

TRIMEDYNE INC  
Form 10-Q  
February 23, 2015

UNITED STATES

SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

FORM 10-Q

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

For the quarterly period ended December 31, 2014

or

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

For the transition period from \_\_\_\_\_ to \_\_\_\_\_

COMMISSION FILE NO. 0-10581

TRIMEDYNE, INC.

Exact Name of Registrant as Specified in its Charter)

NEVADA

(STATE OR OTHER JURISDICTION OF INCORPORATION)

36-3094439

(I.R.S. EMPLOYER IDENTIFICATION NO.)

5 HOLLAND # 223  
IRVINE, CALIFORNIA

(ADDRESS OF PRINCIPAL EXECUTIVE OFFICES)

92618  
(ZIP CODE)

Registrant's Telephone Number, Including Area Code:

(949) 951-3800

Securities Registered Pursuant to Section 12(b) of the Act:

NONE

Securities Registered Pursuant to Section 12(g) of the Act:

Common Stock, \$.01 Par Value per Share

(Title of Class)

Indicate by check mark whether the registrant (1) has filed all reports to be filed by Section 13 or 15(d) of the Securities Exchange Act of 1934 during the preceding 12 months (or for such shorter period that the registrant was required to file such reports) and (2) has been subject to such filing requirements for the past 90 days. Yes ☒ No ☐

Indicate by check mark whether the registrant has submitted electronically and posted on its corporate Web site, if any, every Interactive Data File required to be submitted and posted pursuant to Rule 405 of Regulation S-T (ss. 232.405 of this chapter) during the preceding 12 months (or for such shorter period that the registrant was required to submit and post such files). Yes ☒ No ☐

Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, a non-accelerated filer or a smaller reporting company. See definitions of "large accelerated filer," "accelerated filer" and "smaller reporting company" in Rule 12b-2 of the Exchange Act. (Check one):

Large accelerated filer ☐ Accelerated filer ☐  
Non-accelerated filer ☐ Smaller reporting company ☒

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Indicate by check mark whether the registrant is a shell company (as defined in Rule 12b-2 of the Exchange Act of 1934). Yes ☐ No ☒

As of February 20, 2015, there were outstanding 18,395,960 shares of registrant's Common Stock.

TRIMEDYNE, INC.

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## TRIMEDYNE, INC.

## CONDENSED CONSOLIDATED BALANCE SHEETS

(UNAUDITED)

	December 31, 2014	September 30, 2014
<b>ASSETS</b>		
Current assets:		
Cash and cash equivalents	\$751,000	\$1,292,000
Trade accounts receivable, net of allowance for doubtful accounts of \$11,000 at December 31, 2014 and September 30, 2014, respectively	522,000	463,000
Inventories	1,806,000	1,581,000
Other current assets	116,000	123,000
Total current assets	3,195,000	3,459,000
Property and equipment, net	608,000	635,000
Other	74,000	73,000
Goodwill	544,000	544,000
Total Assets	\$4,421,000	\$4,711,000
<b>LIABILITIES AND STOCKHOLDERS' EQUITY</b>		
Current liabilities:		
Accounts payable	\$201,000	\$278,000
Accrued expenses	550,000	628,000
Deferred revenue	88,000	50,000
Accrued warranty	30,000	27,000
Current portion of note payable and capital leases	71,000	70,000
Total current liabilities	940,000	1,053,000
Deferred rent	4,000	6,000
Long-term debt	36,000	43,000
Total liabilities	980,000	1,102,000
Commitments and contingencies		
Stockholders' equity:		
Preferred stock - \$0.01 par value, 1,000,000 shares authorized, none issued and outstanding	—	—
	186,000	186,000

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Common stock - \$0.01 par value, 30,000,000 shares authorized, 18,497,569 shares issued, 18,395,960 shares outstanding at December 31, 2014 and September 30, 2014, respectively

Additional paid-in capital	51,312,000	51,311,000
Accumulated deficit	(47,344,000)	(47,175,000)
	4,154,000	4,322,000
Treasury stock, at cost (101,609 shares)	(713,000 )	(713,000 )
Total stockholders' equity	3,441,000	3,609,000
Total liabilities and stockholder's equity	\$4,421,000	\$4,711,000

See accompanying notes to condensed consolidated financial statements

TRIMEDYNE, INC.

