TRIMEDYNE INC Form 10QSB February 23, 2004

SECURITIES AND EXCHANGE COMMISSION

WASHINGTON, D.C. 20549 FORM 10-QSB QUARTERLY REPORT

PURSUANT TO SECTION 13 OR 15 (d) OF THE

SECURITIES EXCHANGE ACT OF 1934

FOR THE QUARTER ENDED DECEMBER 31, 2003

COMMISSION FILE NUMBER 0-10581

TRIMEDYNE, INC.

(Exact name of Registrant as specified in its charter)

Nevada
(State or other jurisdiction of incorporation or organization)

36-3094439 (IRS Employer Identification Number)

15091 Bake Parkway, Irvine, CA 92618 (Address of principal executive offices) (Zip Code)

(949/951 - 3800)

(Registrant's telephone number, including area code)

Not Applicable (Former name, former address and former fiscal year, if changed since last report).

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), (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 class of common stock, as of the last practicable date.

Class
-----Common Stock, \$.01 par value

Outstanding at February 23, 2004
-----14,534,831 shares

TRIMEDYNE, INC.

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TRIMEDYNE, INC.
CONSOLIDATED BALANCE SHEET
(UNAUDITED)

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ASSETS

	December 31, 2003
Current assets: Cash and cash equivalents Trade accounts receivable, net of allowance for doubtful accounts of \$82,000 Inventories Other	\$ 1,316,000 656,000 1,515,000 98,000
Total current assets	3,585,000
Goodwill Other assets Property and equipment, net	544,000 45,000 474,000
LIABILITIES AND STOCKHOLDERS' EQUITY	\$ 4,648,000 ======
Current liabilities: Accounts payable Accrued expenses Deferred revenue Accrued warranty	\$ 491,000 394,000 67,000 25,000

Current portion of long-term debt	12,000
Total current liabilities	989,000
Senior convertible secured notes due to officer Accrued interest due officer Long-term debt, net of current portion	200,000 44,000 8,000
Total liabilities	1,241,000
Stockholders' equity:  Preferred stock - \$0.01 par value, 1,000,000 shares authorized, none issued and outstanding  Common stock - \$0.01 par value; 30,000,000 shares authorized, 14,636,440 shares issued, 14,534,831 shares outstanding  Capital in excess of par value  Accumulated deficit	147,000 47,915,000 (43,942,000)
Treasury stock, at cost (101,609 shares)	4,170,000 (713,000)
Total stockholders' equity	3,457,000
	\$ 4,648,000 ======

See accompanying notes to consolidated financial statements

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## TRIMEDYNE, INC. CONSOLIDATED STATEMENTS OF OPERATIONS (UNAUDITED)

	Three Months Ended December 31,		
	2003	2002	
Net revenues Cost of revenues	\$ 1,380,000 704,000		
Gross profit	676,000	823,000	
Operating expenses: Selling, general and administrative Research and development	567,000 67,000	475,000 67,000	
Total operating expenses	634,000	542,000	
Income from operations	42,000	281,000	

Other income (expense) Micellaneous (expense) income Interest expense Loss on disposal of equipment Settlements and recoveries		
Total other income	123,000	9,000
Net income	\$ 165,000 ======	•
Basic net income per share	\$ 0.01	·
Basic weighted average common shares outstanding	14,473,764 ======	13,729,760
Diluted net income per share	\$ 0.01 ======	·
Diluted weighted average		
common shares outstanding	15,055,445	14,204,760
	=========	

See accompanying notes to consolidated financial statements.

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# TRIMEDYNE, INC. CONSOLIDATED STATEMENTS OF CASH FLOWS (UNAUDITED)

	Three Months Er December 31 2003 2		
Cash flows from operating activities:	 		
Net income	\$ 165,000	\$	290,0
Adjustment to reconcile net income to net cash provided by used in operating activities:	,		·
Depreciation and amortization	62,000		31,0
Loss from disposal of property and equipment	5,000		
Changes in operating assets and liabilities:			
Trade accounts receivable	(19,000)		(355,0
Inventories	(10,000)		161,0
Other current assets	48,000		47,0
Accounts payable	(33,000)		(133,0
Accrued expenses	(223,000)		(85,0
Deferred income	8,000		8,0
Accrued warranty	(17,000)		(1,0
Current liabilities	 		(5 <b>,</b> 0
Net cash used in operating activities	(14,000)		(42,0

