ECLIPSE SURGICAL TECHNOLOGIES INC
Form 10-Q
May 15, 2001

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U.S. SECURITIES AND EXCHANGE COMMISSION
WASHINGTON, D.C. 20549

FORM 10-Q

QUARTERLY REPORT PURSUANT TO SECTION 13 OR 15(d)
OF THE SECURITIES EXCHANGE ACT OF 1934

FOR THE QUARTERLY PERIOD ENDED MARCH 31, 2001

Commission file number 0-28288

ECLIPSE SURGICAL TECHNOLOGIES, INC.
(Exact name of Registrant as specified in its charter)

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

1049 KIEL COURT
SUNNYVALE, CALIFORNIA 94089
(Address of principal executive offices)

(408) 548-2100
(Registrant's telephone number, including area code)

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

Yes [X] No [ ]

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

33,696,061 shares of Common Stock, no par value
As of April 30, 2001

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2

ECLIPSE SURGICAL TECHNOLOGIES, INC.
TABLE OF CONTENTS

PART 1
FINANCIAL INFORMATION

3

ECLIPSE SURGICAL TECHNOLOGIES, INC.
CONSOLIDATED BALANCE SHEETS
(IN THOUSANDS)

ASSETS

Current assets:
Cash and cash equivalents .....
Accounts receivable, net of allowance for doubtful accounts of $443 and $353 at March 31, 2001 and December 31, 2000, respectively .....
Inventories, net of reserve of $2,941 and $3,102 at March 31, 2001 and December 31, 2000,

respectively .....
Prepaids and other current assets .....

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

Total assets .....

LIABILITIES AND SHAREHOLDERS' EQUITY

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

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

Total liabilities .....

Shareholders' equity:
Preferred stock:
no par value; 6,600 shares authorized; none issued and outstanding .....
Common stock:
no par value; 82,000 shares authorized; 31,696 and 30,836 shares issued and outstanding at March 31, 2001 and December 31, 2000, respectively .....
Deferred compensation .....
Accumulated other comprehensive loss .....
Accumulated deficit .....

Total shareholders' equity .....

Total liabilities and shareholders' equity .....

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

1

4

ECLIPSE SURGICAL TECHNOLOGIES, INC.
CONSOLIDATED STATEMENTS OF OPERATIONS & COMPREHENSIVE LOSS
(IN THOUSANDS, EXCEPT PER SHARE AMOUNTS)
(UNAUDITED)

THREE MON
MARC

	2001
Net revenues	$ 3,111
Cost of revenues	1,535
Gross profit	1,576
Operating expenses:	
Research and development	543
Sales and marketing	1,952
General and administrative	1,186
Total operating expenses	3,681
Operating loss	(2,105)
Interest expense	(5)
Interest income	30
Equity in net loss of investee	(357)
Net loss	(2,437)
Other comprehensive income (loss), net of tax:	
Unrealized gains on securities:	
Unrealized holding gains (losses) arising during period	3
Less: reclassification adjustment for gains included in net income	--
Foreign currency translation adjustment	(27)
Other comprehensive income (loss)	(24)
Comprehensive loss	$ (2,461)
Net loss per share:	
Basic and diluted	$ (0.08)
Weighted average shares outstanding	30,837

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

ECLIPSE SURGICAL TECHNOLOGIES, INC.
CONSOLIDATED STATEMENTS OF CASH FLOWS
(IN THOUSANDS)
(UNAUDITED)

	THREE MONT MARCH
	2001
Cash flows from operating activities:	

Net loss	$(2,437)
Adjustments to reconcile net loss to net cash used in operating activities:	
Depreciation and amortization	121
Loss from investment in MicroHeart Holdings, Inc.	357
Provision for doubtful accounts	91
Inventory reserves	230
Amortization of deferred compensation	28
Amortization of license fees	48
Changes in operating assets and liabilities:	
Accounts receivable - short term	1,187
Inventories	163
Prepaids and other current assets	428
Accounts receivable - long term	69
Accounts payable	(266)
Accrued liabilities	(809)
Current portion of long term liabilities	--
Long term liabilities	(115)
Customer deposits	--
Deferred revenue	(156)
Net cash used in operating activities	(1,061)
Cash flows from investing activities:	
Purchase of marketable securities	--
Maturities of marketable securities	--
Acquisition of property and equipment	(39)
Net cash (used in) provided by investing activities	(39)
Cash flows from financing activities:	
Net proceeds from issuance of common stock from exercise of options and warrants	1
Net proceeds from sale of common stock	1,000
Proceeds from short term borrowings	(86)
Repayments of capital lease obligations	(6)
Net cash provided by financing activities	909
Effects of exchange rate changes on cash and cash equivalents	(24)
Net (decrease) increase in cash and cash equivalents	(215)
Cash and cash equivalents at beginning of period	3,357
Cash and cash equivalents at end of period	$ 3,142
Supplemental schedule of cash flow information:	
Interest paid	$ 5
Taxes paid	$ 13
Supplemental schedule of noncash investing and financing activities:	
Change in unrealized gain (loss) on marketable securities	$ 3
Deferred compensation	$ 19

