

ENCISION INC  
Form 10-Q  
August 12, 2004

## U. S. Securities and Exchange Commission

Washington, D.C. 20549

### Form 10-QSB

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

**For the quarterly period ended June 30, 2004**

**For the transition period from            to**

**Commission file number    0-28604**

### **ENCISION INC.**

(Exact name of small business issuer as specified in its charter)

**Colorado**  
(State or other jurisdiction of  
incorporation or organization)

**84-1162056**  
(I.R.S. Employer Identification No.)

**4828 Sterling Drive, Boulder, Colorado 80301**

(Address of principal executive offices)

**(303) 444-2600**

(Registrant's telephone number)

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Check whether the issuer (1) filed all reports required to be filed by Section 13 or 15(d) of the Exchange Act during the past 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                        No           

State the number of shares outstanding of each of the issuer's classes of common equity, as of the latest practicable date:

|                                   |                                |
|-----------------------------------|--------------------------------|
| <b>Common Stock, No par value</b> | <b>6,234,309 Shares</b>        |
| Class                             | (outstanding at July 31, 2004) |

**Transitional Small Business Disclosure Format**

Yes                        No           

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ENCISION INC.

FORM 10-QSB

For the Quarter Ended June 30, 2004

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**PART I****FINANCIAL INFORMATION****ITEM 1 – CONDENSED INTERIM FINANCIAL STATEMENTS****ENCISION INC.****CONDENSED BALANCE SHEETS**

(Unaudited)

|  | <b>June 30,<br/>2004</b> | <b>March 31,<br/>2004</b> |
|--|--------------------------|---------------------------|
| <b><u>ASSETS</u></b>   |                          |                           |
| <b>CURRENT ASSETS:</b>   |                          |                           |
| Cash and cash equivalents  | \$ 1,409,389             | \$ 1,356,607              |
| Accounts receivable, net of allowance for doubtful accounts of \$65,000 and \$62,000, respectively                                     | 840,636                  | 947,692                   |
| Inventory, net of reserve for obsolescence of \$95,000 and \$90,000, respectively  | 1,128,665                | 1,060,251                 |
| Prepaid expenses   | 152,223                  | 67,120                    |
| Total current assets   | 3,530,913                | 3,431,670                 |
| <b>EQUIPMENT, at cost:</b>   |                          |                           |
| Furniture, fixtures and equipment  | 798,106                  | 771,916                   |
| Customer-site equipment  | 450,538                  | 436,550                   |
| Less - accumulated depreciation  | (927,843)                | (886,674)                 |
| Equipment, net   | 320,801                  | 321,792                   |
| PATENTS, net of accumulated amortization of \$71,066 and \$68,027, respectively  | 114,721                  | 117,760                   |
| OTHER ASSETS   | 12,972                   | 12,972                    |
| Total assets   | \$ 3,979,407             | \$ 3,884,194              |
| <b><u>LIABILITIES AND SHAREHOLDERS' EQUITY</u></b>   |                          |                           |
| <b>CURRENT LIABILITIES:</b>  |                          |                           |
| Accounts payable   | \$ 448,201               | \$ 430,600                |
| Accrued compensation   | 153,733                  | 107,266                   |
| Other accrued liabilities  | 527,093                  | 285,232                   |
| Capitalized lease obligation   | 15,690                   | 15,690                    |
| Total current liabilities  | 1,144,717                | 838,788                   |
| <b>LONG-TERM LIABILITIES:</b>  |                          |                           |
| Capitalized lease obligation   | 11,767                   | 15,690                    |
| <b>SHAREHOLDERS' EQUITY:</b>   |                          |                           |
| Preferred stock, no par value, 10,000,000 shares authorized, no shares issued or outstanding   |                          |                           |
| Common stock, no par value, 100,000,000 shares authorized, 5,901,059 (June 30, 2004) and 5,845,526 (March 31, 2004) shares outstanding | 18,370,133               | 18,285,991                |
| Accumulated deficit  | (15,547,210)             | (15,256,275)              |
| Total shareholders' equity   | 2,822,923                | 3,029,716                 |

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|  |    |           |    |           |
|--|----|-----------|----|-----------|
| Total liabilities and shareholders' equity | \$ | 3,979,407 | \$ | 3,884,194 |
|--|----|-----------|----|-----------|

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

ENCISION INC.CONDENSED STATEMENTS OF OPERATIONS

(Unaudited)

|  | For the Three Months<br>Ended June 30, |              |
|--|--|--------------|
|  | 2004                                   | 2003         |
| REVENUE, NET   | \$ 1,763,264                           | \$ 1,701,940 |
| COST OF SALES  | 747,300                                | 732,007      |
| Gross profit   | 1,015,964                              | 969,933      |
| OPERATING EXPENSES:  |  |              |
| Sales and marketing  | 760,382                                | 518,403      |
| General and administrative   | 352,845                                | 226,294      |
| Research and development   | 193,857                                | 188,574      |
| Total operating expenses   | 1,307,084                              | 933,271      |
| (LOSS) INCOME FROM OPERATIONS  | (291,120)                              | 36,662       |
| OTHER INCOME (EXPENSE):  |  |              |
| Interest income  | 1,667                                  | 477          |
| Other (expense), net   | (1,482)                                | (2,145)      |
| NET (LOSS) INCOME  | \$ (290,935)                           | \$ 34,994    |
| NET (LOSS) INCOME PER SHARE:   |  |              |
| Basic and diluted net (loss) income per common share                                 | \$ (0.05)                              | \$ 0.01      |
| Weighted average shares used in computing basic net (loss) income per common share   | 5,853,845                              | 5,430,026    |
| Weighted average shares used in computing diluted net (loss) income per common share | 5,853,845                              | 5,881,529    |

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

ENCISION INC.CONDENSED STATEMENTS OF CASH FLOWS

(Unaudited)

|  | For the Three Months<br>Ended June 30, |                  |
|--|--|------------------|
|  | 2004                                   | 2003             |
| <b>CASH FLOWS FROM OPERATING ACTIVITIES:</b>   |  |                  |
| Net (loss) income  | \$ (290,935)                           | \$ 34,994        |
| Adjustments to reconcile net (loss) income to net cash provided by (used in) operating activities- |  |                  |
| Depreciation and amortization  | 44,208                                 | 38,670           |
| Provision for bad debts  | 3,000                                  | (6,000)          |
| Inventory reserves   | 5,000                                  |                  |
| Changes in operating assets and liabilities-   |  |                  |
| Accounts receivable  | 104,056                                | 226,433          |
| Inventory  | (73,414)                               | (153,407)        |
| Other assets   | (85,103)                               | (87,484)         |
| Accounts payable   | 17,601                                 | 66,525           |
| Accrued compensation and other accrued liabilities   | 284,405                                | (143,180)        |
| Net cash provided by (used) in operating activities  | 8,818                                  | (23,449)         |
| <b>CASH FLOWS FROM INVESTING ACTIVITIES:</b>   |  |                  |
| Investment in equipment  | (40,178)                               | (89,215)         |
| Net cash used in investing activities  | (40,178)                               | (89,215)         |
| <b>CASH FLOWS FROM FINANCING ACTIVITIES:</b>   |  |                  |
| Proceeds from the exercise of stock options  | 84,142                                 |                  |
| Net cash provided by financing activities  | 84,142                                 |                  |
| <b>NET INCREASE (DECREASE) IN CASH AND CASH EQUIVALENTS</b>  | <b>52,782</b>                          | <b>(112,664)</b> |
| CASH AND CASH EQUIVALENTS, beginning of period   | 1,356,607                              | 585,552          |
| CASH AND CASH EQUIVALENTS, end of period   | \$ 1,409,389                           | \$ 472,888       |

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

ENCISION INC.