## CONDENSED CONSOLIDATED STATEMENTS OF OPERATIONS

(UNAUDITED)

	For the Three Months Ended December 31,	
	2014	2013
Net revenues	\$ 1,352,000	\$ 1,399,000
Cost of revenues	912,000	1,023,000
Gross profit	440,000	376,000
Operating expenses:		
Selling, general and administrative	478,000	549,000
Research and development	128,000	124,000
Total operating expenses	606,000	673,000
(Loss) from operations	(166,000 )	(297,000 )
Other expense, net	(1,000 )	38,000
(Loss) before income taxes	(167,000 )	(259,000 )
Provision for income taxes	2,000	—
Net (loss)	\$(169,000 )	\$(259,000 )
Net (loss) per share:		
Basic	\$(0.01 )	\$(0.01 )
Diluted	\$(0.01 )	\$(0.01 )
Weighted average number of shares outstanding:		
Basic	18,395,960	18,395,960
Diluted	18,395,960	18,395,960

See accompanying notes to condensed consolidated financial statements





## TRIMEDYNE, INC.

## CONDENSED CONSOLIDATED STATEMENTS OF CASH FLOWS

(UNAUDITED)

	Three Months Ended December 31,	
	2014	2013
Cash flows from operating activities:		
Net loss	\$(169,000 )	(259,000 )
Adjustments to reconcile net loss to net cash (used in) provided by operating activities:		
Stock-based compensation	1,000	1,000
Depreciation and amortization	53,000	57,000
Changes in operating assets and liabilities:		
Trade accounts receivable	(59,000 )	(43,000 )
Inventories	(225,000 )	161,000
Other assets	27,000	13,000
Accounts payable	(77,000 )	55,000
Accrued expenses	(78,000 )	38,000
Deferred revenue	38,000	37,000
Accrued warranty	3,000	9,000
Deferred rent	(2,000 )	(1,000 )
Net cash (used in) provided by operating activities	(488,000 )	68,000
Cash flows from investing activities:		
Purchase of property and equipment	(26,000 )	(4,000 )
Net cash used in investing activities	(26,000 )	(4,000 )
Cash flows from financing activities:		
Principal payments on notes payable and capital leases	(27,000 )	(37,000 )
Net cash used in financing activities	(27,000 )	(37,000 )
Net (decrease) increase in cash and cash equivalents	(541,000 )	27,000
Cash and cash equivalents at beginning of period	1,292,000	1,572,000
Cash and cash equivalents at end of period	\$751,000	\$1,599,000

## Supplemental disclosure of cash flow information:

No cash was paid for income taxes during the three months ended December 31, 2014 and 2013. Cash paid for interest during the three months ended December 31, 2014 and 2013 was approximately \$1,000 and \$3,000, respectively.

During November of the prior year quarter, the Company financed the upgrading of its IT infrastructure with a lease agreement for \$119,000.

During December of the current year quarter, the Company financed an additional insurance policy for \$21,607.

See accompanying notes to condensed consolidated financial statements

TRIMEDYNE, INC.

NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS

DECEMBER 31, 2014

(UNAUDITED)

NOTE 1 - Summary of Significant Accounting Policies

Principles of Consolidation

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

Going Concern

At December 31, 2014, the Company had working capital of \$2,255,000 compared to \$2,406,000 at the end of the fiscal year ended September 30, 2014. Cash decreased by \$541,000 to \$751,000 from \$1,292,000 at September 30, 2014. We intend to fund operations with cash on hand and from operations, however, additional working capital in the next 12 months will be required based upon our current expenditure rate. These factors raise substantial doubt about the Company's ability to continue as a going concern.

We plan to supply our Holmium Lasers and patented Side Firing Fibers to one or more separate companies being organized in which we will own a 30% equity interest at nominal cost. Since we cannot afford to fund large, randomized, controlled clinical trials to prove the safety and efficacy of our new Lasers and Side Firing Fibers in the treatment of multiple medical conditions in various fields of medicine, helping these separate companies may become an outlet for our Lasers and Side Firing Fibers. However, the success of their efforts to raise capital cannot be assured and, if they were able to raise capital, there is no assurance that the clinical trials of any of these separate companies will be successful.