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

6

ECLIPSE SURGICAL TECHNOLOGIES, INC.
NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

1. Summary of Significant Accounting Policies:

Interim Financial Information (unaudited):

The interim financial statements in this report reflect all adjustments, consisting of normal recurring adjustments, that are, in the opinion of management, necessary for a fair presentation of the results of operations and cash flows for the interim periods covered and of the financial position of the Company at the interim balance sheet date. Results for interim periods are not necessarily indicative of results to be expected for the full fiscal year. The year-end balance sheet information was derived from audited financial statements but does not include all disclosures required by generally accepted accounting principles. These financial statements should be read in conjunction with Eclipse's audited financial statements and notes thereto for the year ended December 31, 2000, contained in the Company's Annual Report on Form 10-K as filed with the U.S. Securities and Exchange Commission ("SEC").

These financial statements contemplate the realization of assets and the satisfaction of liabilities in the normal course of business. Eclipse has sustained significant losses for the last several years and expects such losses to continue through at least 2001. Eclipse will require additional funding and may sell additional shares of its common stock or preferred stock through private placement or further public offerings. (See Note 3)

There can be no assurance that Eclipse will be able to obtain additional debt or equity financing, if and when needed, on terms acceptable to the Company. Any additional equity or debt financing may involve substantial dilution to Eclipse's stockholders, restrictive covenants or high interest costs. The failure to raise needed funds on sufficiently favorable terms could have a material adverse effect on Eclipse's business, operating results and financial condition.

Eclipse's 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 Eclipse's business, operating results and financial condition.

Net Loss Per Share:

Basic earnings per share is the weighted-average number of common shares outstanding during the period, and diluted earnings per share is computed by dividing net loss by the weighted-average common shares outstanding and all dilutive potential common shares outstanding. For the three months ended March 31, 2001 and 2000 dilutive potential common shares outstanding reflects shares issuable under the Company's stock option plans. There are no reconciling items in the numerator or denominator of the earnings per share calculation for the periods presented.

Options to purchase 4,004,834 and 3,535,925 shares of common stock were outstanding at March 31, 2001 and 2000 respectively, but were not included in the calculation of diluted EPS because their inclusion would have been antidilutive.

2. Inventories:

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

	MARCH 31, 2001	DECEMBER 31, 2000
	(UNAUDITED)	
Raw materials	$1,898	$2,045
Work in process	759	715
Finished goods	2,350	2,640
	$5,007	$5,400

7

3. SUBSEQUENT EVENTS:

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

In May 2001, we entered into a facility lease for an office facility with terms extending through May 2006. The minimum future rental payments are as follows (in thousands):

Year Ending December 31,	
2001	$ 123
2002	492
2003	492
2004	492
2005	492
2006	205
	$2,296

ITEM 2. MANAGEMENT'S DISCUSSION AND ANALYSIS OF FINANCIAL CONDITION AND RESULTS OF OPERATIONS.

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

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

OVERVIEW

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

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

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

As of March 31, 2001, we had an accumulated deficit of $156,270,000. We expect to continue to incur operating losses related to the expansion of sales and marketing activities. 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, if any, of our products, and the status and timing of regulatory approvals.

RESULTS OF OPERATIONS

Net Revenues

Net revenues of $3,111,000 for the quarter ended March 31, 2001 decreased $2,566,000 or 45% when compared to net revenues of $5,677,000 for the quarter ended March 31, 2000. The decrease in revenues was mainly due to a $2.0 million reduction in sales of laser systems. A new sales model implemented in the end of 1999 emphasized laser system placements to develop the disposable handpiece market more rapidly. Laser sales have consequentially dropped in the current quarter compared to the prior year quarter. In addition, a reduction in handpiece sales accounted for roughly $0.5 million of the decrease in net revenue between the first quarter of 2001 compared to the comparable period of the prior year. Much of this decrease is due to the fact that the sales force was in transition in the quarter ended March 31 2001. New sales representatives were hired to fill openings resulting from the departure of under-performing representatives and general attrition. As a result of the transitioning sales force, disposable sales fell 20% in units domestically. Export sales accounted for approximately 9% and 16% of total sales for the quarters ended March 31, 2001 and 2000, respectively. This percentage decrease in export sales relative to total sales is mainly due to reduced international sales staffing after the reduction in force implemented during the fourth quarter of 2000. We define

export sales as sales to customers located outside of the United States. (See "--Factors Affecting Future Results.")

Gross Profit

Gross profit decreased to $1,576,000 or 51% of net revenues for the quarter ended March 31, 2001 as compared to $3,345,000 or 59% of net revenues for the quarter ended March 31, 2000. The decrease in absolute terms and as a percentage of sales resulted from lower sales volume. With lower sales volume, the fixed component of our cost of goods sold became more significant, negatively impacting gross margins as a percent of sales.

Research and Development

Research and development expenditures of $543,000 decreased $1,243,000 or 70% for the quarter ended March 31, 2001 when compared to $1,786,000 for the quarter ended March 31, 2000. The decrease in these expenses reflects the decrease in activity associated with clinical trials, engineering project expenses and lower employee expenses.