NOTES TO CONDENSED INTERIM FINANCIAL STATEMENTS

JUNE 30, 2004

(Unaudited)

(1) ORGANIZATION AND NATURE OF BUSINESS

Encision Inc. (the Company) is a medical device company that designs, develops, manufactures and markets patented surgical instruments that provide greater safety to patients undergoing minimally-invasive surgery. The Company believes its patented AEM<sup>®</sup> surgical instrument technology is changing the marketplace for electrosurgical devices and instruments by providing a solution to a patient safety risk in laparoscopic surgery. The Company's sales to date have been made principally in the United States.

On June 28, 2004, the Company announced that James A. Bowman resigned as President and CEO of the Company. Mr. Bowman also stepped down from his post on the Company's Board of Directors. On July 6, 2004, Mr. John R. Serino became President and CEO of the Company.

The Company achieved profitable operations in fiscal 2004 and 2003, but prior to that had incurred losses since its inception and has an accumulated deficit of \$15,547,210 at June 30, 2004. Operations have been financed primarily through issuance of common stock.

During fiscal years 2004 and 2003, the Company achieved annual net income for the first time in its history. The Company's strategic marketing and sales plan is designed to expand the use of the Company's products in surgically active hospitals in the United States. Management expects these efforts to result in continued revenue increases for fiscal 2005 which, combined with planned controlled operating expenses and consistent gross profit margins, are expected to maintain profitable operations and conserve the Company's cash resources.

On July 30, 2003 the Company issued a total of 333,334 shares of its common stock to the Wasatch Micro Cap Fund and the Wasatch Micro Cap Value Fund, for gross proceeds of \$1,000,002. Funds managed by Wasatch Advisors, Inc. held shares of the Company's common stock, constituting less than 5% of the issued and outstanding shares of its common stock, prior to that transaction.

(2) SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES



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### Use of Estimates in the Preparation of Financial Statements

The preparation of financial statements in conformity with accounting principles generally accepted in the United States requires management to make estimates and assumptions. Such estimates and assumptions affect the reported amounts of assets and liabilities as well as disclosure of contingent assets and liabilities at the date of the financial statements and the reported amounts of revenue and expense during the reporting period. Actual results could differ from those estimates.

### Cash and Cash Equivalents

For purposes of reporting cash flows, the Company considers all cash and highly liquid investments with an original maturity of three months or less to be cash equivalents.

### Fair Value of Financial Instruments

The Company's financial instruments consist of cash and cash equivalents and short-term trade receivables and payables. The carrying values of cash and cash equivalents and short-term receivables and payables approximate their fair value due to their short maturities.

### Concentration of Credit Risk

The Company has no significant off-balance sheet concentrations of credit risk such as foreign exchange contracts, options contracts or other foreign hedging arrangements. The Company maintains the majority of its cash balances with two financial institutions in the form of demand deposits and money market funds.

Accounts receivables are typically unsecured and are derived from transactions with and from entities in the healthcare industry primarily located in the United States. Accordingly, the Company may be exposed to credit risk generally associated with the

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healthcare industry. The Company maintains allowances for doubtful accounts for estimated losses resulting from the inability of its customers to make required payments.

The net accounts receivable balance at June 30, 2004 of \$840,636 included \$67,633, or approximately 8%, from one distributor. The net accounts receivable balance at March 31, 2004 of \$947,692 included \$48,212, or approximately 5%, from one distributor.

### Warranty Accrual

The Company provides for the estimated cost of product warranties at the time revenue is recognized. While the Company engages in extensive product quality programs and processes, including actively monitoring and evaluating the quality of its component suppliers, the Company's warranty obligation is based upon historical experience and is also affected by product failure rates and material usage incurred in correcting a product failure. Should actual product failure rates or material usage costs differ from the Company's estimates, revisions to the estimated warranty liability would be required.

### Inventories

Inventories are stated at the lower of cost (first-in, first-out basis) or market. The Company reduces inventory for estimated obsolete or unmarketable inventory equal to the difference between the cost of inventory and the estimated market value based upon assumptions about future demand and market conditions. If actual market conditions are less favorable than those projected by management, additional inventory write-downs may be required. Inventory consisted of the following:

|                                 | <b>June 30,<br/>2004</b> | <b>March 31,<br/>2004</b> |
|---------------------------------|--------------------------|---------------------------|
| Raw materials                   | \$ 914,016               | \$ 724,553                |
| Finished goods                  | 309,649                  | 425,698                   |
|                                 | 1,223,665                | 1,150,251                 |
| Less - Reserve for obsolescence | (95,000)                 | (90,000)                  |
|                                 | \$ 1,128,665             | \$ 1,060,251              |

### Property and Equipment

Property and equipment are stated at cost, with depreciation computed primarily on a double-declining basis over the estimated useful life of the asset, generally three to five years. Company-owned AEM Monitors at customer sites are depreciated on a double-declining basis for a period of 5 years. Leasehold improvements are depreciated over the shorter of the remaining lease term or the estimated useful life of the asset. Maintenance and repairs are expensed as incurred and major additions, replacements and improvements are capitalized.

Long-Lived Assets

Long-lived assets are reviewed for impairment whenever events or changes in circumstances indicate that the carrying amount of an asset may not be recoverable. A long-lived asset is considered impaired when estimated future cash flows related to the asset, undiscounted and without interest, are insufficient to recover the carrying amount of the asset. If deemed impaired, the long-lived asset is reduced to its estimated fair value. Long-lived assets to be disposed of are reported at the lower of their carrying amount or estimated fair value less cost to sell.

Patents

The costs of applying for patents are capitalized and amortized on a straight-line basis over the lesser of the patent's economic or legal life (17 years in the United States). Capitalized costs are expensed if patents are not granted. The Company reviews the carrying value of its patents periodically to determine whether the patents have continuing value and such reviews could result in the conclusion that the recorded amounts have been impaired.

Accrued Liabilities

The Company has accrued \$116,000 related to warranty claims and \$58,701 related to sales commissions and has included these amounts in accrued liabilities in the accompanying balance sheets as of June 30, 2004.