Cash flows from investing activities:  Purchase of property and equipment	(46,000)	
Net cash used in investing activities	(46,000)	
Cash flows from financing activities:		
Payments on long-term debt	(9,000)	(14,0
Excercise of stock options	39,000	
Net cash provided by financing activities	30,000	
Net decrease in cash and cash equivalents	(30,000)	(56,0
Cash and cash equivalents at beginning of period	1,346,000	317,0
Cash and cash equivalents at end of period	\$ 1,316,000	\$ 261,0
	========	

See accompanying notes to consolidated financial statements

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# TRIMEDYNE, INC. NOTES TO CONSOLIDATED FINANCIAL STATEMENTS DECEMBER 31, 2003 (UNAUDITED)

NOTE 1 - Summary of Significant Accounting Policies

Principles of Consolidation

The accompanying consolidated financial statements include the accounts of Trimedyne, Inc., its wholly owned subsidiary, Mobile Surgical Technologies, Inc. ("MST"), and its 90% owned subsidiary, Cardiodyne, Inc. ("Cardiodyne") (collectively, the "Company"). All intercompany accounts and transactions have been eliminated in consolidation.

Unaudited Interim Financial Information

In the opinion of management, the accompanying condensed consolidated financial statements contain all adjustments (consisting of only normal recurring adjustments) necessary to present fairly the Company's consolidated financial position as of December 31, 2003 and the results of operations and its cash flows for the three-month periods ended December 31, 2003 and 2002. Results for the three months ended December 31, 2003 are not necessarily indicative of the results to be expected for the year ending September 30, 2004.

While management believes that the disclosures presented are adequate to make the information not misleading, it is suggested that these consolidated financial statements be read in conjunction with the consolidated financial statements and the notes included in the Company's 2003 annual report on Form 10-KSB. Certain prior period amounts have been reclassed to conform to the current period presentation.

Accounts Receivable

The Company performs ongoing credit evaluations of its customers and generally

does not require collateral. The Company maintains reserves for potential credit losses and such losses have been within management's expectation.

#### Revenue Recognition

In accordance with Staff Accounting Bulletin 101, "Revenue Recognition in Financial Statements," the Company recognizes revenue from products sold once all of the following criteria for revenue recognition have been met: (i) persuasive evidence that an arrangement exists, (ii) the products have been shipped, (iii) the prices are fixed and determinable and not subject to refund or adjustment, and (iv) collection of the amounts due is reasonably assured.

Revenues from the sale of delivery and disposable devices are recognized upon shipment and passage of title of the products, provided that all other revenue recognition criteria have been met. Generally, customers are required to insure the goods from the Company's place of business. Accordingly, the risk of loss transfers to the customer once the goods have been shipped from the Company's warehouse. The Company sells its products primarily through commission sales representatives in the United States and distributors in foreign countries. In cases where the Company utilizes distributors, it recognizes revenue upon shipment, provided that all other revenue recognition criteria have been met, and ownership risk has transferred.

#### Goodwill

Goodwill represents the excess of the cost over the acquired assets of MST. On October 1, 2002, the Company adopted the provisions of Statement of Financial Accounting Standards ("SFAS") No. 142, "Goodwill and Other Intangible Assets." As a result of adoption SFAS No. 142, the Company's goodwill is no longer amortized, but is subject to an annual impairment test, or whenever events or changes in circumstances indicate that the carrying value may not be recoverable. There was no impairment of goodwill at December 31, 2003.