The first of these companies, Gastromedix, Inc., has been incorporated and is attempting to raise at least \$10 million of capital to finance three or more, 25 patient “pilot” clinical trials and, if the “pilot” clinical trials are successful, which cannot be assured, one to three, 300 patient, randomized, controlled clinical trials of our Lasers and patented Side Firing Fibers in the treatment of Type II Diabetes, Obesity and GERD, often called “heartburn”, on which two U.S. Patent Applications are pending, in the gastroenterology field of medicine. These conditions affect millions of people in the U.S. and elsewhere and, if these larger clinical trials are successful, and this company receives FDA approval or clearance to market these products in the U.S., the CE Mark to market these products in the European Union and Medicare, other third-party payers in the U.S. and foreign governmental healthcare reimbursement, none of which can be assured, it could generate substantial sales of our Lasers and Side Firing Fibers.

If necessary, we will also attempt to raise additional debt and/or equity capital, sell some of our assets, reduce our costs by eliminating certain personnel positions and continue to reduce certain overhead costs in order to reduce our consumption levels.

The Company is currently pursuing market development efforts in Asia, Latin America and Eastern Europe. We believe that by expanding healthcare infrastructure in these markets, we may be able to create a sustained demand for Holmium Lasers and Fibers in the fields of Laser Spinal Endoscopy, Laser Lithotripsy in the laser treatment of other conditions. Additionally, we expect the global trend toward single-use, disposable laser delivery devices will improve sales and profit margins as more hospitals convert from multi-use devices, due to concerns for sterility and handling costs incurred in product sterilization, and we hope to develop more single-use medical devices.

## Unaudited Interim Financial Information

The accompanying unaudited condensed consolidated financial statements have been prepared by the Company in accordance with accounting principles generally accepted in the United States of America for interim financial information, and pursuant to the instructions to Form 10-Q promulgated by the Securities and Exchange Commission ("SEC"). Accordingly, they do not include all information and disclosures required by generally accepted accounting principles for complete financial statement presentation. 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, 2014 and the results of its operations and its cash flows for the three months ended December 31, 2014 and 2013. Results for the three months ended December 31, 2014 are not necessarily indicative of the results to be expected for the year ending September 30, 2015.

## Use of Estimates

The preparation of financial statements in conformity with accounting principles generally accepted in the United States requires management to make certain estimates and assumptions that affect the reported amounts of assets and liabilities and disclosure of contingent assets and liabilities at the date of the financial statements and the reported amounts of revenues and expenses during the reporting period. Actual results could differ from those estimates. Significant estimates and assumptions include inventory valuation, allowances for doubtful accounts and deferred income tax assets, recoverability of goodwill and long-lived assets and certain accrued liabilities.

While management believes that the disclosures presented are adequate to make the information not misleading, it is suggested that these condensed consolidated financial statements be read in conjunction with the condensed consolidated financial statements and the notes included in the Company's 2014 annual report on Form 10-K for the year ended September 30, 2014.

## Stock-Based Compensation

Stock-based compensation was \$1,000 during the quarters ended December 31, 2014 and 2013. As of December 31, 2014, there was approximately \$1,970 of total unrecognized compensation cost, net of estimated expected forfeitures, related to employee and director stock option compensation arrangements. This unrecognized cost is expected to be recognized on a straight-line basis over the next nine reporting periods.

Per Share Information

Basic per share information is computed based upon the weighted average number of common shares outstanding during the period. Diluted per share information consists of the weighted average number of common shares outstanding, plus the dilutive effects of options and warrants calculated using the treasury stock method. In loss periods, dilutive common equivalent shares are excluded as the effect would be anti-dilutive. During the three months ended December 31, 2014 and 2013, outstanding options of 801,900 and 818,900, respectively, were excluded from the diluted net loss per share as the effects would have been anti-dilutive. In addition, the exercise prices of these options were in excess of the average closing price of the Company's common stock for the quarter ended December 31, 2014 and 2013.

