TRIMEDYNE INC
Form 10-K
January 18, 2011

UNITED STATES

SECURITIES AND EXCHANGE COMMISSION
Washington, D.C. 20549

FORM 10-K

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

For the fiscal year ended September 30, 2010

or

o 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	36-3094439
(STATE OR OTHER JURISDICTION OF INCORPORATION	(I.R.S. EMPLOYER IDENTIFICATION NO.)
25901 COMMERCENTRE DRIVE LAKE FOREST, CALIFORNIA	92630
(ADDRESS OF PRINCIPAL EXECUTIVE OFFICES)	(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 if the Registrant is a well-known seasoned issuer, as defined in Rule 405 of the Securities Act. Yes o No x

Indicate by check mark if the Registrant is not required to file reports pursuant to Section 13 or 15(d) of the Act. Yes o No x

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 x No o

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 o No o

Indicate by check mark if disclosure of delinquent filers pursuant to Item 405 of Regulation S-K is not contained herein, and will not be contained, to the best of the registrants knowledge, in definitive proxy or information statements incorporated by reference in Part III of this Form 10-K or any amendment to this Form 10-K. o

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	o	Accelerated filer	o
Non-accelerated filer	o	Smaller reporting company	x

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

The aggregate market value of voting and non-voting common equity stock held by non-affiliates of registrant on January 12, 2011 based upon the closing price of the common stock on such date was approximately $1,273,482 As of January 12, 2011, there were outstanding 18,365,960 shares of registrant's Common Stock.

DOCUMENTS INCORPORATED BY REFERENCE

None.

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PART I

ITEM 1. BUSINESS

FORWARD LOOKING STATEMENTS

In addition to historical information, this Annual Report contains forward-looking statements. These forward-looking statements are subject to certain risks and uncertainties that could cause actual results to differ materially from those reflected in these forward-looking statements. Factors that might cause such a difference include, but are not limited to, those discussed in the section entitled "Management's Discussion and Analysis or of Financial Condition and Results of Operations". Readers are cautioned not to place undue reliance on these forward-looking statements, which reflect management's opinions only as of the date hereof. The Company undertakes no obligation to revise or publicly release the results of any revision to these forward-looking statements. Readers should carefully review the risk factors described in other documents the Company files from time to time with the U.S. Securities and Exchange Commission, including the Quarterly Reports on Form 10-Q filed by the Company in fiscal year 2010.

GENERAL

Trimedyne, 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 ("FDA") for use in orthopedics, urology, ear, nose and throat ("ENT") 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 most 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. MST's revenues and those of our field service department represented about 45% of our revenues in the fiscal year ended September 30, 2010.

The principal market for our 80 watt and 30 watt Holmium 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. These Orthopedic products represented about 31% of our revenues in the fiscal year ended September 30, 2010.

We recently introduced a fast vaporizing, very durable Side Firing Fiber for use in the Urology field with our 80 watt Holmium Lasers, and 80 watt and 100 watt Holmium Lasers made by others with compatible connectors, for the treatment of benign prostatic hyperplasia or “BPH”, commonly called an enlarged prostate. We also sell optical fibers (“Fibers”) for use with our 80 watt and 30 watt Holmium Lasers and those made by others for fragmenting urinary stones in the kidney, ureter or bladder. These Urology products represented about 24% of our revenues in the fiscal year ended September 30, 2010.

In July 2010, we engaged the services of Wade Hampton of the Baron Minor Group as Director of U.S. Sales on a part-time basis to recruit and train sales representatives and manage our sales activities in the United States. Mr. Hampton was earlier employed by Lumenis Ltd. of Yokneam, Israel (“Lumenis”) in senior executive positions in

Lumenis' U.S. and international sales. Lumenis is one of the world's largest manufacturer of medical lasers, with sales of about $300 million. Mr. Hampton has recruited a number of independent sales representatives ("Sales Reps") to market our Lasers, Fibers, Needles and Tips in the United States, who are presently being trained to sell our products.

THE UROLOGY MARKET

While our Lasers and Fibers are presently used in urology to fragment stones in the kidney, ureter and bladder, we have developed a new, proprietary, Side Firing Fiber for use with our 80 watt Holmium Lasers, and 80 watt and 100 watt Holmium Lasers made by others with a compatible connector, to vaporize a portion of the prostate to treat BPH or an enlarged prostate. Enlargement of the prostate causes difficulty in urinating and an urgency to urinate, which often causes the patient to wake-up one or more times each night, interrupting his sleep.