Sales and Marketing

Sales and marketing expenditures of $1,952,000 decreased $2,597,000 or 57% for the quarter ended March 31, 2001 when compared to $4,549,000 for the quarter ended March 31, 2000. This decrease is mainly due to a reduction in overall sales and marketing staffing between the first quarter of 2001 and the first quarter of 2000. Many of these reductions were permanent reductions in staffing. However, as we continue to rebuild the sales and marketing team, we expect sales and marketing expense to increase in the quarters to come.

General and Administrative

General and administrative expenses of $1,186,000 decreased by $370,000 or 24% to $1,186,000 in the quarter ended March 31, 2001. The decrease is due to reductions in staffing, legal and patent expense and deferred compensation expense to consultants.

Non-Operating Expenses

Equity in net loss of investee of $357,000 in the quarter ended March 31, 2001 represents our share of the net loss of Microheart Holding Inc. On November 15th 2000, we exercised warrants to increase our ownership of Microheart to 32.1%. This non-cash expense did not exist in the quarter ended March 31, 2000.

Interest income of $30,000 in the quarter ended March 31, 2001 declined 74% or $87,000 compared to $117,000 in the quarter ended March 31, 2000. The reduction in interest income was a result of lower investments in marketable securities, and cash and cash equivalents.

Interest expense of $5,000 in the quarter ended March 31, 2001 decreased 50% or $5,000 compared to $10,000 in the quarter ended March 31, 2000. This decrease reflects a lower level of debt outstanding.

LIQUIDITY AND CAPITAL RESOURCES

Cash and cash equivalents were $3,142,000 at March 31, 2001 compared to $3,357,000 at December 31, 2000, a decrease of 6%. We used $1,061,000 of cash for operating activities, including funding our operating loss and decreases in

accrued liabilities in the first three months of 2001. A decrease in accounts receivable provided $1,187,000 in cash. Investing activities used cash of $36,000 in the first three months of 2001. Financing activities provided cash of $909,000 in the first three months of 2001, primarily from the issuance of common stock to a private company.

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

In March 2001, we sold 898,202 shares of common stock to Acqua Wellington at a negotiated purchase price of $1.1133 per share. We did not pay any other compensation in conjunction with the sale of our common stock. We are contractually prohibited from obtaining any future financings with Acqua Wellington.

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

We have incurred significant losses for the last several years and at March 31, 2001 have an accumulated deficit of $156,270,000. The accompanying financial statements have been prepared assuming we will continue as a going concern. Our ability to continue as a going concern is dependent upon achieving profitable operations in the future. Our plans include increasing sales through increased direct sales and marketing efforts on existing products and pursuing timely regulatory approval for certain other products under clinical trials. We believe our cash balance as of March 31, 2001, as supplemented by the proceeds received from the April 2001 issuance of our common stock, will be sufficient to meet our capital and operating requirements through the end of 2001. We have recognized the need for infusion of cash. In September 2000, March 2001 and April 2001, we raised approximately $1,873,000, $1,000,000 and $1,925,000, respectively, net of offering costs, from the sale of shares of common stock. We are continuing negotiations with a financing company for a revolving line of credit as well as exploring other financing alternatives. There can be no assurance that we will be successful in obtaining such financing. We believe that if revenue from sales or new funds from debt or equity instruments is insufficient to maintain the current expenditure rate, it will be necessary to significantly reduce our operations until an appropriate solution is implemented.

FACTORS AFFECTING FUTURE RESULTS

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

WE MAY NOT BE ABLE TO SECURE ADDITIONAL FINANCING IN THE FUTURE. In the future, we may require additional funds for operating expenses. Our capital requirements may vary and will depend on both internal and external factors. Internal factors affecting our capital requirements include our ability to generate increased sales, profits and cash flow from operations. External factors affecting our capital requirements include the progress of our PTMR submission with the FDA, and competing technological and market developments. We may be required to seek additional sources of financing, which could include short-term debt, long-term debt or equity. There is a risk that we may be unsuccessful in obtaining such financing and will not have sufficient cash to fund our operations. If this occurs, we may have to significantly reduce our operations until an appropriate solution is implemented.

WE MAY FAIL TO OBTAIN REQUIRED REGULATORY APPROVALS TO MARKET OUR

PRODUCTS IN THE UNITED STATES. Our business, financial condition and results of operations could be harmed by any of the following events, circumstances or occurrences related to the regulatory process:

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

In 1997, we submitted a PMA application to the FDA for certain applications of our TMR laser system. On October 27, 1998, an advisory panel of the FDA recommended that the FDA approve our PMA application for the TMR laser system. Along with our approval, the FDA panel requested that we conduct postmarket surveillance in a form to be determined through further discussions with the FDA. On February 11, 1999, we received final approval from the FDA for use of our TMR products for treatment of stable patients with angina (Canadian Cardiovascular Society Class 4) refractory to other medical treatments and secondary to objectively demonstrated coronary artery atherosclerosis and with a region of the myocardium with reversible ischemia not amenable to direct coronary revascularization.