Income Taxes

The Company accounts for income taxes under the provisions of Statement of Financial Accounting Standards ( SFAS ) No. 109, Accounting for Income Taxes ( SFAS No. 109 ). SFAS No. 109 requires recognition of deferred income tax assets and liabilities for the expected future income tax consequences, based on enacted tax laws, of temporary differences between the financial reporting and tax bases of assets and liabilities. SFAS No. 109 also requires recognition of deferred tax assets for the expected future tax effects of all deductible temporary differences, loss carryforwards and tax credit carryforwards. Deferred tax assets are then reduced, if deemed necessary, by a valuation allowance for the amount of any tax benefits which, more likely than not based on current circumstances, are not expected to be realized. Should the Company achieve sufficient, sustained income in the future, the Company may conclude that some or all of the valuation allowance should be reversed.

Revenue Recognition

Revenue from product sales is recorded when the Company ships the product and title has passed to the customer, provided that the Company has evidence of a customer arrangement and can conclude that collection is probable. The Company's shipping policy is FOB Shipping Point. The Company recognizes revenue from sales to stocking distributors when there is no right of return, other than for normal warranty claims. The Company has no ongoing obligations related to product sales, except for normal warranty.

Research and Development Expenses

The Company expenses research and development costs for products and processes as incurred.

Stock-Based Compensation

The Company has adopted the disclosure-only provisions of SFAS No. 123, Accounting for Stock-Based Compensation ( SFAS No. 123 ), and applies Accounting Principles Board Opinion No. 25, Accounting for Stock Issued to Employees ( APB No. 25 ), and related interpretations in accounting for stock options granted to employees. If the Company had accounted for its stock-based compensation plans in accordance with SFAS 123, the Company's net income or loss and pro forma net income or loss per basic and diluted common share for the three months ended June 30, 2004 would have been reported as follows:

| Three months ended June 30, 2004                               |    |           |
|--|----|-----------|
| Net (Loss)   |    |           |
| As Reported  | \$ | (290,935) |
| Stock-based compensation based upon estimated fair values      |    | (41,647)  |
| Pro forma  | \$ | (332,582) |
| Pro Forma Net Income (Loss) Per Basic and Diluted Common Share |    |           |
| As Reported  | \$ | (0.05)    |
| Pro Forma  | \$ | (0.06)    |

Segment Reporting

The Company has concluded that it has one operating segment.

Basic and Diluted Income and Loss per Common Share

Net income or loss per share is calculated in accordance with SFAS No. 128, Earnings Per Share ( SFAS No. 128 ). Under the provisions of SFAS No. 128, basic net income or loss per common share is computed by dividing net income or loss for the period by the weighted average number of common shares outstanding for the period. Diluted net income or loss per common share is computed by dividing the net income or loss for the period by the weighted average number of common and potential common shares outstanding during the period if the effect of the potential common shares is dilutive. As a result of the Company's net loss for the three month period ended June 30, 2004, all potentially dilutive securities would be anti-dilutive and thus, are excluded from diluted earnings per share.

For the three month period ended June 30, 2004, the Company had financial instruments that could create future dilution to the Company's common shareholders and are not currently classified as outstanding common shares of the Company. The common stock number is based on specific conversion or issuance assumptions pursuant to the corresponding terms of each instrument. Potential stock issuance excluded from earnings per share because their effect was anti-dilutive are 775,286 for the three months ended June 30, 2004.

(3) COMMITMENTS AND CONTINGENCIES

The Company currently leases its facilities under noncancelable lease agreements through October 31, 2004. The minimum future lease payments are \$38,260 for the fiscal year ended March 31, 2005. The Company has entered a new lease for its facilities under noncancelable lease agreements through August 14, 2009 at 6797 Winchester Circle, Boulder, Colorado. The minimum future lease payments are as follows:

|                      |            |
|----------------------|------------|
| Year ended March 31, |            |
| 2005                 |            |
| 2006                 | 86,826     |
| 2007                 | 154,179    |
| 2008                 | 166,930    |
| 2009                 | 172,685    |
| 2010                 | 65,566     |
|                      | \$ 646,186 |

The Company had notified one of its distributors that it was in breach of its Distributor Agreement with the Company in several respects, and that if the distributor did not cure the breaches the Agreement may be terminated. The distributor had informed the Company that it believed the Company's interpretations of the Agreement were incorrect. The distributor disputed the Company's position and asserted that the Company had breached the Agreement. The dispute was proceeding in arbitration pursuant to the terms of the Agreement. On July 23, 2004, the dispute was resolved. During the first quarter ended June 30, 2004, the Company had expensed approximately \$201,000, and as of June 30, 2004, the balance in other accrued liabilities was \$185,000 (including legal and arbitrator fees) for this dispute.

The Company is subject to regulation by the United States Food and Drug Administration (FDA). The FDA provides regulations governing the manufacture and sale of the Company's products and regularly inspects the Company and other manufacturers to determine their compliance with these regulations. As of June 30, 2004 the Company believes it was in substantial compliance with all known regulations. The Company was last inspected in November 1998 and has not been notified of any deficiencies from that inspection. FDA inspections are conducted periodically at the discretion of the FDA.

The results of operations for the quarter ended June 30, 2004 should not be taken as an indication of the results of operations for all or any part of the balance of the year.

The accounts receivable balance at June 30, 2004 of \$840,636 included \$27,960 (3%) from international customers.

(4) MANAGEMENT'S REPRESENTATIONS

The condensed interim financial statements included herein have been prepared by the Company, without audit, pursuant to the rules and regulations of the Securities and Exchange Commission. Certain information and footnote disclosures normally included in financial statements prepared in accordance with generally accepted accounting principles have been condensed or omitted pursuant to such rules and regulations, although the Company believes that the disclosures made are adequate to make the information presented not misleading. The condensed interim

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financial statements and notes thereto should be read in conjunction with the financial statements and the notes thereto, included in the Company's Annual Report to the Securities and Exchange Commission for the fiscal year ended March 31, 2004, filed on Form 10-KSB on June 29, 2004.

The accompanying condensed interim financial statements have been prepared, in all material respects, in conformity with the standards of accounting measurements set forth in Accounting Principles Board Opinion No. 28 and reflect, in the opinion of management, all adjustments necessary to summarize fairly the financial position and results of operations for such periods in accordance with accounting principles generally accepted in the United States of America. All adjustments are of a normal recurring nature. The results of operations for the most recent interim period are not necessarily indicative of the results to be expected for the full year.

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

Certain statements contained in this section on Management's Discussion and Analysis are not historical facts, including statements about the Company's strategies and expectations about new and existing products, market demand, acceptance of new and existing products, technologies and opportunities, market and industry segment growth, and return on investments in products and markets. These statements are forward looking statements within the meaning of the Private Securities Litigation Reform Act of 1995 and involve substantial risks and uncertainties that may cause actual results to differ materially from those indicated by the forward looking statements. All forward looking statements in this section on Management's Discussion and Analysis are based on information available to the Company on the date of this document, and the Company assumes no obligation to update such forward looking statements. Readers of this Form 10-QSB are strongly encouraged to review the section entitled *Factors Which May Affect Future Performance and Financial Condition*.