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#### Stock Option Plans

The Company accounts for its stock-based compensation plans under the recognition and measurement principles of Accounting Principles Board Opinion No. 25, "Accounting for Stock Issued to Employees," and related interpretations. The Company has adopted the disclosure provisions of SFAS No. 123, "Accounting for Stock-Based Compensation," as amended by SFAS No. 148, "Accounting for Stock-Based Compensation - Transition and Disclosure" - an amendment of FASB Statement No. 123. The following table illustrates the effect on net income and net income per share if the Company had applied the fair value recognition provisions of SFAS No. 123 to stock-based employee compensation:

Three Months Ended
December 31,
2003 2002

Net income, as reported

\$ 165,000 \$ 290,0

Deduct: total stock-based employee compensation expense determined under fair value based method

for awards, net of related tax effects		28,000		23,0
Pro forma net income	\$	137,000	\$	267 <b>,</b> 0
Net income per share - basic:				
As reported	\$	0.01	\$	0.
Pro forma	\$ ===	0.01	\$ ===	0.
Net income per share - diluted:				
As reported	\$	0.01	\$	0.
Pro forma	\$ ===	0.01	\$ ===	0.

The fair value of each option grant is estimated on the date of grant using the Black-Scholes option-pricing model with the following weighted-average assumptions used:

Three Months Ended December 31,

	2003	2002
Dividend yield		
Expected volatility	185%	114%
Risk-free interest rate	2.25%	2.50%
Expected lives	5 years	5 years

The Black-Scholes option valuation model was developed for use in estimating the fair value of traded options that have no vesting restrictions and are fully transferable. In addition, option valuation models require the input of highly subjective assumptions, including the expected stock price volatility and time to exercise. Because awards held by employees and directors have characteristics significantly different from those of traded options, and because changes in the subjective input assumptions can materially affect the fair value estimate, in the opinion of management, the existing models do not necessarily provide a reliable single measure of the fair value of these options.

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		2003
Inventories consist of the following:		
Raw material Work-in-process Finished goods	\$	944,000 407,000 164,000
Total inventory		1,515,000
Property and equipment consist of the following:		
Furniture and equipment Leasehold improvements Other	\$	2,355,000 218,000 166,000
Less accumulated depreciation and amortization		2,739,000 2,265,000)
Total property and equipment	-	474 <b>,</b> 000
Accrued expenses consist of the following:		
Loss contigency Accrued compensation Sales and use tax Accrued payroll tax Sublease deposit Customer deposits Accrued insurance Accrued commissions Other	\$	100,000 83,000 60,000 22,000 15,000 12,000 10,000 9,000 83,000
Total accrued expenses	\$	394 <b>,</b> 000

## NOTE 3 - Earnings Per Share Information

Basic income per share is based on the weighted-average number of shares of common stock outstanding during the period. Diluted income per share also includes the effect of stock options and other common stock equivalents outstanding during the period, and assumes the conversion of the Company's senior convertible secured notes due to officers for the period of time such notes were outstanding, if such stock options and convertible notes are dilutive.

The following table sets forth the computation of the numerator and denominator of basic and diluted earnings per share:

	Three Months Ended December 31,	
	2003	2002
Denominator		
Weighted average common shares outstanding used in calculating basic earnings per share	14,473,764	13,729,760
Effect of Dilutive Options	106,681	

Effect of Senior Convertible Secured Notes due to Officer	475,000	475,000
Weighted average common shares outstanding used in calculating diluted earnings per share	15,055,445 =======	14,204,760
Numerator		
Net income	\$ 165,000	\$ 290,000
Add - interest on Senior Convertible Secured Note due to Officer	6,000	6,000
Net income available to common shareholders	\$ 171,000	\$ 296,000

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## NOTE 4 - Contingencies

#### Litigation

The Company was a defendant and counterclaimant in Lumenis, Inc. ("Lumenis") v. Trimedyne, Inc. Lumenis alleged that the Company had infringed on two of its patents. The Company filed an answer to Lumenis' complaint and also filed counterclaims against Lumenis alleging infringement of two of the Company's patents, unfair business practices, libel and anti-trust violations. The Company was a party to a license agreement (the "License Agreement"), which required it to pay royalties to Lumenis. At September 30, 2003, the Company had accrued royalties under this license agreement in the amount of \$88,000, which were in dispute.

On November 25, 2003, the Company and Lumenis entered into a settlement agreement (the "Settlement Agreement"), under which the court dismissed the litigation between them. The Settlement Agreement also provided that Lumenis would apply a credit to royalties due by the Company under the License Agreement, and pay the Company \$5,000 for the remaining overpayment of royalties due under the License Agreement. The Settlement Agreement also provided that the Company and Lumenis would enter into an original equipment manufacture ("OEM") agreement whereby Lumenis would pay the Company a technology access fee of \$150,000 and purchase from the Company certain side-firing and angled-firing fiber optic devices, which Lumenis will market with its lasers, plus an amount equal to 7.5% of Lumenis' sales of side-firing and angled-firing devices manufactured by Lumenis or purchased by Lumenis from third-party suppliers.