In February 1996, we obtained FDA clearance to undertake Phase I of a clinical study of TMR intended to assess the safety and effectiveness of "TMR Used in Conjunction with CABG" as compared with coronary artery bypass graft, known as CABG, alone. In September 1996, the FDA provided us with clearance to begin Phase II of this study, which was subsequently completed. In July 1999, we submitted a PMA supplement to FDA for an expanded indication to our approved TMR labeling to include TMR in conjunction with CABG. In January 2000, we received a response from the FDA requesting that we either provide more information or modify our labeling request. Since TMR and CABG are each presently utilized to treat separate regions of the heart, we concluded that our present FDA approved labeling is adequate, and that the physician can best decide how to use the laser system within the approved labeling. As a result, in March 2000, we decided that we will not pursue any wording changes to our already approved TMR labeling and have withdrawn our submission to the FDA for TMR in conjunction with CABG.

In December 1999, we submitted a PMA application to the FDA seeking marketing clearance for PTMR in the United States. To date, the FDA has not granted approval of this application. The FDA may not approve this application in a timely manner, if ever.

THE MEDICAL COMMUNITY HAS NOT BROADLY ADOPTED OUR PRODUCTS, AND UNLESS OUR PRODUCTS ARE BROADLY ADOPTED, OUR BUSINESS WILL SUFFER. Our TMR products have not yet achieved broad commercial adoption, and our PTMR products are experimental and have not yet achieved broad clinical adoption. We cannot predict whether or at what rate and how broadly our products will be adopted by the medical community. Our business would be harmed if our TMR and PTMR systems fail to achieve significant market acceptance.

Positive endorsements by physicians are essential for clinical adoption of our TMR and PTMR laser systems. Even if the clinical efficacy of TMR and PTMR laser systems is established, physicians may elect not to recommend TMR and PTMR laser systems for any number of reasons. The reasons why TMR or PTMR laser systems may effectively treat coronary artery disease are not fully understood. Although we intend to use research, development and clinical efforts to

understand better the physiological effects of TMR and PTMR treatment, we may not achieve such understanding on a timely basis, or at all. TMR and PTMR laser systems may not be clinically adopted unless we:

- understand thoroughly the physiological effects of the products;
- provide scientific evidence of long term benefits for treated patients, and
- disseminate such understanding within the medical community.

Clinical adoption of these products will also depend upon:

- our ability to facilitate training of cardiothoracic surgeons and interventional cardiologists in TMR and PTMR therapy;
- willingness of such physicians to adopt and recommend such procedures to their patients; and
- raising the awareness of TMR and then PTMR with the targeted patient population.

Patient acceptance of the procedure will depend on:

- physician recommendations;
- the degree of invasiveness;

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

TO EXPAND OUR BUSINESS, WE MUST ESTABLISH EFFECTIVE SALES, MARKETING AND DISTRIBUTION SYSTEMS, AND WE HAVE LIMITED EXPERIENCE TO DATE ESTABLISHING THESE OPERATIONS. To expand our business, we must establish effective systems to sell, market and distribute products. To date, we have had limited sales which have consisted primarily of U.S. sales of our TMR lasers and disposable handpieces on a commercial basis since February 1999 and PTMR lasers and disposable catheters for investigational use only.

In the fourth quarter of 1999, we changed our U.S. sales strategy to include both selling lasers to hospitals outright, as well as loaning lasers to hospitals in return for the hospital purchasing a minimum number of handpieces at a premium over the list price. During the current year, the majority of lasers shipped have been under this loan program. The purpose of this strategy is to focus our sales force on increasing market penetration and selling disposable handpieces used in connection with our TMR procedure. If the sales force is not successful in increasing market share and selling our disposable handpieces our business will suffer.

With FDA approval of our TMR laser system, we are marketing our products primarily through our direct sales force. We have been expanding our operations by hiring additional sales and marketing personnel. This has required and will continue to require substantial management efforts and financial resources. If we are not able to establish effective sales and marketing capabilities our business will suffer.

THE EXPANSION OF OUR BUSINESS MAY PUT ADDED PRESSURE ON OUR MANAGEMENT AND OPERATIONAL INFRASTRUCTURE AND COULD CREATE NUMEROUS RISKS AND CHALLENGES. The growth in our business may place a significant strain on our limited personnel, management and other resources. The evolving growth of our business involves numerous risks and challenges, including:

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

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

- successfully and rapidly expand sales to potential customers;
- implement operating, manufacturing and financial procedures and controls;
- improve coordination among different operating functions;
- continue to attract, train and motivate additional qualified personnel in all areas; and
- achieve manufacturing efficiencies as production volume increases.

We may not be able to manage these activities and implement these strategies successfully, and any failure to do so could harm our operating results.

OUR OPERATING RESULTS WILL FLUCTUATE AND QUARTER TO QUARTER COMPARISONS OF OUR RESULTS MAY NOT INDICATE FUTURE PERFORMANCE. Our operating results have fluctuated significantly from quarter to quarter and are expected to fluctuate significantly from quarter to quarter due to a number of events and factors, including:

- the level of product demand and the timing of customer orders;
- changes in strategy;
- delays associated with the FDA and other regulatory approval processes;
- personnel changes;
- the level of international sales;
- changes in competitive pricing policies;

- the ability to develop, introduce and market new and enhanced versions of products on a timely basis;
- deferrals in customer orders in anticipation of new or enhanced products;
- product quality problems; and

- the enactment of health care reform legislation and any changes in third party reimbursement policies.