## NOTE 2 - Composition of Certain Balance Sheet Captions

Inventories, net of reserves, consist of the following:

	December 31, 2014	September 30, 2014
Raw materials	\$698,000	\$549,000
Work-in-process	276,000	298,000
Finished goods	832,000	734,000
	\$1,806,000	\$1,581,000

For the three months ended December 31, 2014 and 2013, the aggregate net realizable value of demonstration and evaluation lasers did not comprise a material amount in inventories.

Other current assets consist of the following:

	December 31, 2014	September 30, 2014
Prepaid insurance	54,000	55,000
Prepaid income tax	10,000	11,000
Prepaid rent	13,000	13,000
Short-term deposits	8,000	8,000
Other	31,000	36,000
Total other current assets	\$116,000	\$123,000

Property and equipment consist of the following:

	December 31, 2014	September 30, 2014
Furniture and equipment	\$3,474,000	\$3,474,000
Leasehold improvements	57,000	57,000
Other	342,000	316,000
	3,873,000	3,847,000

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Less accumulated depreciation and amortization	(3,265,000)	(3,212,000)
Total property and equipment	\$ 608,000	\$ 635,000

Accrued expenses consist of the following:

	December 31, 2014	September 30, 2014
Accrued vacation	\$ 190,000	\$ 181,000
Accrued salaries and wages	127,000	60,000
Accrued bonus	4,000	17,000
Medical device tax	89,000	83,000
Sales and use tax	52,000	58,000
Customer deposits	5,000	190,000
Property tax	17,000	—
Commissions	27,000	19,000
Other	39,000	20,000
Total accrued expenses	\$ 550,000	\$ 628,000



## NOTE 3. Note Payable and Capital Lease

Note payable and capital leases consist of the following:

	December 31, 2014	September 30, 2014
Capital lease agreement in connection with the update of our IT infrastructure bearing an effective interest rate of 8.41% per annum. The lease requires monthly payments of \$3,766 through October 2016	\$ 77,000	\$ 83,000
Finance agreement issued in connection with the purchasing of an insurance policy. The note bears interest at 4.75% per annum and requires monthly payments principal and interest payments of \$2,011 through November 2015.	19,000	—
Finance agreement issued in connection with the purchasing of insurance policies. The note bears interest at 3.35% per annum and require monthly principal and interest payments of \$5,693 through March 2015.	11,000	30,000
	\$ 107,000	\$ 113,000
Less: current portion	(71,000 )	(70,000 )
	\$ 36,000	\$ 43,000

## NOTE 4 - Commitments and Contingencies

## Litigation

We are subject to various claims and actions that arise in the ordinary course of business. The litigation process is inherently uncertain, and it is possible that the resolution of any future litigation may adversely affect us.

## Guarantees and Indemnities

The Company has made certain indemnities and guarantees, under which it may be required to make payments to a guaranteed or indemnified party. The Company indemnifies its directors, officers, employees and agents to the maximum extent permitted under the laws of the State of California. In connection with its facility leases, the Company has indemnified its users of lasers for certain claims arising from the use of the lasers. The duration of the guarantees and indemnities varies, and in many cases is indefinite. These guarantees and indemnities do not provide for any limitation of the maximum potential future payments the Company could be obligated to make. Historically,

the Company has not been obligated to make any payments for these obligations and no liabilities have been recorded for these indemnities and guarantees in the accompanying condensed consolidated balance sheet.

## Risks and Uncertainties

The Centers for Medicare and Medicaid Services (CMS), the agency of the U.S. Government that administers the Medicare Program, does not reimburse for thermal intradiscal procedures to treat spinal discs including the use of the Company's pulsed Holmium Lasers. Since most people suffering from a herniated or ruptured spinal disc are below Medicare age, we do not believe CMS's decision will have an adverse impact on our business.

## NOTE 5 - Segment Information

The Company's segments consist of individual companies managed separately with each manager reporting to the Principal Executive Officer. Revenues, and operating or segment profit, are reflected net of inter-segment sales and profits. Segment profit is comprised of net sales less operating expenses. Other income and expense and income taxes are not allocated and reported by segment since they are excluded from the measure of segment performance reviewed by management.