### General

Encision Inc. (Encision or the Company), a medical device company based in Boulder, Colorado, has developed and launched innovative technology that is emerging as a standard of care in minimally-invasive surgery. The Company believes its patented AEM® Surgical Instruments are changing the marketplace for electrosurgical devices and laparoscopic instruments by providing a solution to a well documented patient safety risk in laparoscopic surgery.

Encision was founded to address market opportunities created by the increase in minimally-invasive surgery (MIS) and surgeons' preference for using electrosurgery devices in these procedures. The product opportunity was created by surgeons' continued widespread demand for using monopolar electrosurgery instruments which, when used in laparoscopic surgery, are susceptible to causing inadvertent collateral tissue damage outside the surgeon's field of view. The risk of unintended electrosurgical burn injury to the patient in laparoscopic surgery has been well documented. This risk poses a threat to patient safety and creates liability exposure for surgeons and hospitals that do not adequately address the issue.

Encision's patented AEM technology provides surgeons with the desired tissue effects, while preventing stray electrosurgical energy that can cause unintended and unseen tissue injury. AEM Laparoscopic Instruments are equivalent to conventional instruments in size, shape, ergonomics and functionality but they incorporate active electrode monitoring technology to dynamically and continuously monitor the flow of electrosurgical current, thereby helping to prevent patient injury. With Encision's shielded and monitored instruments, surgeons are able to perform electrosurgical procedures more safely and effectively than is possible using conventional instruments. In addition, the AEM instruments are cost competitive with conventional non-shielded, non-monitored instruments. The result is advanced patient safety at comparable cost and with no change in surgeon technique.

AEM technology has been recommended and endorsed by sources from all groups involved in minimally-invasive surgery. Surgeons, nurses, biomedical engineers, the medicolegal community, malpractice insurance carriers and electrosurgical device manufacturers advocate the use of AEM technology. The breadth of endorsements continues to expand with the recognition of active electrode monitoring technology as an *AORN Recommended Practice* by the Association of periOperative Registered Nurses and with insurance and medicolegal endorsements.



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The Company has focused its marketing strategies on expanding the market awareness of the AEM technology and its broad independent endorsements, and has continued efforts to expand the AEM product line. With the broad array of AEM instruments now available from the Company, the surgeon has a wide choice of instrument options and does not have to change surgical technique. This coincides with the continued expansion of independent endorsements for AEM technology. Recommendations from the malpractice insurance and medicolegal communities complement the broad clinical endorsements AEM technology has garnered over the past few years.

Adding further credibility to the benefits of Encision's AEM technology are the Company's supplier agreements with Novation and Premier, two of the largest Group Purchasing Organizations (GPO) in the United States. Together, Novation and Premier represent over 3,000 hospitals and over 50% of all surgery in the U.S. Management believes that these GPO supplier agreements give further indication that AEM technology is gaining broader acceptance in the market. Management believes that having the nation's leading medical purchasing groups recognize the value of the Company's technology reflects the potential impact that AEM instruments products can have in the market and in advancing patient safety in surgery nationwide. These agreements do not involve purchase commitments but the Company expects these relationships to expand the market visibility of AEM technology and smooth the procurement and conversion process for new hospital customers.

When a hospital converts to AEM technology it provides recurring revenue to the Company from sales of replacement instruments. There is a strong retention rate of customers who have converted to AEM technology. Management believes this indicates strong customer satisfaction and is further supported by the fact that there is no directly competing technology to supplant AEM products once the hospital has converted. The replacement market of reusable and disposable AEM products in converted hospitals represents

over 90% of Encision's revenue over the past three months and this revenue stream is expected to grow as the base of newly converted hospitals continues to grow.

Until fiscal 2003, the Company incurred annual losses since its inception, and has an accumulated deficit of \$15,547,210 at June 30, 2004. Operations have been financed primarily through issuance of equity. The Company's liquidity has stabilized after a history of operating losses. On July 30, 2003 the Company issued 333,334 shares of its common stock to the Wasatch Micro Cap Fund and the Wasatch Micro Cap Value Fund, for gross proceeds of \$1,000,002. Funds managed by Wasatch Advisors, Inc. held shares of the Company's common stock, constituting less than 5% of the issued and outstanding shares of its common stock, prior to that transaction.

During the three months ended June 30, 2004, the Company generated \$8,818 of cash from operations and used \$40,178 for investments in equipment (primarily capital equipment owned by the Company at customer locations). As of June 30, 2004, the Company had \$1,409,389 in cash and cash equivalents available to fund future operations, an increase of \$52,782 from March 31, 2004. The Company's working capital is \$2,386,196 at June 30, 2004.

### **Historical Perspective**

The Company was organized in 1991 and spent several years developing the AEM monitoring system and protective sheaths to adapt to conventional electrosurgical instruments. During this period, the Company conducted product trials and applied for patents with the United States Patent Office and with the International patent agencies. Patents were issued in 1994, 1996, 1997, 1998 and 2002.

As the Company evolved, it was clear to the Company that its active electrode monitoring technology needed to be integrated into the standard laparoscopic instrument design. As the development program proceeded, it also became apparent that the merging of electrical and mechanical engineering skills in the instrument development process for the Company's patented, integrated electrosurgical instruments was a complex and difficult task. As a result, instruments with integrated AEM technology were not completed for several years. Prior to offering a full range of laparoscopic electrosurgical instrumentation, it was difficult for hospitals to commit to the AEM solution, as the Company did not have adequate comparable surgical instrument options to match what the surgeon demanded. As of fiscal 2001, a sufficiently broad product line was available to provide hospital operating rooms with AEM Instruments in most of the designs common for laparoscopic surgery.

The launch of an expanded line of AEM Laparoscopic Instruments was accomplished over the past two years. With the broad array of AEM instruments now available, the surgeon has a wide choice of instrument options and does not have to change surgical technique. Because conversion to AEM technology is transparent to the surgeon, hospitals can now universally convert to AEM technology, thus providing their laparoscopic surgery patients a higher level of safety. This coincides with the continued expansion of independent endorsements for AEM technology. Recommendations from the malpractice insurance and medicolegal communities complement the broad clinical endorsements AEM technology has garnered over the past few years.

### **Outlook**

*Installed Base of AEM Monitoring Equipment:* The Company believes that the installed base of AEM monitors has the potential for increasing as the inherent risks associated with monopolar laparoscopic electro-surgery become more widely acknowledged and as the network of independent sales representatives becomes more adept at selling the AEM products to our customers. The Company expects that the replacement sales of electro-surgical instruments and accessories will increase as additional hospitals are converted to AEM technology. During the quarter ended June 30, 2004, the Company hired three direct territory representatives. The Company believes that the efforts to improve the quality of sales representatives carrying the AEM product line, along with increased marketing efforts and the introduction of new products, may provide the basis for increased revenue and continuing profitable operations. However these measures, or any others that the Company may adopt, may not result in either increased revenue or continuing profitable operations.