We believe that quarter to quarter comparisons of our operating results are not a good indication of our future performance. Our operating results have, in the past, fallen below expectations and it is likely or possible that our operating results for a future quarter will fall below the expectations of public market analysts and investors. When this occurred in the past the price of our common stock fell substantially and if this occurs, the price of our common stock may fall again, perhaps substantially.

WE WILL BE ABLE TO OBTAIN FDA APPROVAL ONLY FOR THOSE PRODUCTS THAT ARE PROVEN SAFE AND EFFECTIVE IN CLINICAL SITES. The FDA has not approved our PTMR laser systems for any indication in the United States. We submitted a PMA Supplement for our Axcis PTMR system to the FDA in December 1999. The PTMR study compares PTMR to conventional medical therapy in patients with no option for other treatment. The FDA may not accept the study as safe and effective, and PTMR may not be approved for commercial use in the United States. Responding to FDA requests for additional information could require substantial financial and management resources and take several years.

In October 2000, preliminary results from a competitor's clinical trial of a catheter-based device employing "Direct Myocardial Revascularization" ("DMR") were presented at a medical conference in Washington D.C. The trial's principal investigator concluded that the DMR device did not show significant evidence of clinical benefit with regard to angina class reduction or exercise tolerance, and questioned the efficacy of other devices and procedures relying on TMR. We believe that the preliminary results of the DMR device study should not call the results of our PTMR study into question because the devices and procedures are substantially different. We cannot assure you, however, that the preliminary results of the DMR device study will not impact our submission for the Axcis PTMR system to the FDA.

WE MAY NOT BE ABLE TO SUCCESSFULLY MARKET OUR PRODUCTS IF WE FAIL TO OBTAIN THIRD PARTY REIMBURSEMENT FOR THE PROCEDURES PERFORMED WITH OUR PRODUCTS. Few individuals are able to pay directly for the costs associated with the use of our products. In the United States, hospitals, physicians and other healthcare providers that purchase medical devices generally rely on third party payors, such as Medicare, to reimburse all or part of the cost of the procedure in which the medical device is being used. A failure by third party payors to provide adequate reimbursement for the TMR and PTMR procedures that use our products would harm our business.

Effective July 1, 1999 the Health Care Financing Administration commenced Medicare coverage for TMR systems for any manufacturer's TMR procedures. Hospitals are now eligible to receive Medicare reimbursement for TMR procedures. The Health Care Financing Administration may not approve reimbursement for PTMR. If it does not provide reimbursement, our business will suffer. We have limited experience to date with the acceptability of our TMR procedures for reimbursement by private insurance and private health plans. Private insurance and private health plans may not approve reimbursement for TMR or PTMR procedures. If they do not provide reimbursement, our business will suffer.

Third party payors may deny reimbursement if they determine that the device used in a treatment is:

- unnecessary;

- inappropriate;

- experimental;

- used for a non-approved indication; or

- not cost-effective.

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

- the additional cost or the additional effort required to obtain prior authorization or coverage; and

13

- the uncertainty of actually obtaining such authorization or coverage.

WE FACE INTENSE COMPETITION AND COMPETITIVE PRODUCTS COULD RENDER OUR PRODUCTS OBSOLETE. The market for TMR and PTMR laser systems is intensely competitive and is constantly becoming more competitive. If our competitors are more effective in developing new products and procedures and marketing existing and future products, our business will suffer.

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

- are more effective than our products;

- are more effectively marketed than our products; or

- may render our products or technology obsolete.

We currently compete with PLC Systems, Inc., Johnson & Johnson and Boston Scientific. PLC is currently selling TMR commercially in the United States and abroad, while Johnson & Johnson is currently selling PTMR products for investigational use. Boston Scientific has acquired radio frequency technology to begin a percutaneous feasibility trial in the United States under a preliminary Investigational Device Exemption ("IDE"). PLC recently announced a co-marketing agreement with Edwards Life Sciences to distribute their lasers and disposables. This action will add another 18 direct domestic sales representatives involved in promoting the PLC technology.

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

- develop products;

- complete clinical testing and regulatory approval processes;

- obtain third party reimbursement acceptance; and

- supply adequate quantities of the product to the market.

OUR PRODUCTS ALSO COMPETE WITH ALTERNATIVE TREATMENT METHODS AND OUR PRODUCTS MUST REPLACE THESE METHODS TO BE COMMERCIALLY SUCCESSFUL. Many of the medical indications that may be treatable with TMR and PTMR laser systems are currently being treated by drug therapies or surgery and other interventional

therapies, including percutaneous transluminal coronary angioplasty ("PTCA") and coronary artery bypass graft ("CABG"). Our business would be materially harmed if TMR technology fails to replace or augment existing therapies or to be more effective, safer or more cost effective than new therapies. A number of the existing therapies are widely accepted in the medical community, have a long history of use and continue to be enhanced rapidly. Procedures using TMR and PTMR technology may not be able to replace or augment such established treatments.