Data with respect to these operating activities for the three months ended December 31, 2014 and 2013 are as follows:

	For the Three Months Ended December 31, 2014			For the Three Months Ended December 31, 2013		
	Products	Service and Rental	Total	Products	Service and Rental	Total
Revenue	\$669,000	\$683,000	\$1,352,000	\$760,000	\$639,000	\$1,399,000
Cost of sales	414,000	498,000	912,000	527,000	496,000	1,023,000
Gross profit	255,000	185,000	440,000	233,000	143,000	376,000
Expenses:						
Selling, general and administrative	320,000	158,000	478,000	391,000	158,000	549,000
Research and development	128,000	—	128,000	124,000	—	124,000
Income (loss) from operations	\$(193,000)	\$27,000	(166,000 )	\$(282,000)	\$(15,000 )	(297,000 )
Other:						
Interest expense			(1,000 )			(3,000 )
Royalty income			—			30,000
Other income			—			11,000
Provision for income tax			2,000			—
Net loss			\$(169,000 )			\$(259,000 )

Sales and gross profit to customers by similar products and services for the three months ended December 31, 2014 and 2013 were as follows:

For the Three Months  
Ended

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December 31,  
2014              2013

By similar products and services:

Revenues:

Laser equipment and accessories	\$ 247,000	\$ 283,000
Delivery and disposable devices	422,000	477,000
Service and rental	683,000	639,000
Total	\$ 1,352,000	\$ 1,399,000

Gross profit

Laser equipment and accessories	\$ 27,000	\$ 56,000
Delivery and disposable devices	228,000	177,000
Service and rental	185,000	143,000
Total	\$ 440,000	\$ 376,000

Sales in foreign countries for the three months ended December 31, 2014 and 2013 accounted for approximately 26.1% and 13.7%, respectively, of the Company's total sales. The breakdown by geographic region is as follows:

	Three Months Ended December 31,	
	2014	2013
Asia	\$254,000	\$167,000
Europe	11,000	5,000
Latin America	88,000	10,000
Australia	—	9,000
	\$353,000	\$191,000

Total segment assets at December 31, 2014 and 2013 for the Products segment were \$2,846,000 and \$2,992,000, respectively, and for the Service and Rental segment were \$1,553,000 and \$1,665,000, respectively. Total segment assets differ from total assets on a consolidated basis as a result of unallocated corporate assets primarily comprised of immaterial amounts of property and equipment, etc.

#### NOTE 6 – Subsequent Events

On January 30, 2015, Marvin P. Loeb, Sc.D., per his request, was relieved from the offices of Chairman of the Board and CEO of the Company, due to his age and a recent injury temporarily limiting his mobility. This resignation was not a result of any disagreement with the Company, its management, the Company's Board or any matter relating to the Company's operations, policies or practices. In addition, Dr. Loeb was elected to the office of Chief Scientific Officer of the Company at his current cash compensation, and remains a member of the Board of Directors of the Company.

Further, Glenn D. Yeik, current President, COO and Director of the Company, was elected to the additional office of Chairman of the Board, effective immediately and is the acting Principal Executive Officer of the Company.

Additionally, Alan E. Loeb, age 50, was appointed to the Company's Board of Directors effective immediately. He is the sole Trustee of the four Trusts established by Dr. Loeb, which together constitute the Company's principal stockholder.

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

### FORWARD-LOOKING STATEMENTS

This information should be read in conjunction with the condensed consolidated financial statements and notes thereto included in Item 1 of Part I of this Quarterly Report and the audited consolidated financial statements and notes thereto and Management's Discussion and Analysis of Financial Condition and Results of Operations for the year ended September 30, 2014, contained in our 2014 Annual Report on Form 10-K.

The statements contained in this Quarterly Report on Form 10-Q 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. We do not undertake any duty to update forward-looking statements after the date they are made or to conform them to actual results or to changes in circumstances or expectations.