*Possibility of Continued Operating Losses:* Until fiscal 2003, the Company had incurred losses from operations since inception and has an accumulated deficit of \$15,547,210 as of June 30, 2004. The Company has made significant strides toward improving its operating results. Approximately \$247,000 of cash was used in the Company's activities in fiscal 2004. Due to the ongoing need to develop, optimize and train the independent sales rep network and the need to increase sustained revenues to a level adequate to cover fixed and variable operating costs, the Company may operate at a net loss from time to time. On July 30, 2003 the Company issued a total of 333,334 shares of its common stock to the Wasatch Micro Cap Fund and the Wasatch Micro Cap Value Fund, for gross proceeds of \$1,000,002. Funds managed by Wasatch Advisors, Inc. held shares of the Company's common stock, constituting less than 5% of the issued and outstanding shares of its common stock, prior to that transaction.

*Revenue Growth:* The Company expects to generate increased revenue in the U.S. from sales to new hospital customers as the network of independent sales representatives becomes more proficient and expands the number of hospital conversions to AEM Surgical Instruments. The Company believes that the visibility and credibility of the independent clinical endorsements for AEM technology will contribute to new hospital conversions and increased revenues in fiscal 2005. The Company also expects that supplier agreements with Novation and Premier, which together represent over 3,000 U.S. hospitals, will expose more hospitals to the benefits

of AEM technology and may stimulate new hospital conversions and increased revenues. The Company also expects to increase market share gains through promotional programs of placing Company-owned AEM monitors at no charge into hospitals that commit to standardize on AEM instruments. However the Company's efforts to increase market share and grow revenues will depend in part on the Company's ability to expand the efficiency and effective coverage range of its independent sales representative network. During the quarter ended June 30, 2004, the Company hired three direct territory representatives.

*Gross Profit and Gross Margins:* Gross profit and gross margin can be expected to fluctuate from quarter to quarter, as a result of product sales mix and sales volume. Gross margins on products manufactured or assembled by the Company are expected to improve at higher levels of production and sales.

*Sales and Marketing Expenses:* The Company continues its efforts to expand domestic and international distribution capability and it believes that sales and marketing expenses will decrease as a percentage of net revenue with increasing sales volume.

*Research and Development Expenses:* Research and development expenses are expected to increase modestly to support development of additions to our AEM product line, further expanding the instrument options for the surgeon. New additions to the AEM product line are planned for introduction in fiscal year 2005.

## **Results of Operations**

*For the three months ended June 30, 2004 compared to the three months ended June 30, 2003.*

*Net revenue.* Revenue for the quarter ended June 30, 2004, was \$1,763,264, compared to \$1,701,940 for the quarter ended June 30, 2003, an increase of 4%. The increase is attributable to the conversion of new hospitals using our AEM technology. The Company converted seven new hospitals to AEM technology in the three months ended June 30, 2004 versus ten new hospitals that converted to AEM technology in the three months ended June 30, 2003. New hospital prospects remains strong; however, progress has slowed and we have seen a lower rate of new hospital conversions during the past three months. This is due to the Company having encountered a higher turnover in its direct and independent sales representatives and the resulting time needed to train their replacements. While it will take a number of months before new independent sales representatives generate new hospital conversions, the combination of the new representative additions and an expanded sales management team is intended to provide the field focus necessary to achieve market gains.

*Gross Profit.* The gross profit for the quarter ended June 30, 2004 of \$1,015,964 increased by 5% from the quarter ended June 30, 2003 gross profit of \$969,933. Gross profit as a percentage of revenue (gross margin) increased from

57% for the quarter ended June 30, 2003 to 58% in the quarter ended June 30, 2004. The increase in gross margin was primarily the result of purchasing efficiencies compared with one year ago. For the three months ended June 30, 2004, the Company provided \$13,988 in AEM monitors to customers at no-charge to newly converted hospitals as part of a sales incentive program.

*Sales and marketing expenses.* Sales and marketing expenses of \$760,382 for the quarter ended June 30, 2004 increased by 47% compared to \$518,403 for the quarter ended June 30, 2003. The increase was a result of compensation for increased sales employees and resolution of an arbitration dispute. The Company had notified one of its distributors that it was in breach of its Distributor Agreement with the Company in several respects, and that if the distributor did not cure the breaches the Agreement may be terminated. The distributor had informed the Company that it believed the Company's interpretations of the Agreement were incorrect. The distributor disputed the Company's position and asserted that the Company had breached the Agreement. The dispute was proceeding in arbitration pursuant to the terms of the Agreement. On July 23, 2004, the dispute was resolved. During the first quarter ended June 30, 2004, the Company had expensed approximately \$201,000.

*General and administrative expenses.* General and administrative expenses of \$352,845 for the quarter ended June 30, 2004 increased by 56% compared to \$226,294 for the quarter ended June 30, 2003. The increase is the result of increases in compensation, legal fees and use taxes compared with one year ago.

*Research and development expenses.* Research and development expenses of \$193,857 for the quarter ended June 30, 2004 increased by 3% compared to \$188,574 for the quarter ended June 30, 2003. The increase is a result of increases in compensation.

#### **Liquidity and Capital Resources**

To date, operating funds have been provided primarily by sales of common stock and warrants to purchase the Company's common stock, which totaled \$18,370,133 through June 30, 2004, and, to a lesser degree, funds provided by sales of the Company's products. On July 30, 2003 the Company issued a total of 333,334 shares of its common stock to the Wasatch Micro Cap Fund and the Wasatch Micro Cap Value Fund, for gross proceeds of \$1,000,002. Funds managed by Wasatch Advisors, Inc. held shares of the Company's common stock, constituting less than 5% of the issued and outstanding shares of its common stock, prior to that transaction.

The Company's operations generated \$8,818 of cash in the three months ended June 30, 2004 on sales of \$1,763,264 and used \$23,449 of cash in the three months ended June 30, 2003 on sales of \$1,701,940. Prior to fiscal 2003, the use of cash in our

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operations resulted primarily from the funding of the Company's annual net losses. These amounts of cash generated from and used in operations are not indicative of the expected cash to be generated from or used in operations in FY 05. As of June 30, 2004, the Company had \$1,409,389 in cash and cash equivalents available to fund future operations. Working capital was \$2,386,196 at June 30, 2004 compared to \$2,592,882 at March 31, 2004. Current liabilities were \$1,144,717 at June 30, 2004, compared to \$838,788 at March 31, 2004.