Others are developing new surgical procedures and new drug therapies to treat coronary artery disease. These new procedures and drug therapies could be more effective, safer or more cost effective than TMR and PTMR laser systems.

The market acceptance and commercial success of our TMR and PTMR laser systems will depend not only upon their safety and effectiveness, but also upon the relative safety and effectiveness of alternative treatments.

OUR PRODUCTS DEPEND ON TMR TECHNOLOGY THAT IS RAPIDLY CHANGING WHICH COULD REQUIRE US TO INCUR SUBSTANTIAL PRODUCT DEVELOPMENT EXPENDITURES TO RESPOND TO INDUSTRY CHANGES. TMR and PTMR laser systems are our only products. Accordingly, if we fail to develop and commercialize successfully our TMR and PTMR laser systems, then our business would suffer.

The medical device industry is characterized by rapid and significant technological change. Our future success will depend in large part on our ability to respond to such changes. In addition, we must expand the

indications and applications for our products by developing and introducing enhanced and new versions of our TMR and PTMR laser systems. Product research and development requires substantial expenditures and is inherently risky. We may not be able to:

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

Even if we identify and develop such products, we may not receive regulatory approval and may not be commercially successful.

OVERALL INCREASES IN MEDICAL COSTS COULD ADVERSELY AFFECT OUR BUSINESS. We believe that the overall escalating cost of medical products and services has led, and will continue to lead, to increased pressures on the health care industry, both foreign and domestic, to reduce the cost of products and services, including products offered by them. We can not assure you that in either United States or international markets that:

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

Fundamental reforms in the healthcare industry in the United States and Europe continue to be considered. We cannot predict whether or when any healthcare reform proposals will be adopted and what effect such proposals might

have on our business.

WE HAVE A HISTORY OF LOSSES AND MAY NOT BE PROFITABLE IN THE FUTURE. We have incurred significant losses since inception. Our revenues and operating income will be constrained:

- until such time, if ever, as we obtain broad commercial adoption of our TMR laser systems by healthcare facilities in the United States;

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

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

We may not achieve or sustain profitability in the future.

IF WE EXPERIENCE INCREASED DEMAND FOR OUR PRODUCTS, WE MAY NOT BE ABLE TO EXPAND OUR BUSINESS TO MEET SUCH DEMAND. We may be required to expand our business to:

- respond to increasing clinical adoption of the TMR procedure;

- develop future products;

- generally compete successfully;

- complete the clinical trials that are currently in progress; and

- prepare additional products for clinical trials.

Such expansion could place a significant strain on managerial, operational and financial systems and resources. To accommodate such expansion and compete effectively, we must improve information systems, procedures and controls and expand, train, motivate and manage our employees.

THIRD PARTIES MAY LIMIT THE DEVELOPMENT AND PROTECTION OF OUR INTELLECTUAL PROPERTY, WHICH COULD ADVERSELY AFFECT OUR COMPETITIVE POSITIONS. 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 PTMR procedures. We do not know if such competitors, potential competitors or others have filed and hold international patents covering other TMR or PTMR technology. In addition, international patents may not be interpreted the same as any counterpart United States patents.

In September 1995, one of our competitors sent us a notice of potential infringement of their patent regarding a method for TMR utilizing

synchronization of laser pulses to the electrical signals from the heart. After discussion with patent counsel, we concluded that we did not utilize the process and/or apparatus that was the subject of the patent at issue, and we provided a response to the competitor to that effect. We have not received any additional correspondence from this competitor on these matters.

In 1996, prior to the merger with us, CardioGenesis initiated a suit in the United States against PLC seeking a judgment that the PLC patent is invalid and unenforceable. In 1997, PLC counterclaimed in that suit alleging infringement by CardioGenesis of the PLC patent. Also in 1997, PLC initiated suit in Germany against CardioGenesis and CardioGenesis' former German sales agent alleging infringement of a European counterpart to the PLC patent. In 1997, CardioGenesis filed an Opposition in the European Patent Office to a European counterpart to the PLC patent, seeking to have the European patent declared invalid.

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

The Settlement and License Agreement applies only to those products or that technology covered by the PLC patents, and the agreement does not provide PLC any rights to any CardioGenesis intellectual property. The Eclipse TMR 2000 laser system does not use the technology associated with the PLC patents.

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

We may not be able to protect our intellectual property because:

- patents may not be issued;
- patents may be challenged, invalidated or designed around by competitors; or
- patent protection may not continue to be available for surgical methods in the future.

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

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

- enforce our issued patents;
- protect our trade secrets or know-how; or

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

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

- subject us to significant liabilities to third parties;

- require us to seek licenses from third parties;

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

- require us to modify our products.