### OVERVIEW

Trimeddyne, Inc. (the "Company", "we", "our" or "us") is engaged in the development, manufacturing and marketing of 80 and 30 watt Holmium "cold" pulsed lasers ("Lasers") and a variety of disposable and reusable, fiber optic laser energy delivery devices ("Fibers", "Needles" and "Tips") for use in a broad array of medical applications.

Our Lasers, Fibers, Needles and Tips have been cleared for sale by the U.S. Food and Drug Administration for use in orthopedics, urology, ear, nose and throat surgery, gynecology, gastrointestinal surgery, general surgery and other medical specialties. Many of the medical procedures in which our Lasers, Fibers, Needles and Tips are used are being reimbursed by Medicare and many insurance companies and health plans.

Our 100% owned subsidiary, Mobile Surgical Technologies, Inc. ("MST"), is engaged in the rental of lasers, along with the services of a trained operator and, if requested, the provision of applicable Fibers, Needles or Tips, on a "fee

per case" basis to hospitals, surgery centers, group practices and individual physicians in Texas and nearby areas.

The principal market for our Lasers and Side Firing Needles is presently in orthopedics to treat herniated (bulging) and ruptured lumbar, thoracic and cervical discs in the spine, two of the four major causes of lower back, neck and leg pain, typically on an outpatient basis. Our Lasers and Tips are also used in orthopedics to treat damage in joints, such as the knee, shoulder, elbow, hip, ankle and wrist, in outpatient, arthroscopic procedures.

The Company's Lasers and Fibers are also used in Urology to fragment stones in the Kidney, ureter or bladder. The Company's VaporMAX(R) Side Firing Optical Fiber device is also used to vaporize a portion of the male prostate which is used with the Company's Lasers in the treatment of benign prostate hyperplasia or "BPH", commonly referred to as an "enlarged prostate."

#### CRITICAL ACCOUNTING POLICIES

We prepare our consolidated financial statements in accordance with accounting principles generally accepted in the United States of America. The preparation of these consolidated financial statements require the use of estimates and assumptions that affect the reported amounts of assets and liabilities and the disclosure of contingent assets and liabilities at the date of the consolidated financial statements and the reported amount of revenues and expenses during the reporting period. Our management periodically evaluates the estimates and judgments made. Management bases its estimates and judgments on historical experience and on various factors that are believed to be reasonable under the circumstances. Actual results may differ from these estimates as a result of different assumptions or conditions.

The methods, estimates, and judgment we use in applying our most critical accounting policies have a significant impact on the results we report in our consolidated financial statements. The SEC has defined "critical accounting policies" as those accounting policies that are most important to the portrayal of our financial condition and results, and require us to make our most difficult and subjective judgments, often as a result of the need to make estimates of matters that are inherently uncertain based upon this definition. We also have other key accounting estimates and policies, but we believe that these other policies either do not generally require us to make estimates and judgments that are as difficult or as subjective, or it is less likely that they would have a material impact on our reported results of operations for a given period. For additional information see Note 1, "Summary of Significant Accounting Policies" in the notes to our reviewed consolidated financial statements appearing elsewhere in this quarterly report and our annual audited consolidated financial statements appearing on Form 10-K. Although we believe that our estimates and assumptions are reasonable, they are based upon information presently available, and actual results may differ significantly from these estimates.

## RESULTS OF OPERATIONS

### Method of Presentation

The unaudited condensed consolidated financial statements include the accounts of Trimeddyne, Inc., its wholly owned subsidiary Mobile Surgical Technologies, Inc. ("MST") and its 90% owned subsidiary, Cardiodyne.

### Quarter Ended December 31, 2014 Compared to Quarter Ended December 31, 2013

During the quarter ended December 31, 2014, net revenues were \$1,352,000 as compared to \$1,399,000 for the same period of the previous year, a \$47,000 or 3.4% decrease. Net sales from Lasers and accessories decreased by \$36,000 or 12.7% to \$247,000 during the three months ended December 31, 2014 from \$283,000 in the same period of the prior year. Net sales from Fibers, Needles and Tips decreased \$55,000, or 11.6% to \$422,000 during the current period ended December 31, 2014 as compared to \$477,000 in the same period of the prior year. The decrease in sales from Fibers, Needles and Tips was primarily due to the delaying of shipments resulting from the impact on manufacturing due to the relocation of our facility in California. Net sales from service and rental increased by \$44,000, or 7.0%, to \$683,000 from \$639,000 for the same quarters. The increase was primarily due to an increase in sales of service parts from our facility in California.