We are marketing this new Side Firing Fiber under our VaporMAX registered trademark through our limited number of Sales Reps in the United States and by distributors in certain foreign countries.

SETTLEMENT WITH LUMENIS

On August 24, 2005, we entered into a Five Year OEM Agreement with Lumenis. Under the OEM Agreement, Lumenis agreed to pay us a royalty of 7.5% of its worldwide sales of side firing and angled firing laser fibers, and Lumenis also agreed to purchase 100% of its needs for side firing laser fibers and 75% of its needs for angled firing laser fibers from us, subject to our laser fibers meeting certain performance standards and satisfactory completion of an audit of our manufacturing process and quality system. This Agreement expired on August 23, 2010.

We had a contract dispute with Lumenis over the last two years. We reached an amicable settlement of this dispute with Lumenis, Lumenis entered into a Settlement Agreement and a License Agreement with us, and we exchanged mutual releases.

Under the Settlement Agreement, Lumenis paid us $2,000,000. While the Settlement Agreement was executed at a later date, the Settlement Agreement is dated as of August 23, 2010, the date of expiration of the OEM Agreement. As a result, the $2 million payment by Lumenis is reflected in the Company's financial statements for the calendar quarter and the year ended September 30, 2010.

Under the License Agreement, Lumenis extended the 7.5% royalty payment period to July 21, 2014. While the License Agreement was also executed at a later date, the License Agreement was dated as of August 23, 2010, the date of expiration of the OEM Agreement, which contained a non-exclusive license to Lumenis of the same two U.S. patents.

THE ENLARGED PROSTATE MARKET

An enlarged prostate affects about 50% of men over age 55, and a higher percentage of men at advanced ages. While drugs are used to treat millions of men with an enlarged prostate, when the drugs are no longer able to adequately treat this condition, removal of a portion of the prostate is needed to permit proper urine flow.

Each year, about 200,000 men in the United States and an estimated one million men in foreign countries are treated with a procedure using radiofrequency ("RF") energy or laser energy to remove a portion of the prostate to permit proper urine flow. While RF energy has been used for more than 50 years to do this, today, laser vaporization or resection of the prostate is becoming increasingly popular. The laser procedure can be performed on an outpatient basis, with minimal adverse affects, whereas the RF procedure usually entails a hospital stay, significant bleeding, a variety of adverse effects and a recuperation period of days to weeks.

The development of our new Side Firing Fiber for use with our 80 watt Holmium Lasers and those of others took much longer than expected, due to obstacles imposed by the high peak powers and other characteristics of Holmium Lasers, which make them excellent at vaporizing tissue, but also makes them very hard on the glass components of the Fibers. However, we were able to overcome these obstacles, resulting in our new, faster vaporizing and very durable Side Firing Fiber.

Our new Side Firing Fiber has been shown in our bench testing on animal tissue to vaporize tissue faster and to be significantly more durable than the angled firing fibers manufactured by others. Our new Side Firing Fiber was also tested by an Independent Testing Laboratory, whose bench testing confirmed the results of our testing of its vaporization rate and durability.

Our new Side Firing Fiber has been cleared for sale by the FDA for use in Orthopedics, Urology and a variety of other medical specialties.

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PATENTED DEVICES

We have been issued two U.S. Patents on an improved Side Firing Fiber, which has the potential to shorten the time to treat an enlarged prostate and reduce or eliminate most of the adverse effects of both RF and laser resection or vaporization of the prostate. In addition, this new Side Firing Fiber has the potential to reduce adverse effects in the treatment of herniated or ruptured spinal discs, as well as in other applications. Our improved Side Firing Fiber has been cleared for sale by the FDA.

We have also been issued two U.S. Patents on an improved optical fiber device for fragmenting stones in the kidney, ureter or bladder, which has the potential to shorten the fragmentation time and reduce the risk of damage to nearby tissues during the stone fragmentation procedure.