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

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

WE RELY ON PATENT AND TRADE SECRET LAWS, WHICH ARE COMPLEX AND MAY BE DIFFICULT TO ENFORCE. The validity and breadth of claims in medical technology patents involve complex legal and factual questions and, therefore, may be highly uncertain. Issued patent or patents based on pending patent applications or any future patent application may not exclude competitors or may not provide a competitive advantage to us. In addition, patents issued or licensed to us may not be held valid if subsequently challenged and others may claim rights in or ownership of such patents.

Furthermore, we cannot assure you that our competitors:

- have not developed or will not develop similar products;

- will not duplicate our products; or

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

Because patent applications in the United States were, until recently maintained in secrecy until patents issue, we cannot be certain that:

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

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

The United States patent laws 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 amendment will materially affect our ability to protect our proprietary methods and procedures.

Competitors may independently develop proprietary information substantially equivalent to our proprietary information and techniques, or otherwise gain access to our proprietary technology.

In addition to our patents, we rely upon trade secrets, technical know-how and continuing technological innovation to develop and maintain our competitive position. We may not be able to meaningfully protect our unpatented technology because:

- our employees, consultants and advisors may breach their confidentiality and invention assignment agreements and there may not be an adequate remedy for such breach;

- our competitors may independently develop substantially equivalent proprietary information and techniques; or

- competitors may otherwise gain access to our proprietary technology.

Our inability to protect our unpatented intellectual property could materially harm our business.

WE DEPEND ON SINGLE SOURCE SUPPLIERS FOR CERTAIN KEY COMPONENTS AND PRODUCTION WOULD BE INTERRUPTED IFA KEY SUPPLIER HAD TO BE REPLACED. We currently purchase certain critical laser and fiber-optic components from single sources. Although we have identified alternative suppliers, a lengthy process would be required to qualify them as additional or replacement suppliers. Any significant interruption in the supply of critical materials or components could delay our ability to manufacture our products and could harm our manufacturing operations, business and results of operations.

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

Certain of our suppliers could have difficulty expanding their manufacturing capacity to meet our needs if demand for our TMR and PTMR laser systems were to increase rapidly or significantly. In addition, any defect or malfunction in the laser or other products provided by such suppliers could cause a delay in regulatory approvals or adversely affect product acceptance. We can not predict if:

- materials obtained from outside suppliers will continue to be available in adequate quantities; or

- alternative suppliers can be located on a timely basis.

We operate on a purchase order basis with most of our suppliers. Such vendors could at any time determine to cease the supply and production of such components.

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

experience in manufacturing products. Manufacturers often encounter difficulties in increasing production, including problems involving:

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

We also may not be able to successfully increase manufacturing capacity or avoid manufacturing difficulties or product recalls.

OUR PRODUCTS MAY CONTAIN DEFECTS WHICH COULD DELAY REGULATORY APPROVAL OR MARKET ACCEPTANCE OF OUR PRODUCTS. We may experience future product defects, malfunctions, manufacturing difficulties or recalls related to the lasers or other components used in our TMR and PTMR laser systems. Any such occurrence could cause a delay in regulatory approvals or adversely affect the commercial acceptance of our products and could cause harm to our business.

WE MUST COMPLY WITH FDA MANUFACTURING STANDARDS OR FACE FINES OR OTHER PENALTIES INCLUDING SUSPENSION OF PRODUCTION. We are required to demonstrate compliance with the FDA's current good manufacturing practices regulations if we market devices in the United States or manufacture finished devices in the United States. The FDA inspects manufacturing facilities on a regular basis to determine compliance. If we fail to comply with applicable FDA or other regulatory requirements, we can be subject to:

- fines, injunctions, and civil penalties;
- recalls or seizures of products;
- total or partial suspensions of production; and
- criminal prosecutions.

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. Our products are designed to be used in life-threatening situations where there is a high risk of serious injury or death, and we could be subject to product liability claims if the use of our TMR or PTMR laser systems is alleged to have caused adverse effects on a patient or such products are believed to be defective.

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

OUR INSURANCE MAY BE INSUFFICIENT TO COVER PRODUCT LIABILITY CLAIMS AGAINST US. Our product liability insurance may not be adequate for any future product liability problems or continue to be available on commercially reasonable terms, or at all.

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

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

WE DEPEND HEAVILY ON KEY PERSONNEL. Our future business and results of operations depend in significant part upon the continued contributions of our key technical and senior management personnel.

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

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. The 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.

Our products will be subject to other regulatory requirements in the European Union and other countries. Any enforcement action by international regulatory authorities with respect to past or future regulatory noncompliance could cause our business to suffer.

The time required to obtain approval for sale in foreign countries may be longer or shorter than required for FDA approval, and the requirements may differ. In addition, there may be foreign regulatory barriers other than regulatory approval. Except as stated in the following sentence, the FDA must approve exports of devices that require a PMA but are not yet approved domestically. An unapproved device may be exported without prior FDA approval to any member country of the European Union and the other "listed" countries, including Australia, Canada, Israel, Japan, New Zealand, Switzerland and South Africa:

- if the device is approved for sale by that country; or

- for investigational use in accordance with the laws of that country.