The Company has entered a new lease for its facilities under noncancelable lease agreements through August 14, 2009 at 6797 Winchester Circle, Boulder, Colorado. The minimum future lease payments are as follows:

| Year ended March 31, |            |
|----------------------|------------|
| 2011                 |            |
| 2012                 | 86,826     |
| 2013                 | 154,179    |
| 2014                 | 166,930    |
| 2015                 | 172,685    |
| 2016                 | 65,566     |
|                      | \$ 646,186 |

Capital expenditures in the three months ended June 30, 2004 (\$40,178) result primarily from the capitalization of AEM monitors placed in hospitals under various promotional programs. Placing Company-owned AEM monitors into hospitals at no charge to facilitate their use of AEM instruments is an initiative to accelerate new hospital conversions to AEM instruments. Under these promotional programs the Company maintains ownership of the AEM monitor and the cost is capitalized and depreciated as cost of sales over the projected five year life of the asset.

The Company's fiscal year 2005 (FY 05) operating plan is focused on increasing hospital conversions to AEM products, growing revenue, increasing gross profits and conserving cash. The Company can not predict with certainty the expected revenue, gross profit, net income or loss and usage of cash and cash equivalents for FY 05. However, management believes that its cash resources will be sufficient to fund its operations for at least the next twelve months under its current operating plan. If management is unable to manage the Company's business operations in line with budget expectations, it could have a material adverse effect on the Company's business viability, financial position, results of operations and cash flows. Further, if the Company is not successful in sustaining profitability and remaining at least cash flow break-even, additional capital may be required to maintain ongoing operations.

The Company believes the unique performance of the AEM technology and its breadth of independent endorsements provides an opportunity for continued market share growth. The Company believes that the market awareness of the AEM technology and its endorsements is continually improving and that this will benefit the sales efforts in FY 04. The Company believes that the Company entered FY 04 having achieved improvements in the clinical credibility of its technology. The Company's objective in FY 04 is to maintain expense controls while optimizing sales execution in the field, expand market awareness of the AEM technology and maximize the number of additional hospital conversions to AEM instruments.

### Income Taxes

As of March 31, 2004, net operating loss carryforwards totaling approximately \$15,300,000 are available to reduce taxable income in the future. The net operating loss carryforwards expire, if not previously utilized, at various dates beginning in the year 2006. The Company has not paid income taxes since its inception. The Tax Reform Act of 1986 and other income tax regulations contain provisions which may limit the net

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operating loss carryforwards available to be used in any given year, if certain events occur, including changes in ownership interests. The Company has established a valuation allowance for the entire amount of its deferred tax asset since inception due to its history of losses. Should the Company achieve sufficient, sustained income in the future, the Company may conclude that some or all of the valuation allowance should be reversed.

### **Contractual Obligations**

Aside from the operating lease commitments, the Company does not have any material contractual commitments requiring settlement in the future.

**At June 30, 2004, the Company's commitments under these obligations were as follows:**

| <b>Operating Leases</b> |            |
|-------------------------|------------|
| Year ended March 31,    |            |
| 2005                    | 38,260     |
| 2006                    | 86,826     |
| 2007                    | 154,179    |
| 2008                    | 166,930    |
| 2009                    | 172,685    |
| 2010                    | 65,566     |
|                         | \$ 684,446 |

### **Critical Accounting Policies and Estimates**

Our discussion and analysis of our financial condition and results of operations are based upon our financial statements, which have been prepared in accordance with accounting principles generally accepted in the United States. The preparation of these financial statements requires us to make estimates and judgments that affect the reported amounts of assets, liabilities, revenue and expenses, and related disclosure of contingent assets and liabilities. On an on-going basis, we evaluate our estimates, including those related to bad debts, inventories, sales returns, warranty, contingencies and litigation. We base our estimates on historical experience and on various other assumptions that are believed to be reasonable under the circumstances, the results of which form the basis for making judgments about the carrying values of assets and liabilities that are not readily apparent from other sources. Actual results may differ from these estimates under different assumptions or conditions. We believe the following critical accounting policies affect our more significant judgments and estimates used in the preparation of our financial statements.

The Company maintains allowances for doubtful accounts for estimated losses resulting from the inability of its customers to make required payments. If the financial condition of our customers were to deteriorate, resulting in an impairment of their ability to make payments, additional allowances may be required, which would increase our expenses during the periods in which any such allowances were made. The amount recorded as a provision for bad debt in each period is based upon our assessment of the likelihood that we will be paid on our outstanding receivables, based on customer-specific as well as general considerations. To the extent that our estimates prove to be too high, and we ultimately collect a receivable previously determined to be impaired, we may record a reversal of the provision in the period of such determination.

We provide for the estimated cost of product warranties at the time revenue is recognized. While we engage in extensive product quality programs and processes, including actively monitoring and evaluating the quality of its component suppliers, we have experienced some costs related to warranty. The warranty accrual is based upon historical experience and is adjusted based on current experience. Should actual warranty experience differ from our estimates, revisions to the estimated warranty liability would be required.

We reduce inventory for estimated obsolete or unmarketable inventory equal to the difference between the cost of inventory and the estimated market value based upon assumptions about future demand and market conditions. If actual market conditions are less favorable than those projected by management, additional inventory write-downs may be required. Any write-downs of inventory would reduce our reported net income during the period in which such write-downs were applied. To the extent that our estimates prove to be too high, and we ultimately utilize or sell inventory previously determined to be impaired, we may record a reversal of the provision in the period of such determination.

We recognize deferred income tax assets and liabilities for the expected future income tax consequences, based on enacted tax laws, of temporary differences between the financial reporting and tax bases of assets and liabilities. Deferred tax assets are then reduced, if deemed necessary, by a valuation allowance for the amount of any tax benefits which, more likely than not based on current circumstances, are not

At June 30, 2004, the Company's commitments under these obligations were as follows:



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expected to be realized. Should we achieve sufficient, sustained income in the future, we may conclude that all or some of the valuation allowance should be reversed

We depreciate our property and equipment primarily on a double-declining basis over the estimated useful life of the asset, generally three to five years. The Company-owned, consignment AEM Monitors are depreciated on a double-declining basis for a period of 5 years. Leasehold improvements are depreciated over the shorter of the remaining lease term or the estimated useful life of the asset. Maintenance and repairs are expensed as incurred and major additions, replacements and improvements are capitalized.

We amortize our patent costs over their estimated useful lives, which is typically the remaining statutory life. From time to time, we may be required to adjust these lives based on advances in technology, competitor actions, and the like. We review the recorded amounts of patents at each period end to determine if their carrying amount is still recoverable based on our expectations regarding sales of related products. Such an assessment, in the future, may result in a conclusion that the assets are impaired, with a corresponding charge against earnings.

### **Factors Which May Affect Future Performance and Financial Condition:**

You should carefully consider the risk factors described below. If any of the following risk factors actually occur, the Company's business, prospects, financial condition or results of operations would likely suffer. In such case, the trading price of the Company's common stock could fall resulting in the loss of all or part of your investment. You should look at all these risk factors in total. Some risk factors may stand on their own. Some risk factors may affect (or be affected by) other risk factors. You should not assume the

Company has identified these connections. You should not assume that the Company will always update these and future risk factors in a timely manner. The Company is not undertaking any obligation to update these risk factors to reflect events or circumstances after the date of this report or to reflect the occurrence of unanticipated events.