Cost of sales during the quarter ended December 31, 2014 was 67% of net revenue as compared to 73% of net revenues for the prior year quarter. The higher gross profit in the current quarter as compared to the prior year quarter was the result of many factors, including the updated application of overhead rates to reflect the Company's current cost structure, the amount of inventory that was scrapped, and labor requirements in each unique period which also



effects overhead application. Gross profit from the sale of Lasers and accessories was 11% as compared to 20% for the prior year three-month period. The decrease in gross profit from the sale of Lasers in the current period as compared to the prior period was primarily due to incentive discounts afforded to an international distributor to facilitate the opening of a new market. Gross profit from the Fibers, Needles and Tips was 54% for the quarter as compared to 37% for the same period of the prior fiscal year. The higher gross profit from the sale of Fibers, Needles and Tips was primarily a result of the updated overhead application rates which reduces monthly manufacturing variances. Gross profit from revenue received from service and rentals was 27% in the current quarter, as compared to 22% for the prior three-month period. The increase in gross profit as a percentage of sales from service and revenue as compared to the prior year period was primarily due to the increase in the sales of service parts from our California facility, which carry a higher margin.

Selling, general and administrative expenses decreased in the current quarter to \$478,000 from \$549,000 in the prior year quarter, a decrease of \$71,000 or 13%. The decrease in selling, general and administrative expenses was primarily the result of decreases of \$13,000 in payroll related expense, \$12,000 in commission expense, \$13,000 in audit fees, \$23,000 legal expense and \$11,000 in insurance expense. The overall decrease during the current period was the result of the Company's continuing efforts to reduce its overhead expenses.

Research and development expenditures increased to \$128,000 or 3% for the quarter ended December 31, 2014, as compared \$124,000 for the quarter ended December 31, 2013. During the current quarter ended December 31, 2014, R&D activities consisted of updating documentation for existing products due to design changes, renewal of foreign approvals, supplier and third party audits, and updating risk management files in compliance with current international standards.

Other income and expense, decreased by \$39,000 or 103% to a net expense of \$1,000 during the current quarter ended December 31, 2014 from \$38,000 of income in the first quarter of the prior year. Other income during the prior year quarter ended December 31, 2013 primarily consisted of \$30,000 of royalty income from Lumenis, Ltd. During the current quarter ended December 31, 2014, no royalties were received from Lumenis, Ltd., due to the expiration of the royalty agreement in August, 2014.

For the current quarter, the Company had a net loss of \$169,000, or \$0.01 per share, as compared to net loss of \$259,000, or \$0.01 per share during the same period of the prior year, based on 18,395,960 basic weighted average number of common shares outstanding. The reduction in loss for the current quarter was primarily the result more favorable margins from sale of Fibers, Needles and Tips and a 13% reduction of selling, general and administrative expenses.

#### Liquidity and Capital

At December 31, 2014, the Company had working capital of \$2,255,000 compared to \$2,406,000 at the end of the fiscal year ended September 30, 2014. Cash decreased by \$541,000 to \$751,000 from \$1,292,000 at September 30, 2014. Cash used in financing activities was \$27,000 which was the result of payment on notes payable and a lease. During the quarter ended December 31, 2014, the Company financed an additional insurance policy for \$22,000.

As of December 31, 2014, we had cash on hand of \$751,000. We intend to fund operations with cash on hand and from operations, however, additional working capital in the next 12 months will be required based upon our current expenditure rate. These factors raise substantial doubt about the Company's ability to continue as a going concern.

We plan to supply our Holmium Lasers and patented Side Firing Fibers to one or more separate companies being organized in which we will own a 30% equity interest at nominal cost. Since we cannot afford to fund large, randomized, controlled clinical trials to prove the safety and efficacy of our new Lasers and Side Firing Fibers in the treatment of multiple medical conditions in various fields of medicine, helping these separate companies may become an outlet for our Lasers and Side Firing Fibers. However, the success of their efforts to raise capital cannot be assured and, if they were able to raise capital, there is no assurance that the clinical trials of any of these separate companies will be successful.