We received the CE Mark for our TMR laser system in May 1997 and for our PTMR laser system in April 1998. In the European Economic Area, we will be:

- subject to continued supervision;

- required to report any serious adverse incidents to the appropriate authorities; and

- required to comply with additional national requirements that are outside the scope of the Medical Device Directive.

We became ISO 9001 certified in May 1997. We may not be able to:

- achieve or maintain the compliance required for CE marking on all or any of our products; and

- produce our products profitably and in a timely manner while complying with the requirements of the Medical Device Directive and other regulatory requirements.

If we fail to comply with applicable regulatory requirements we could face:

- fines, injunctions, civil penalties;

- recalls or seizures of products;

- total or partial suspensions of production;

- refusals by foreign governments to permit product sales; and

- criminal prosecution.

Furthermore, if existing regulations are changed or new regulations or policies are adopted, we may:

- not be able to obtain, or affect the timing of, future regulatory approvals or clearances;

- not be able to obtain necessary regulatory clearances or approvals on a timely basis or at all; and

- be required to incur significant costs in obtaining or maintaining such foreign regulatory approvals.

WE SELL OUR PRODUCTS INTERNATIONALLY WHICH SUBJECTS US TO CERTAIN RISKS OF TRANSACTING BUSINESS IN FOREIGN COUNTRIES. Our international revenue is subject to the following risks:

- foreign currency fluctuations;

- economic or political instability;

- foreign tax laws;

- shipping delays;

- various tariffs and trade regulations;

- restrictions and foreign medical regulations;

- customs duties, export quotas or other trade restrictions; and

- difficulty in protecting intellectual property rights.

Any of these factors could have an adverse effect on our international

sales revenues. In future quarters, international sales could become a significant portion of our revenue.

WE MAY NOT ACHIEVE WIDE ACCEPTANCE OF OUR PRODUCTS IN FOREIGN MARKETS IF WE FAIL TO OBTAIN THIRD PARTY REIMBURSEMENT FOR THE PROCEDURES PERFORMED WITH OUR PRODUCTS. If we obtain the necessary foreign regulatory registrations or approvals, market acceptance of our products in international markets would be dependent, in part, upon the availability of reimbursement within prevailing health care payment systems. Reimbursement and health care payment systems in international markets vary significantly by country. They include both government sponsored health care and private insurance. Although we expect to seek international reimbursement approvals, any such approvals may not be obtained in a timely manner, if at all. Failure to receive international reimbursement approvals could hurt market acceptance of TMR products in the international markets in which such approvals are sought.

WE MAY ENGAGE IN FUTURE ACQUISITIONS THAT DISTRACT OUR MANAGEMENT, CAUSE

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

THE PRICE OF OUR COMMON STOCK MAY FLUCTUATE SIGNIFICANTLY, WHICH MAY RESULT IN LOSSES FOR INVESTORS. The market price for our common stock has been and may continue to be volatile. For example, during the 52-week period ended March 31, 2001, the closing prices of our common stock as reported on the NASDAQ National Market ranged from a high of $7.688 to a low of $0.50. We expect our stock price to be subject to fluctuations as a result of a variety of factors, including factors beyond our control. These factors include:

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

Because of this volatility, we may fail to meet the expectations of our

shareholders or of securities analysts at some time in the future, and our stock price could decline as a result.

In addition, the stock market has experienced significant price and volume fluctuations that have particularly affected the trading prices of equity securities of many high technology companies. These fluctuations have often been unrelated or disproportionate to the operating performance of these companies. Any negative change in the public's perception of medical device companies could depress our stock price regardless of our operating results. If our common stock were to trade under $1.00 for 30 consecutive days on the NASDAQ National Market, our common stock could be subject to certain consequences established by the NASDAQ National Market, such as being delisted.

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

ITEM 3. QUANTITATIVE AND QUALITATIVE DISCLOSURES ABOUT MARKET RISK

QUANTITATIVE DISCLOSURES

The Company is exposed to market risks inherent in its operations, primarily related to interest rate risk. These risks arise from transactions and operations entered into in the normal course of business. The Company does not use derivatives to alter the interest characteristics of its debt instruments. The Company has no holdings of derivative or commodity instruments.

Interest Rate Risk. The Company is subject to interest rate risks on cash and cash equivalents, existing long-term debts and any future financing requirements. The long-term debt at March 31, 2001 consists of outstanding balances on lease obligations.

Assets

21

Cash and cash equivalents.....	$3,142
Average interest rate.....	4.0%

22

ECLIPSE SURGICAL TECHNOLOGIES, INC.
PART II OTHER INFORMATION

ITEM 1. LEGAL PROCEEDINGS

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

ITEM 6. EXHIBITS AND REPORTS ON FORM 8-K

a) Exhibits required to be filed by Item 601 st Regulation S-K: None
b) Reports on Form 8-K
No reports on Form 8-K were filed by Eclipse during the three-month period ended March 31, 2001.

ECLIPSE SURGICAL TECHNOLOGIES, INC.

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.

ECLIPSE SURGICAL TECHNOLOGIES, INC.
Registrant

Date: May 15, 2001

/s/ Michael J. Quinn

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

Date: May 15, 2001

/s/ J. Stephen Wilkins

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