On January 30, 2004, the Company received \$155,000 in connection with the terms of the Settlement Agreement, which will be recorded as other income in the subsequent period.

#### Product liability

The Company is currently a defendant in three product liability lawsuits. These cases relate to injuries that occurred in connection to medical procedures in which the Company's lasers were used. All of these cases are currently in litigation. The Company has insurance to cover product liability claims. This

insurance provides the Company with \$5,000,000 of coverage for each occurrence with a general aggregate of \$5,000,000. Trimedyne's liability is limited to a maximum of \$50,000 per occurrence unless the judgment against the Company exceeds the insurance coverage. In such case, Trimedyne would be liable for any liability in excess of \$5,000,000. Management has recorded a loss contingency for these claims in the amount of \$100,000 (\$50,000 for each of the two claims), based on the deductible under the insurance policy. In another product liability lawsuit, the cost of defense has exceeded the insurance deductible that was accrued in prior periods. Management is not accruing any additional provision for this claim, as it is not expected that this claim will exceed the limits of the insurance coverage.

In the ordinary course of business, the Company is from time to time involved in various pending or threatened legal actions. The litigation process is inherently uncertain and it is possible that the resolution of such matters might have a material adverse effect upon the financial condition and/or results of operations of the Company. However, in the opinion of the Company's management, matters currently pending or threatened against the Company, as discussed above, are not expected to have a material adverse effect on the financial position, results of operations or cash flows of the Company.

#### Licensing

The Company has license agreements with a number of universities and inventors, under which royalties on sales, if any, are payable. Sales of products covered by these licenses are presently not material. The Company has two license agreements with a competitor under which royalties are payable by the Company, one of which terminated on September 30, 2000. Patent applications have been filed with the U.S. Patent Office and U.S. Patents covering certain of the Company's products have been issued to officers and employees of the Company and have been assigned to the Company without royalty. The above patent applications are currently being processed by the U.S. Patent Office and, to the Company's knowledge, are proceeding in the normal course of review.

#### NOTE 5 Other Income (Expense)

During the three months ended December 31, 2003, the Company settled litigation with Lumenis which resulted in a reduction of \$88,000 accrued for royalties. The Company also received \$53,000 from an insurance settlement for a damaged

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#### NOTE 6 Segment Information

The Company's revenue base is derived from the sales of medical products and services. Products consist of lasers, and related products such as disposable systems and component parts. Services consist of rentals, fees on a per-case basis, as well as service and warranty repairs and maintenance. Data with respect to these operating activities for the three months ended December 31, 2003 and December 31, 2002 are as follows:

For the quarter ended December 31, 2003 For the quarter e

Service and Rental Total Products

Products

Revenue	\$ 965,000	\$ 415,000	\$ 1,380,000	\$ 1,287,000	\$
Cost of sales	 464,000	 240,000	704,000	 634,000	
Gross Profit	501,000	175,000	676 <b>,</b> 000	653,000	
Operating expenses: Selling, general and administrative Research and development	415,000 67,000	•	567,000 67,000	 341,000 67,000	
Income from operations	\$ 19,000	\$ 23,000	42,000	\$ 245,000	\$
Other Interest income Interest expense Loss on disposal of equipm Settlements and recoveries		 	(1,000) (12,000) (5,000) 141,000	 =	
Net Income			\$ 165,000		

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Sales and gross profit to customers by similar products and services for the three months ended December 31, 2003 (unaudited) and December 31, 2002 were:

	December 31,		
	2003	2002	
By similar products and services:			
Revenues:			
Products:			
Laser equipment and accessories	\$ 84,000	\$ 439,000	
Delivery and disposable devices	881,000	848,000	
Service and rental	415,000	398,000	
Total	\$1,380,000	\$1,685,000	
	=======	=======	
Gross profit			
Products:			
Laser equipment and accessories	\$ 22,000	\$ 200,000	
Delivery and disposable devices	479,000	453,000	
Service and rental	175,000	170,000	
Total	\$ 676 <b>,</b> 000	\$ 823,000	
	========	========	

