exchange Commission rules and forms, and that such information is accumulated and communicated to our management, including our Chief Executive Officer and Chief Financial Officer, as appropriate, to allow timely decisions regarding required disclosure.

During the fiscal quarter ended March 31, 2005, no change in our internal control over financial reporting occurred that materially affected, or is reasonably likely to materially affect, our internal control over financial reporting.

Part II Other Information

Item 1. Legal Proceedings

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

Item 2. Unregistered Sales of Equity Securities and Use of Proceeds

From January 1 through March 31, 2005, Laurus elected to convert an aggregate of $413,000 of principal and interest under the Note into an aggregate of 825,000 shares of Cardiogenesis common stock at a conversion price of $0.50 per share. Of this amount, $332,000 in principal was converted into shares of common stock and a corresponding amount was released from restricted cash as available for use by the Company in the first quarter of 2005. The issuance of shares upon conversion was made in reliance upon Section 4(2) of the Securities Act of 1933, as amended.

Item 6. Exhibits

The exhibits below are filed or incorporated herein by reference.

Exhibit No.	Description
3.1.1 (1)	Restated Articles of Incorporation, as filed with the California Secretary of State on May 1, 1996
3.1.2 (2)	Certificate of Amendment of Restated Articles of Incorporation, as filed with California Secretary of State on July 18, 2001

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Exhibit No.	Description
3.1.3 (3)	Certificate of Determination of Preferences of Series A Preferred Stock, as filed with the California Secretary of State on August 23, 2001
3.1.4 (4)	Certificate of Amendment of Restated Articles of Incorporation, as filed with the California Secretary of State on January 23, 2004
3.2 (5)	Amended and Restated Bylaws
4.1 (6)	Form of Common Stock Purchase Warrant issued in connection with Facilities Lease for 26632 Towne Center Drive, Suite 320, Foothill Ranch, California
4.2 (7)	Third Amendment to Rights Agreement, dated October 26, 2004, between the Company and Equiserve Trust Company N.A
4.3 (8)	Second Amendment to Rights Agreement, dated as of January 21, 2004, between Cardiogenesis Corporation and EquiServe Trust Company, N.A., as Rights Agent
4.4 (9)	First Amendment to Rights Agreement, dated as of January 17, 2002, between Cardiogenesis Corporation and EquiServe Trust Company, N.A., as Rights Agent
4.5 (10)	Rights Agreement, dated as of August 17, 2001, between Cardiogenesis Corporation and EquiServe Trust Company, N.A., as Rights Agent
4.6 (11)	Securities Purchase Agreement, dated as of January 21, 2004, by and among Cardiogenesis Corporation and each of the investors identified therein
4.7 (12)	Registration Rights Agreement, dated as of January 21, 2004, by and among Cardiogenesis Corporation and the investors identified therein
4.8 (13)	Form of Common Stock Purchase Warrant, dated January 21, 2004, having an exercise price of $1.37 per share
4.9 (14)	Form of Common Stock Purchase Warrant, dated January 21, 2004, having an exercise price of $1.00 per share
4.10 (15)	Securities Purchase Agreement, dated October 26, 2004, between the Company and Laurus Master Fund, Ltd.
4.11 (16)	Secured Convertible Term Note, dated October 26, 2004, in favor of Laurus Master Fund, Ltd.
4.12 (17)	Registration Rights Agreement, dated October 26, 2004, between the Company and Laurus Master Fund, Ltd.
4.13 (18)	Common Stock Purchase Warrant, dated October 26, 2004, in favor of Laurus Master Fund, Ltd.
4.14 (19)	Security Agreement, dated October 26, 2004, in favor of Laurus Master Fund, Ltd.

31.1 (20)	Certification of the Chief Executive Officer pursuant to Rule 13a-14(a) of Securities Exchange Act of 1934, as adopted pursuant to Section 302 of the Sarbanes-Oxley Act of 2002
31.2 (20)	Certification of the Chief Financial Officer pursuant to Rule 13a-14(a) of Securities Exchange Act of 1934, as adopted pursuant to Section 302 of the Sarbanes-Oxley Act of 2002
32.1 (20)	Certifications of the Chief Executive Officer and Chief Financial Officer pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002

(1) Incorporated by reference to Exhibit 3.1 to the Registrant s Registration Statement on Form S-1/A (File No. 33-03770), filed on May 21, 1996

Table of Contents

(2) Incorporated by reference to Exhibit 3.2 to the Registrant s Quarterly Report on Form 10-Q filed on August 14, 2001

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

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

(5) Incorporated by reference to Exhibit 3.1.5 to the Registrant s Annual Report on Form 10-K filed on March 10, 2004

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

(7) Incorporated by reference to Exhibit 4.1 to the Registrant s Current Report on Form 8-K filed October 28, 2004

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(20) Filed herewith

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 16, 2005	/s/ Michael J. Quinn Michael J. Quinn Chief Executive Officer, Chairman of the Board and Director (Principal Executive Officer)
Date: May 16, 2005	/s/ Christine Ocampo Christine Ocampo Vice President, Chief Financial Officer (Principal Accounting and Financial Officer, Secretary and Treasurer)

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