ECLIPSE SURGICAL TECHNOLOGIES INC
Form 10-Q/A
June 13, 2001
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U.S. SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

AMENDMENT NO. 1
TO
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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PART 1
FINANCIAL INFORMATION

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ECLIPSE SURGICAL TECHNOLOGIES, INC.
CONSOLIDATED BALANCE SHEETS
(in thousands)

ASSETS

	March 31, 2001	December 31, 2000
	(unaudited)	
Current assets:		
Cash and cash equivalents	$3,142	$3,357
Accounts receivable, net of allowance for doubtful accounts of $443 and $353 at March 31, 2001 and December 31, 2000, respectively	2,376	3,654
Inventories, net of reserve of $2,024 and $2,180 at March 31, 2001 and December 31, 2000, respectively	5,007	5,400
Prepaids and other current assets	409	837

Total current assets	10,93413,248
Property and equipment, net	9661,048
Accounts receivable over one year, net of allowance for doubtful accounts of $443 and $443 at March 31, 2001 and December 31, 2000, respectively	50119
Other assets	2,1452,550
Total assets	$14,095$16,965
LIABILITIES AND SHAREHOLDERS EQUITY	
Current liabilities:	
Accounts payable	$423$689
Accrued liabilities	4,9805,789
Customer deposits	186186
Deferred revenue	1,1541,310
Note payable	86
Current portion of capital lease obligation	2626
Current portion of long-term liabilities	500500
Total current liabilities	7,2698,586
Capital lease obligation, less current portion	6066
Long-term liabilities, less current portion	224339
Total liabilities	7,5538,991
Shareholders equity:	

Preferred stock: no par value; 6,600 shares authorized; none issued and outstanding	
Common stock: no par value; 50,000 shares authorized; 31,696 and 30,836 shares issued and outstanding at March 31, 2001 and December 31, 2000, respectively	162,958
Deferred compensation	(57)
Accumulated other comprehensive loss	(89)
Accumulated deficit	(156,270)
Total shareholders equity	6,542
Total liabilities and shareholders equity	$14,095

Preferred stock: no par value; 6,600 shares authorized; none issued and outstanding	
Common stock: no par value; 50,000 shares authorized; 31,696 and 30,836 shares issued and outstanding at March 31, 2001 and December 31, 2000, respectively	161,938
Deferred compensation	(66)
Accumulated other comprehensive loss	(65)
Accumulated deficit	(153,833)
Total shareholders equity	7,974
Total liabilities and shareholders equity	$16,965

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

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ECLIPSE SURGICAL TECHNOLOGIES, INC.
CONSOLIDATED STATEMENTS OF OPERATIONS & COMPREHENSIVE LOSS
(in thousands, except per share amounts)
(unaudited)

	Three months ended March 31,	
	2001	**2000**
Net revenues	$3,111	$5,677
Cost of revenues	1,535	2,332
Gross profit	1,576	3,345

Operating expenses:		
Research and development	5431,786	
Sales and marketing	1,9524,549	
General and administrative	1,1861,556	
Total operating expenses	3,6817,891	
Operating loss	(2,105)(4,546)	
Interest expense	(5)(10)	
Interest income	30117	
Equity in net loss of investee	(357)	
Net loss	(2,437)(4,439)	
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	(3)	
Foreign currency translation adjustment	(27)	
Other comprehensive income (loss)	(24)(3)	
Comprehensive loss	$(2,461)$(4,442)	
Net loss per share:		
Basic and diluted	(0.08)(0.15)	

Weighted average shares outstanding	30,83729,664

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

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ECLIPSE SURGICAL TECHNOLOGIES, INC.
CONSOLIDATED STATEMENTS OF CASH FLOWS
(in thousands)
(unaudited)

	Three months ended March 31,	
	2001	**2000**
Cash flows from operating activities:		
Net loss	$(2,437)	$(4,439)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation and amortization	121	246
Loss from investment in MicroHeart Holdings, Inc.		357
Provision for doubtful accounts	9	110
Inventory reserves	230	456
Amortization of deferred compensation	28	248
Amortization of license fees		48
Changes in operating assets and liabilities:		
Accounts receivable short term	1,187	1,856
Inventories		

	163(565)
Prepaids and other current assets	428315
Accounts receivable long term	69316
Accounts payable	(266)(341)
Accrued liabilities	(809)(2,299)
Current portion of long term liabilities	(243)
Long term liabilities	(115)(179)
Customer deposits	69
Deferred revenue	(156)223
Net cash used in operating activities	(1,061)(4,279)
Cash flows from investing activities:	
Purchase of marketable securities	(775)
Maturities of marketable securities	4,218
Acquisition of property and equipment	(39)(116)
Net cash (used in) provided by investing activities	(39)3,327
Cash flows from financing activities:	
Net proceeds from issuance of common stock from exercise of options and warrants	11,033
Net proceeds from sale of common stock	1,000
Proceeds from short term borrowings	(86)

Repayments of capital lease obligations	(6)(6)
Net cash provided by financing activities	9091,027
Effects of exchange rate changes on cash and cash equivalents	(24)(1)
Net (decrease) increase in cash and cash equivalents	(215)74
Cash and cash equivalents at beginning of period	3,3575,566
Cash and cash equivalents at end of period	$3,142$5,640
Supplemental schedule of cash flow information: Interest paid	$5$9
Taxes paid	$13$11
Supplemental schedule of noncash investing and financing activities: Change in unrealized gain (loss) on marketable securities	3(3)
Deferred compensation	$19$245

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

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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 the 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.

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2. Inventories:

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

	March 31,	December 31,

	2001	2000
	(unaudited)	
Raw materials	$1,898	$2,045
Work in process	759715	
Finished goods	2,3502,640	
	$5,007$5,400	

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.

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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 first quarter of 2000. Much of this decrease is due to the fact that the sales force was in transition in the quarter ended March 31 2001. At year-end a sales force transition was underway which is expected to continue through the second quarter of 2001. New sales representatives are being hired to fill openings resulting from general attrition and the release of sales representatives who did not meet their sales objectives. 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

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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 a $600,000 reduction in clinical trials expenses, a $400,000 reduction in employee expenses, as headcount was reduced by 14 employees as a result of the December reduction in force or not replacing general attrition. Lastly, there was also a $200,000 reduction in engineering project 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 reduction was caused by the elimination of fifteen clinical sales positions for a quarter to quarter saving of $750,000, while a reduced presence in international sales caused a $700,000 reduction in expense. Other reductions include $400,000 lower travel, $350,000 lower outside service in marketing and $300,000 lower commissions due to lower sales. At year-end a sales force transition was underway which is expected to continue through the second quarter of 2001. New sales representatives are being hired to fill openings resulting from general attrition and the release of sales representatives who did not meet their sales objectives. 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 mainly due to a $210,000 reduction in deferred compensation expense to consultants, a $140,000 reduction in legal and patent expense.

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 a decrease of $809,000 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, the Board adopted an amendment to our Bylaws which precludes the Company from entering into or exercising any rights under any equity line agreement, including the Acqua Wellington equity line agreement, unless approval

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from the shareholders holding a majority of the shares is obtained.

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.

Recently Issued Accounting Standards

In March 2000, the Financial Accounting Standards Board issued Interpretation No. 44, Accounting for Certain Transactions Involving Stock Compensation an Interpretation of APB 25. FIN 44 provides updated accounting guidance regarding implementing and interpreting APB 25, and should be applied on a prospective basis from July 1, 2000. The Company s adoption of this pronouncement had no impact on the Company s financial position or results of operations.

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

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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;

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- 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

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 mark