The Company's revenue base is derived from the sales of medical products and services on a worldwide basis originating from the United States. Export sales during the three months ended December 31, 2003 and December 31, 2002, were \$264,000 and \$415,000, respectively. Although discrete components that earn revenues and incur expenses exist, significant expenses such as research and development and corporate administration are not incurred by nor allocated to these operating units but rather are employed by the entire enterprise. Additionally, the chief operating decision maker evaluates resource allocation not on a product or geographic basis, but rather on an enterprise-wide basis. Therefore, the Company has concluded that it contains only one reportable segment, which is the medical systems business.

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Sales in foreign countries for the quarters ended December 31, 2003 and December 31, 2002 accounted for approximately 19% and 25% of the Company's total sales, respectively. The breakdown by geographic region is as follows:

	Three months ended December 31, 2003	Three months ended December 31, 2002
Asia	\$ 89 <b>,</b> 000	\$ 238,000
Europe	163,000	165,000
Latin America		9,000
Middle East	9,000	3,000
Other	3,000	
	\$ 264,000	\$ 415,000
		========

All long-lived assets were located in the United States during the three months ended December 31, 2003.

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MANAGEMENT'S DISCUSSION AND ANALYSIS OF RESULTS OF OPERATIONS AND FINANCIAL CONDITION

CRITICAL ACCOUNTING POLICIES

#### Revenue Recognition

In accordance with Staff Accounting Bulletin 101, "Revenue Recognition in Financial Statements," the Company recognizes revenue from products sold once all of the following criteria for revenue recognition have been met: (i) persuasive evidence that an arrangement exists, (ii) the products have been shipped, (iii) the prices are fixed and determinable and not subject to refund or adjustment, and (iv) collection of the amounts due is reasonably assured.

Revenues from the sale of delivery and disposable devices are recognized upon shipment and passage of title of the products, provided that all other revenue recognition criteria have been met. Generally, customers are required to insure the goods from the Company's place of business. Accordingly, the risk of loss transfers to the customer once the goods have been shipped from the Company's warehouse. The Company sells its products primarily through commission sales representatives in the United States and distributors in foreign countries. In cases where the Company utilizes distributors, it recognizes revenue upon shipment, provided that all other revenue recognition criteria have been met, and ownership risk has transferred.

#### Allowance for Doubtful Accounts

The Company maintains allowances for doubtful accounts for estimated losses resulting from the inability of the Company's customers to make required payments. The allowance for doubtful accounts is based on specific identification of customer accounts and the Company's best estimate of the

likelihood of potential loss, taking into account such factors as the financial condition and payment history of major customers. The Company evaluates the collectibility of our receivables at least quarterly. If the financial condition of the Company's customers were to deteriorate, resulting in an impairment of their ability to make payments, additional allowances may be required. The differences could be material and could significantly impact cash flows from operating activities.

#### Goodwill

Goodwill represents the excess of the cost over the acquired assets of MST. On October 1, 2002, the Company adopted the provisions of Statement of Financial Accounting Standards ("SFAS") No. 142, "Goodwill and Other Tangible Assets." As a result of adoption SFAS No. 142, the Company's goodwill is no longer amortized, but is subject to an annual impairment test, or whenever events or changes in circumstances indicate that the carrying value may not be recoverable. There was no impairment of goodwill at December 31, 2003.

#### Deferred Taxes

The Company records a valuation allowance to reduce the deferred tax assets to the amount that is more likely than not to be realized. The Company has considered estimated future taxable income and ongoing tax planning strategies in assessing the amount needed for the valuation allowance. Based on these estimates, all of the Company's deferred tax assets have been reserved. If actual results differ favorably from those estimates used, the Company may be able to realize all or part of the Company's net deferred tax assets. Such realization could positively impact our operating results and cash flows from operating activities.