Among the factors that could cause future results and financial condition to be materially different from expectations are:

1. *Our products may not be accepted by the market.* The success of our products and our financial condition depends on the acceptance of AEM products by the medical community in commercially viable quantities during fiscal year 2005 and beyond. We cannot predict how quickly or how broadly AEM products will be accepted by the medical community. We need to continually educate the marketplace about the potential hazards involved in the use of conventional electrosurgical products during minimally-invasive surgical procedures and the expected benefits associated with the use of AEM products. If we are unsuccessful in educating the marketplace about our technology and the hazards of conventional instruments, we will not create sufficient demand by hospitals and surgeons for AEM products and our financial condition, results of operations and cash flows could be adversely affected.
2. *We need to continually develop and train our network of independent sales representatives and expand our distribution efforts in order to be successful.* Our attempts to develop and train a network of independent sales representatives in the U.S. and to expand our international distribution efforts may take longer than expected and may result in considerable amounts of retraining effort as the independent sales reps change their product lines, product focus and personnel. We may not be able to obtain full coverage of the U.S. by independent sales representatives as quickly as anticipated. The independent sales representative network has inherent flaws and inefficiencies, which can include conflicts of interest and competing products. Optimizing the quality of the network and the performance of independent sales representatives in the U.S. is an ongoing challenge. We may also encounter difficulties in developing our international presence due to regulatory issues and our ability to successfully develop international distribution options. Our inability to expand our network of independent sales representatives and optimize their performance could adversely affect our financial results.
3. *We may need additional funding to support our operations.* We were formed in 1991 and have incurred losses of over \$15 million since that date. We have primarily financed research, development, and operational activities with sales of our common stock. At June 30, 2004, we had \$1,409,389 in cash available to fund future operations. During FY 2004, we issued a total of 333,334 shares of our common stock to the Wasatch Micro Cap Fund and the Wasatch Micro Cap Value Fund, for gross proceeds of \$1,000,002. Funds managed by Wasatch Advisors, Inc. held shares of our common stock, constituting less than 5% of the issued and outstanding shares of common stock, prior to that transaction. We may have profitable operations in FY 2005 but there is no guarantee we will do so. We may find that investment in sales and marketing initiatives, merited by market opportunity, may result in the Company operating at a net loss from quarter to quarter. We may also find ourselves at a competitive disadvantage due to our constrained liquidity.

4. *We may not be able to compete successfully against current manufacturers of conventional ( unshielded, unmonitored ) electrosurgical instruments or against competitors who manufacture products that are based on surgical technologies that are alternatives to monopolar electrosurgery.* The electrosurgical products market is intensely competitive. We expect that manufacturers of unshielded, unmonitored electrosurgical instruments will resist any loss of market share that might result from the presence of our shielded and monitored instruments in the marketplace. We also believe that manufacturers of products that are based upon surgical technologies that are alternatives to monopolar electrosurgery are our competitors. These technologies include bipolar electrosurgery, the harmonic scalpel and lasers. The alternative technologies may gain market share and new competitive technologies may be developed and introduced. Most of our competitors and potential competitors have significantly greater financial, technical, product development, marketing and other resources than we do. Most of our competitors also currently have substantial installed customer bases in the medical products market and have significantly greater market recognition. As a result of these factors, our competitors may be able to respond more quickly to new or emerging technologies and changes in customer requirements or to devote greater resources to the development, promotion and sale of their products. It is possible that new competitors or new alliances among competitors may emerge and rapidly acquire significant market share. The competitive pressures we face may materially adversely affect our financial position, results of operations and cash flows, and this may hinder our ability to respond to competitive threats.

5. *If we do not continually enhance our products and keep pace with rapid technological changes, we may not be able to attract and retain customers.* Our future success and financial performance will depend in part on our ability to meet the increasingly sophisticated needs of customers through the timely development and successful introduction of product upgrades, enhancements and new products. These upgrades, enhancements and new products are subject to significant technical risks. The medical device market is subject to rapid technological change, resulting in frequent new product introductions and enhancements of existing products, as well as the risk of product obsolescence. While we are currently developing new products and enhancing our existing product lines, we may not be successful in completing the development of the new products or enhancements. In addition, we must respond effectively to technological changes by continuing to enhance our existing products to incorporate emerging or evolving standards. We may not be successful in developing and marketing product enhancements or new products that respond to technological changes or evolving industry standards. We may experience difficulties that could delay or prevent the successful development, introduction and marketing of those products, and our new products and product enhancements may not adequately meet the requirements of the marketplace and achieve commercially viable levels of market acceptance. If any potential new products, upgrades, or enhancements are delayed, or if any potential new products, upgrades, or enhancements experience quality problems or do not achieve such market

acceptance, or if new products make our existing products obsolete, our financial position, results of operations and cash flows would be materially adversely affected.

6. *If government regulations change or if we fail to comply with existing and/or new regulations, we might miss market opportunities and experience increased costs and limited growth.* The research, manufacturing, marketing and distribution of our products in the United States and other countries are subject to extensive regulation by numerous governmental authorities including, but not limited to, the U. S. Food and Drug Administration. Under the Federal Food, Drug and Cosmetic Act, medical devices must receive clearance from the U. S. Food and Drug Administration through the Section 510(k) pre-market notification process or through the more lengthy pre-market approval process before they can be sold in the United States. The process of obtaining required regulatory approvals is lengthy and has required the expenditure of substantial resources. There can be no assurance that we will be able to continue to obtain the necessary approvals. As part of our strategy, we also intend to pursue commercialization of our products in international markets. Our products are subject to regulations that vary from country to country. The process of obtaining foreign regulatory approvals in certain countries can be lengthy and require the expenditure of substantial resources. We may not be able to obtain necessary regulatory approvals or clearances on a timely basis or at all, and delays in receipt of or failure to receive such approvals or clearances, or failure to comply with existing or future regulatory requirements would have a material adverse effect on our financial position, results of operations and cash flows.

7. *If we fail to comply with the extensive regulatory requirements governing the manufacturing of our products, we could be subject to fines, suspensions or withdrawals of regulatory approvals, product recalls, suspension of manufacturing, operating restrictions and/or criminal prosecution.* The manufacturing of our products is subject to extensive regulatory requirements administered by the Food and Drug Administration and other regulatory bodies. Inspection of our manufacturing facilities and processes can be conducted at any time, without prior notice, by the agencies. In addition, future changes in regulations or interpretations made by the Food and Drug Administration or other regulatory bodies, with possible retroactive effect, could adversely affect us. Changes in existing regulations or adoption of new regulations or policies could prevent us from obtaining, or affect the timing of, future regulatory approvals or clearances. We may not be able to obtain necessary regulatory approvals or clearances on a timely basis in the future, or at all. Delays in receipt of, failure to receive such approvals or clearances and/or failure to comply with existing or future regulatory requirements would have a material adverse effect on our financial position, results of operations and cash flows.