The first of these companies, Gastromedix, Inc., has been incorporated and is attempting to raise at least \$10 million of capital to finance three or more, 25 patient "pilot" clinical trials and, if the "pilot" clinical trials are successful, which cannot be assured, one to three, 300 patient, randomized, controlled clinical trials of our Lasers and patented Side Firing Fibers in the treatment of Type II Diabetes, Obesity and GERD, often called "heartburn", on which two U.S. Patent Applications are pending, in the gastroenterology field of medicine. These conditions affect millions of people

in the U.S. and elsewhere and, if these larger clinical trials are successful, and this company receives FDA approval or clearance to market these products in the U.S., the CE Mark to market these products in the European Union and Medicare, other third-party payers in the U.S. and foreign governmental healthcare reimbursement, none of which can be assured, it could generate substantial sales of our Lasers and Side Firing Fibers.

If necessary, we will also attempt to raise additional debt and/or equity capital, sell some of our assets, reduce our costs by eliminating certain personnel positions and continue to reduce certain overhead costs in order to reduce our consumption levels.

The Company is currently pursuing market development efforts in Asia, Latin America and Eastern Europe. We believe that by expanding healthcare infrastructure in these markets, we may be able to create a sustained demand for Holmium Lasers and Fibers in the fields of Laser Spinal Endoscopy, Laser Lithotripsy in the laser treatment of other conditions. Additionally, we expect the global trend toward single-use, disposable laser delivery devices will improve sales and profit margins as more hospitals convert from multi-use devices, due to concerns for sterility and handling costs incurred in product sterilization, and we hope to develop more single-use medical devices.

## OFF BALANCE SHEET ARRANGEMENTS

None.

## ITEM 3. QUANTITATIVE AND QUALITATIVE DISCLOSURES ABOUT MARKET RISK. N/A

## ITEM 4. CONTROLS AND PROCEDURES

**Disclosure Controls and Procedures.** Our management has evaluated, under the supervision and with the participation of our principal executive officer and principal financial officer, the effectiveness of our disclosure controls and procedures as of the end of the period covered by this report pursuant to Rule 13a-15(b) under the Securities Exchange Act of 1934 (the "Exchange Act"). Based on that evaluation, our principal executive officer and principal financial officer have concluded that, as of the end of the period covered by this report, our disclosure controls and procedures are effective in ensuring that information required to be disclosed in our Exchange Act reports is (1) recorded, processed, summarized and reported in a timely manner, and (2) accumulated and communicated to our management, including our principal executive officer and principal financial officer, as appropriate to allow timely decisions regarding required disclosure.

**Changes in Internal Control Over Financial Reporting.** There have been no changes in our internal control over financial reporting that occurred during the period covered by this report that have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

PART II Other Information

Item 1. Legal Proceedings

None

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

None

Item 3. Defaults Upon Senior Securities

None

Item 4. [Removed and Reserved]

Item 5. Other Information

None

Item 6. Exhibits

(a) Exhibits

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- 31.1 Certification pursuant to Section 302 of the Sarbanes-Oxley Act of 2002 for Glenn D. Yeik
- 31.2 Certification pursuant to Section 302 of the Sarbanes-Oxley Act of 2002 for Jeffrey S. Rudner
- 32.1 Principal Executive Officer Certification pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002
- 32.2 Principal Financial Officer Certification pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002
- 101.INS XBRL Instance document
- 101.SCH XBRL Schema
- 101.CAL XBRL Calculation Linkbase
- 101.DEF XBRL Definition Linkbase
- 101.LAB XBRL Label Linkbase
- 101.PRE XBRL Presentation Linkbase

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, 2015 By: s/ Glenn D. Yeik  
Glenn D. Yeik  
Chairman and Principal Executive Officer

TRIMEDYNE, INC.

Date: February 23, 2015 By: s/ Jeffrey S. Rudner  
Jeffrey S. Rudner  
Principal Financial Officer