#### Stock Option Plans

The Company accounts for its stock-based compensation plans under the recognition and measurement principles of Accounting Principles Board Opinion No. 25, "Accounting for Stock Issued to Employees," and related interpretations. The Company has adopted the disclosure provisions of SFAS No. 123, "Accounting for Stock-Based Compensation," as amended by SFAS No. 148, "Accounting for Stock-Based Compensation - Transition and Disclosure" - an amendment of FASB Statement No. 123.

## RESULTS OF OPERATIONS

The statements contained in this Quarterly Report on Form 10-QSB that are not historical facts may contain forward-looking statements that involve a number of known and unknown risks and uncertainties that could cause actual results to differ materially from those discussed or anticipated by management. Potential risks and uncertainties include, among other factors, general business conditions, government regulations governing medical device approvals and manufacturing practices, competitive market conditions, success of the Company's business strategy, delay of orders, changes in the mix of products sold, availability of suppliers, concentration of sales in markets and to certain customers, changes in manufacturing efficiencies, development and introduction of new products, fluctuations in margins, timing of significant orders, and other risks and uncertainties currently unknown to management.

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#### Method of Presentation

The consolidated financial statements include the accounts of the Trimedyne,

Inc., its wholly owned subsidiary Mobile Surgical Technologies, Inc. ("MST") and its 90% owned subsidiary, Cardiodyne, Inc. ("Cardiodyne").

Quarter ended December 31, 2003 compared to quarter ended December 31, 2002

During the quarter ended December 31, 2003, net revenues were \$1,380,000 as compared to \$1,685,000 for the same period of the previous year, a \$305,000 or 18% decrease. This overall decrease was the result of lower laser sales during the current period. Lasers typically sell between \$35,000 and \$120,000, depending upon the type of laser, and the quantity sold in a typical quarter during the past two years has ranged from one to six per quarter. During the quarter ended December 31, 2003, the Company only sold one laser, or two units less than average per quarter in the last two years. Net sales from delivery and disposable devices increased by \$33,000 or 4% to \$881,000 in the current quarter from \$848,000 in the same quarter of the prior year. Net sales from service and rental increased by \$17,000 or 4% to \$415,000 from \$398,000 for the same quarters. This increase was primarily due to the growth of the Company's subsidiary MST.

Cost of goods sold remained unchanged at 51% of net sales in the first quarter of fiscal 2003 compared to the first quarter of fiscal 2002.

Selling, general and administrative expenses increased in the current quarter to \$567,000 from \$475,000 in the prior year quarter, an increase of \$92,000 or 19%. The increase in selling, general and administrative expenses is the result of Trimedyne being named in an additional product liability lawsuit and accruing a charge of \$50,000 representing the contingency for insurance deductible combined with a rent increase of \$11,000 per the leasing contract of the Company's Irvine location and a \$12,000 increase in salaries and wages due to the hiring of additional operations staff.

Research and development expenditures for the quarter ended December 31, 2003, remained unchanged at \$67,000 as compared to the quarter ended December 31, 2002.

Other income increased by \$114,000 or 1,267% from income of \$9,000 in the first quarter of fiscal 2002 to income of \$123,000 in the first quarter of 2003. During the three months ended December 31, 2003, the Company settled litigation with a competitor which resulted in the reduction of \$88,000 in liability for royalties and the receipt of a \$53,000 cash insurance settlement for a damaged laser offset by interest accrued on notes due to the CEO.

For the current quarter, the Company had net income of \$165,000 or \$0.01 per share, based on 14,473,764 basic weighted average number of common shares outstanding, as compared to net income of \$290,000, or \$0.02 per share, based on 13,729,760 basic weighted average number of common shares outstanding in the same quarter of the previous year, resulting from the above mentioned factors.

## Liquidity and Capital Resources

At December 31, 2003, the Company had working capital of \$2,596,000 compared to \$1,312,000 at the end of the first quarter ending December 31, 2002. Cash decreased by \$30,000 to \$1,316,000 from \$1,346,000 at the fiscal year ending September 30, 2003. We believe our existing working capital will be sufficient to meet Trimedyne's operating needs, and the operating needs of our 100% owned laser rental subsidiary for the next twelve months. During the period ending December 31, 2003, MST generated approximately \$16,000 in cash flows from operations. While we expect to continue to operate at a profit, we could incur losses in the future if we fail to generate revenues sufficient to offset the costs associated with manufacturing and marketing our current products, our overhead, and the development of new products. If we fail to continue to operate

profitability, or if we undertake the development, testing and marketing of new products in the future, we will likely need to raise substantial additional capital. There can be no assurance that we will be able to operate profitably in the future.