We plan to use some of the proceeds of our settlement with Lumenis to expand our efforts in selling our existing products and, perhaps, to conduct limited testing of the two new products described above. If the test results are encouraging, we plan to seek financing to conduct larger, randomized, controlled clinical trials of these new products or find a marketing partner who will bear these costs for exclusive distribution rights to the products.

THE LITHOTRIPSY MARKET IN UROLOGY

Many people in the Unites States and elsewhere throughout the world develop stones in the kidney, some of which pass into the ureter, or develop in the bladder. Holmium Lasers are ideal for fragmenting these stones, as our Holmium Lasers produce very short, 350 micrsecond pulses of energy, which create thermal ablation that can fragent stones of any hardness, composition or color.

We manufacture FLEXMAX(R) straight-ahead firing Fibers, which are reusable and can be used for 20-30 times or more. As a result, we developed and are introducing new FLEXMAX(R) Single Use, disposable optical fibers at a somewhat lower price, which are more likely to be used only once and discarded.

THE SPINAL DISC MARKET

Our 80 watt and 30 watt Holmium Lasers and those of others are used with Side Firing Needles to treat herniated or ruptured lumbar, thoracic or cervical discs in the spine in minimally invasive procedures, which are typically performed on an outpatient basis in as little as 45 minute procedures, usually with only local anesthesia. The lower back, leg and neck pain disappears on the operating table, and the patient walks out with a Band Aid(R) on the puncture (stitches are usually not required). Most patients can return to light activities in a few days. Clinical Studies on our laser/disc procedures, published in medical journals, show success rates (good or excellent results, based on accepted pain score criteria) of 80% to 94%.

Approximately 600,000 conventional surgical laminectomy or discectomy procedures are performed each year in the United States to treat herniated or ruptured discs. These surgeries typically require general anesthesia and entail a two to three day or longer hospital stay, bleeding, post-operative pain and a recovery period of a month or longer, often with physical therapy or exercise programs for up to six months. Papers on conventional surgery to treat herniated or ruptured discs in the spine, published in medical journals, show the success rates of disc surgery to be only 40% to 77%, based on similar pain score criteria.

While our laser procedures to treat herniated or ruptured spinal discs have demonstrated higher success rates, fewer adverse effects and typically do not require hospitalization, which are common to the conventional surgical procedures to treat herniated or ruptured discs, and are less costly to third party payors, surgeons must attend one or more training courses in which they practice the procedure on cadavers before they can perform our laser procedures.

In addition to difficulty in convincing busy surgeons to take two to three days away from their practice to attend a training course, we incur substantial costs in conducting the training courses.

In addition, surgeons are generally paid more by Medicare and insurance companies for performing conventional disc surgery than for our outpatient laser procedures, reducing their desire to take time away from their practice to attend a training course for a lower-paying procedure. However, once experienced in our shorter procedure, many spinal surgeons are able to perform two, three or more of our outpatient laser procedures a day, compared to usually one procedure a day for conventional disc surgery.

Since we can afford to conduct (or participate with makers of endoscopes used in these procedures) in only a few training courses each year in the U.S. and only occasionally in Europe, Latin America and Asia, our spinal disc market is expected to grow only if we are able to conduct or participate in a larger number of training courses. The $2 million received from the settlement with Lumenis will allow us to conduct or participate in more training courses.

OTHER MARKETS

Our Lasers, Fibers, Needles and Tips are also used in a variety of other procedures in gynecology, ear, nose and throat surgery, gastrointestinal surgery and general surgery.

We also plan to develop new optical fiber devices for use with our Holmium Lasers and others to treat other conditions. Developing new optical fiber devices for new medical applications entails considerable risk. While we have almost twenty years of experience in designing, developing, manufacturing and marketing Holmium Lasers and Side Firing Fibers, we cannot assure that any new optical fiber devices or different lasers we attempt to develop for new applications can be completed at a reasonable cost or in a timely manner, will be clinically successful, can compete successfully in the marketplace or be profitable to us.

THE LASER RENTAL MARKET

Many hospitals, surgery centers and physicians are reluctant to purchase "big ticket" medical equipment, such as our Lasers, which sell for $50,000 to $127,000, particularly for new medical procedures. Hospitals also traditionally suffer from a lack of funds to buy expensive medical equipment, and they prefer to avoid having to train their staff to operate new, complex equipment. As a result, laser rental companies have been formed in the United States and elsewhere to fill this void. These companies typically provide lasers, endoscopes and other types of medical equipment, along with a trained operator, to hospitals, surgery centers and physicians on a "fee per case" basis.