8. *Our current patents, trade secrets and know-how may not provide a competitive advantage, the pending applications may not result in patents being issued, and our competitors may design around any patents issued to us.* Our success will continue to depend in part on our ability to maintain patent protection for our products and processes, to preserve our trade secrets and to operate without infringing the proprietary rights of third parties. We have four issued U.S. patents on several technologies embodied in our AEM Monitoring System, AEM Instruments and related accessories and we have applied for additional U.S. patents. In addition, we have four issued foreign patents. The validity and breadth of claims coverage in medical technology patents involve complex legal and factual questions and may be highly uncertain. Also, patents may not protect our proprietary information and know-how or provide adequate remedies for us in the event of unauthorized use or disclosure of such information, and others may be able to develop, independently, such information. There has been substantial litigation regarding patent and other

At June 30, 2004, the Company's commitments under these obligations were as follows:

intellectual property rights in the medical device industry. Litigation may be necessary to enforce patents issued to us, to protect trade secrets or know-how owned by us, to defend us against claimed infringement of the rights of others or to determine the ownership, scope or validity of our proprietary rights or those of others. Any such claims may require us to incur substantial litigation expenses and to divert substantial time and effort of management personnel and could substantially decrease the amount of capital available for our operations. An adverse determination in litigation involving the proprietary rights of others could subject us to significant liabilities to third parties, could require us to seek licenses from third parties, and could prevent us from manufacturing, selling or using our products. The occurrence of any such actual or threatened litigation or the effect on our business of such litigation may materially adversely affect our financial position, results of operations and cash flows. Additionally, our assessment that a patent is no longer of value could result in a significant charge against our earnings.

9. *We depend on single source suppliers for certain of the key components and sub-contractors to provide much of our products used in the manufacturing of our products. The loss of a supplier or limitation in supply from existing suppliers could have a material adverse effect on our ability to manufacture our products until a new source of supply is located.* Although we believe that there are alternative suppliers, any interruption in the supply of key components could have a material adverse effect on us. A sudden increase in customer demand may create a backorder situation as lead times for some of our critical materials are in excess of 12 weeks. We rely on subcontractors to provide products, either in the form of finished goods or sub-assemblies that we then assemble and test. While these sub-contractors reduce our total cost of manufacturing, they may not be as responsive to increased demand as we would be if we had our manufacturing capacity entirely in-house, which may limit our growth strategy and revenues.

10. *The potential fluctuation in future quarterly results may cause our stock price to fluctuate.* We expect that our operating results could fluctuate significantly from quarter to quarter in the future and will depend upon a number of factors, many of which are outside our control. These factors include the extent to which our AEM technology and related accessories gain market acceptance; our investments in marketing, sales, research and development and administrative personnel necessary to support growth; our ability to expand our market share; actions of competitors and general economic conditions. The market value of our common stock has

dramatically fluctuated in the past and is likely to fluctuate in the future. Any deviation could have an immediate and significant negative impact on the market price of our stock.

11. *Our common stock is thinly traded, the prices at which it trades are volatile and the buying or selling actions of a few shareholders may adversely affect our stock price.* At March 31, 2004, we had a public float of 2,714,083 shares or 46% of the outstanding common stock. The average number of shares traded in any given day over the past year has been relatively small compared to the public float. Thus, the actions of a few shareholders either buying or selling shares of our common stock may adversely affect the price of the shares. Historically, thinly traded securities such as our common stock have experienced extreme price and volume fluctuations that do not necessarily relate to operating performance.

12. *Our insurance coverage for product liability claims is up to \$5,000,000.* We face an inherent business risk of exposure to product liability claims in the event that the use of our products is alleged to have resulted in adverse effects to a patient. We maintain a general liability insurance policy up to the amount of \$5,000,000 that includes coverage for product liability claims. Liability claims may be excluded from the policy, may exceed the coverage limits of the policy, or the insurance may not continue to be available on commercially reasonable terms or at all. Consequently, a product liability claim or other claim with respect to uninsured liabilities or in excess of insured liabilities could have a material adverse effect on our financial position, results of operations and cash flows.

13. *We depend on revenue from some major customers.* We depend on revenue that is generated from hospitals' ongoing usage of the AEM surgical instruments. In FY 2004, we generated revenue from over 350 hospitals that have converted to AEM products, but no hospital customer contributed more than 2% to the total revenues. We utilize a small number of stocking distributors, which sell AEM products to multiple hospital customers. In FY 2004, we generated revenue of \$437,307 (6%) from one of these distributors. While it is infrequent that a hospital customer stops using AEM instruments after they convert, a loss of ongoing revenue from a hospital customer could have a material adverse effect on our revenues and cash flows.

14. *We depend on certain key personnel.* We are highly dependent on a limited number of key management personnel, particularly our CEO and President, John R. Serino, and our Chairman of the Board and Vice President of Business Development, Roger C. Odell. Our loss of key personnel to death, disability or termination, or our inability to hire and retain qualified personnel, could have a material adverse effect on our financial position, results of operations and cash flow.

**ITEM 3 – CONTROLS AND PROCEDURES**

(a) The Company has carried out an evaluation under the supervision and with the participation of the Company's management, including the Company's Chief Executive Officer and Principal Accounting Officer, of the effectiveness of the Company's disclosure controls and procedures (as defined in Rules 13a-14(c) and 15d-14c of the Securities and Exchange Act of 1934 (the Exchange Act)). Based upon that evaluation, the Chief Executive Officer and the Principal Accounting Officer concluded as of June 30, 2004 that the Company's disclosure controls and procedures were effective in ensuring that information required to be disclosed by the Company under the Exchange Act was recorded, processed, summarized and reported within the time periods specified under the Exchange Act rules and forms.

(b) There were no significant changes in the Company's internal controls or in other factors that could significantly affect the Company's disclosure controls and procedures subsequent to the date of the evaluation discussed above, nor any significant deficiencies or material weaknesses in such disclosure controls, internal controls and procedures requiring corrective actions. As a result no corrective actions were taken.





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### 32.1 Certification of Periodic Reports pursuant to Sarbanes-Oxley Act of 2002

#### (b) Reports on Form 8-K

On April 8, 2004, the Company filed a current report on Form 8-K reporting the Company's change of auditors, under Item 4. The Company also filed an amendment on Form 8-K/A on April 27, 2004 to provide the outgoing auditors' statement of agreement with the Company's disclosures in the Form 8-K filed on April 8.

On April 13, 2004, the Company furnished a press release under Item 9 of Form 8-K.

On May 19, 2004, the Company furnished a press release under Item 12 of Form 8-K.

**SIGNATURE**

Pursuant to the requirements of Section 13 or 15(d) of the Securities Exchange Act of 1934, Encision has duly caused this report to be signed on its behalf by the undersigned thereunto duly authorized.

| Name                |  | Title                          | Date            |
|---------------------|--|--------------------------------|-----------------|
| /s/ Marcia McHaffie |  | Controller                     | August 12, 2004 |
| Marcia McHaffie     |  | (Principal Accounting Officer) |                 |