We have \$200,000 of Senior Convertible Notes due to our chief executive officer (the "Notes") outstanding which are due, with interest at 12% per annum, in 2007. The Notes and accrued interest are convertible at prices of \$0.40 and \$0.50 per share. If the Notes and accrued interest are not converted, we may have to raise additional capital to pay the Note holder the principal and interest due on the Notes. Sources of such financing may include the sale of additional equity securities or the sale or licensing of patent rights. The issuance of additional common stock or shares of preferred stock will dilute the equity interests of our shareholders. There is no assurance such financing, if and when needed, will be available to us on acceptable terms.

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#### Item 3. Controls and Procedures

Evaluation of Disclosure Controls and Procedures

The Company's chief executive officer and chief financial officer carried out an evaluation of the effectiveness and operation of the Company's disclosure controls and procedures. They have concluded after evaluating the effectiveness of the Company's disclosure controls and procedures as of a date (the "Evaluation Date") within 90 days before the filing date of this quarterly report, that as of the Evaluation Date, the Company's disclosure controls and procedures were effective and designed to ensure that material information relating to the Company would be made known to them by others.

Changes in Internal Controls

There have been no significant changes in the Company's internal controls or in other factors that could significantly affect those controls subsequent to the Evaluation Date.

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Part II Other Information

## Item 1. Legal Proceedings

The Company was a defendant and counterclaimant in Lumenis, Inc. ("Lumenis") v. Trimedyne, Inc. Lumenis alleged that the Company had infringed on two of its patents. The Company filed an answer to Lumenis' complaint and also filed counterclaims against Lumenis alleging infringement of two of the Company's patents, unfair business practices, libel and anti-trust violations. The Company was a party to a license agreement (the "License Agreement"), which required it to pay royalties to Lumenis. At September 30, 2003, the Company had accrued royalties under this license agreement in the amount of \$88,000, which were in dispute.

On November 25, 2003, the Company and Lumenis entered into a settlement agreement (the "Settlement Agreement"), under which the court dismissed the litigation between them. The Settlement Agreement also provided that Lumenis

would apply a credit to royalties due by the Company under the License Agreement, and pay the Company \$5,000 for the remaining overpayment of royalties due under the License Agreement. The Settlement Agreement also provided that the Company and Lumenis would enter into an original equipment manufacture ("OEM") agreement whereby Lumenis would pay the Company a technology access fee of \$150,000 and purchase from the Company certain side-firing and angled-firing fiber optic devices, which Lumenis will market with its lasers, plus an amount equal to 7.5% of Lumenis' sales of side-firing and angled-firing devices manufactured by Lumenis or purchased by Lumenis from third-party suppliers.

On January 30, 2004, the Company received \$155,000 in connection with the terms of the Settlement Agreement, which will be recorded as other income in the subsequent period.

The Company is currently a defendant in three product liability lawsuits. These cases relate to injuries that occurred in connection to medical procedures in which the Company's lasers were used. All of these cases are currently in litigation. The Company has insurance to cover product liability claims. This insurance provides the Company with \$5,000,000 of coverage for each occurrence with a general aggregate of \$5,000,000. Trimedyne's liability is limited to a maximum of \$50,000 per occurrence unless the judgment against the Company exceeds the insurance coverage. In such case, Trimedyne would be liable for any liability in excess of \$5,000,000. Management has recorded a loss contingency for these claims in the amount of \$100,000 (\$50,000 for each claim), based on the deductible under the insurance policy. In one product liability lawsuit, the cost of defense has exceeded the insurance deductible that was accrued in prior periods. Management is not accruing any additional provision for this claim, as it is not expected that this claim will exceed the limits of the insurance coverage.