Mobile Surgical Technologies, Inc. ("MST") was organized in 1997 to rent lasers with a trained operator to hospitals, surgery centers and physicians in Texas on a "fee per case" basis. We acquired MST in late 2000 and expanded its "fee per case" rental Business. MST is particularly well suited to our introduction and testing of new laser products. If requested, MST also supplies Side Firing or plain Fibers or Tips and includes their price in the "per case" fee.

We also plan to rent Lasers, without an operator, to hospitals and surgery centers in other states on a month-to-month basis. When a surgeon is trained to perform a new procedure, such as our Laser procedures for treating an enlarged prostate or a herniated or ruptured disc in the spine, instead of waiting for his hospital or surgery center to purchase the Laser, the hospital or surgery center can rent it on a "per case" basis or for a fixed monthly rental.

When the hospital's or surgery center's staff has been trained and is comfortable with the patient results, the volume of patients and the amount third-party payors are reimbursing for the procedure, they can buy the Laser, lease it under a conventional, long term lease or continue to rent it. Since the six to twelve month average delay in purchasing "big ticket" medical equipment is eliminated, the hospital or surgery center can immediately start buying Fibers, Needles and Tips from us, which typically carry higher profit margins than our Lasers.

LICENSE AGREEMENTS

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. 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, all of which have been assigned to the Company without royalty. The Company's 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.

RESEARCH AND DEVELOPMENT

From its inception to September 30, 2010, an aggregate of $54,187,000 has been expended by the Company for research and development ("R&D"), including clinical and regulatory activities, of which $1,060,000 and $$1,316,000 was expended during the fiscal years ended September 30, 2010 and 2009, respectively. These expenditures have resulted in the issuance of a number of patents to the Company (See “PATENTS”),the receipt of significant royalty payments and, since the Company’s inception, more than $100 million in sales revenue.

MANUFACTURING AND SUPPLY AGREEMENTS

The Company believes that it has adequate engineering, design and manufacturing facilities (see "PROPERTIES" section herein).

The Company has supply agreements with several suppliers for components and materials used in the production of its products. However, the Company has no long-term volume commitments. The materials used in the Company's products, consisting primarily of certain plastics, optical fibers, lenses, various metal alloys, lasers and laser assemblies and components used in the manufacture of its lasers are, in most cases, available from several vendors. The Company has, on occasion, experienced temporary delays or increased costs in obtaining these materials. An extended shortage of required materials and supplies could have an adverse effect upon the revenue and earnings of the Company. In addition, the Company must allow for significant lead time when procuring certain materials and supplies. Where the Company is currently using only one source of supply, the Company believes that a second source could be obtained within a reasonable period of time. However, no assurance can be given that the Company's results of operations would not be adversely affected until a new source could be located.

MARKETING

The principal markets for the Company's current products are hospitals with orthopedic, urology, ENT, gynecology, gastrointestinal, general surgery and other surgical operating room facilities, as well as outpatient surgery centers. In the United States, this market represents approximately 5,500 hospitals, as well as 1,000 or more outpatient surgery centers. Any new products the Company develops will, if cleared for sale by the FDA and marketed, be sold to hospitals and outpatient surgery centers, as well as to physicians for use in their offices. The Company anticipates marketing only those products which are customarily sold to the same customer groups to whom its Lasers and Fibers, Needles and Tips are presently marketed. There is no assurance as to the extent to which the Company will be able to penetrate these markets.

At September 30, 2010, the Company had marketing arrangements for the sale of its Lasers, Fibers, Needles and Tips with a limited number of straight commission sales representatives in the United States. Outside the United States, the Company sells its products through 22 independent distributors who sell our products and other medical products in approximately 28 foreign countries. Our U.S. sales representatives and our foreign distributors devote only a portion of their time to selling our products. The Company presently employs a Vice President of Sales and Marketing , who directs the Company's sales and marketing activities in the United States and elsewhere, and a Director of Sales on a consulting basis who recruits Sales Reps and manages our sales activities in the United States.