- Item 2. Changes in Securities
   None
- Item 3. Defaults Upon Senior Securities  $\label{eq:None} \mbox{None}$
- Item 4. Submission of Matters to Vote of Security Holders  $$\operatorname{\textsc{None}}$$
- Item 5. Other Information
   None
- Item 6. Exhibits and Reports on Form 8-K
  - (a) Exhibits
     99.1 Officer Certification
     99.2 Controller Certification
  - (b) Reports on Form 8-K None

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#### SIGNATURE PAGE

Pursuant to the requirements of the Securities Exchange Act of 1934, the Registrant has duly caused this Report to be signed on its behalf by the undersigned hereunto duly authorized.

TRIMEDYNE, INC.

Date: February 23, 2004 /s/ Marvin P. Loeb

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Marvin P. Loeb President and

Chief Executive Officer

Date: February 23, 2004 /s/ Jeffrey S. Rudner

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Jeffrey S. Rudner

Controller

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#### CERTIFICATION

I, Marvin P. Loeb, hereby certify that:

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- I have reviewed this quarterly report on Form 10-QSB of Trimedyne, Inc.;
- 2. Based on my knowledge, this quarterly report does not contain any untrue statement of a material fact, or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this quarterly report; and
- 3. Based on my knowledge, the financial statements, and other financial information included in this quarterly report, fairly present in all material respects the financial position, results of operations, and cash flows of the issuer as of, and for, the periods presented in this quarterly report.
- 4. I am responsible for establishing and maintaining disclosure controls and procedures for the issuer and have:
  - (i) Designed such disclosure controls and procedures to ensure that material information relating to the issuer is made known to me, particularly during the period in which the periodic reports are being prepared;
  - (ii) Evaluated the effectiveness of the issuer's disclosure controls and procedures as of December 31, 2003; and
  - (iii) Presented in the report our conclusions about the effectiveness of the disclosure controls and procedures based on my evaluation as of the Evaluation Date;
- 5. I have disclosed, based on my most recent evaluation, to the issuer's auditors and the audit committee of the board of directors (or persons fulfilling the equivalent function):
  - (i) All significant deficiencies in the design or operation of internal controls which could adversely affect the issuer's ability to record, process, summarize and report financial data and have identified for the issuer's auditors any material weaknesses in internal controls; and

- (ii) Any fraud, whether or not material, that involves management or other employees who have a significant role in the issuer's internal controls; and
- 6. I have indicated in the report whether or not there were significant changes in internal controls or in other factors that could significantly affect internal controls subsequent to the date of our most recent evaluation, including any corrective actions with regard to significant deficiencies and material weaknesses.

Date: February 23, 2004

/s/ Marvin P. Loeb
----Marvin P. Loeb, CEO

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#### CERTIFICATION

- I, Jeffrey Rudner, hereby certify that:
  - I have reviewed this quarterly report on Form 10-QSB of Trimedyne, Inc.;
  - 2. Based on my knowledge, this quarterly report does not contain any untrue statement of a material fact, or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this quarterly report; and
  - 3. Based on my knowledge, the financial statements, and other financial information included in this quarterly report, fairly present in all material respects the financial position, results of operations, and cash flows of the issuer as of, and for, the periods presented in this quarterly report.
  - 4. I am responsible for establishing and maintaining disclosure controls and procedures for the issuer and have:
    - a. Designed such disclosure controls and procedures to ensure that material information relating to the issuer is made known to me, particularly during the period in which the periodic reports are being prepared;
    - Evaluated the effectiveness of the issuer's disclosure controls and procedures as of December 31, 2003; and
    - c. Presented in the report our conclusions about the effectiveness of the disclosure controls and procedures based on my evaluation as of the Evaluation Date;
  - 5. I have disclosed, based on my most recent evaluation, to the issuer's auditors and the audit committee of the board of directors (or persons fulfilling the equivalent function):
    - a. All significant deficiencies in the design or operation of internal controls which could adversely affect the issuer's

ability to record, process, summarize and report financial data and have identified for the issuer's auditors any material weaknesses in internal controls; and

- b. Any fraud, whether or not material, that involves management or other employees who have a significant role in the issuer's internal controls; and
- 6. I have indicated in the report whether or not there were significant changes in internal controls or in other factors that could significantly affect internal controls subsequent to the date of our most recent evaluation, including any corrective actions with regard to significant deficiencies and material weaknesses.

Date: February 23, 2004

/s/ Jeffrey Rudner

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