The Company intends in the future to increase the number of domestic sales representatives and appoint additional distributors in foreign countries for the purpose of expanding sales of the Company's VaporMAX Fibers, Side Firing Needles, Reuseable and Single Use FLEXMAX(R) optical fibers and other products. There is no assurance that the Company will be able to enter into marketing arrangements with any sales persons or distributors, as the Company is devoting limited resources to these activities, or that the Company will be able to maintain its existing selling arrangements.

GOVERNMENT REGULATION

All of the Company's products are, and will in the future, be subject to extensive governmental regulation and supervision, principally by the FDA and comparable agencies in other countries. The FDA regulates the introduction, advertising, manufacturing practices, labeling and record keeping of all drugs and medical devices. The FDA has the power to seize adulterated or misbranded devices, require removal of devices from the market, enjoin further manufacture or sale of devices, and publicize relevant facts regarding devices.

Prior to the sale of any of its products, the Company is required to obtain marketing clearance or approval for each product from the FDA and comparable agencies in foreign countries. Extensive clinical testing of each product, which is both costly and time-consuming, may be required to obtain such approvals. The Company's business would be adversely affected if it were unable to obtain such approvals or to comply with continuing regulations of the FDA and other governmental agencies. In addition, the Company cannot predict whether future changes in government regulations might increase the cost of conducting its business or affect the time required to develop and introduce new products. The Company's facilities were inspected by the FDA in September 2008 and no deficiencies in the Company's compliance with the FDA's requirements were cited by the FDA.

Specific areas of regulation by the FDA and other related matters are described in detail below.

INVESTIGATIONAL DEVICE EXEMPTION

Before a new medical device may be used for investigational research in the United States, an Investigational Device Exemption ("IDE") application must be approved by the FDA. In order to obtain an IDE, the sponsor of the

investigational research must first obtain approval for the research from an Institutional Review Board or Committee ("IRB") established for this purpose at the institution (e.g. hospital, medical center, etc.) at which the research is to be conducted.

510(k) PREMARKET NOTIFICATION

The procedure for obtaining clearance from the FDA to market a new medical device involves many steps, such as IDE's and PMA's (see "Premarket Approval"). However, if a device is substantially equivalent to a product marketed prior to May 28, 1976, or a comparable product subsequently cleared by the FDA under a 510(k) Premarket Notification, a 510(k) Premarket Notification may be filed to establish the device's equivalence. The FDA's review process can take three months or longer. However, if additional testing or data are requested by the FDA, it is common for the overall review process to be extended.

All of the Company's currently marketed lasers and fiber-optic laser energy delivery devices were cleared for sale under 510(k) Notifications. However, some or all of the new products the Company plans to develop may require extensive clinical trials and the filing of a PMA, which will entail substantially more cost over a significantly longer period of time.

PREMARKET APPROVAL

Under the Medical Device Amendments of 1976, all medical devices are classified by the FDA into one of three classes. A "Class I" device is one that is subject only to general controls, such as labeling requirements and good manufacturing practices ("GMP"). A "Class II" device is one that is subject to general controls and must comply with performance standards established by the FDA. A "Class III" device is one for which general controls and performance standards alone are insufficient to assure safety and effectiveness, unless the device qualifies for sale under a 510(k) Premarket Notification. Such devices require clinical testing to establish their safety and efficacy in treating specific diseases or conditions, and a Premarket Approval ("PMA"). Application for the intended use must be approved by the FDA before the device can be marketed in the United States. A device is generally classified as a Class I, II, or III device based on recommendations of advisory panels appointed by the FDA.

The filing of a PMA Application entails a rigorous review by the FDA, which can take one year or longer, unless additional testing or data are requested by the FDA, in which case the review process can be considerably longer. The Company believes the majority of its urology, orthopedic and other surgical products can be cleared for sale pursuant to 510(k) Premarket Notifications, which in some cases may require limited clinical trials, although such cannot be assured.

There is no assurance that required PMA approvals or 510(k) clearances for any new products the Company may develop can be obtained or that 510(k) clearances for the Company's present products can be maintained. The failure to maintain 510(k) clearances for existing products or to obtain needed PMA approvals or 510(k) clearances for new products might have a material adverse effect on the Company's future operations.

INSPECTION OF PLANTS

The FDA also has authority to conduct detailed inspections of manufacturing plants, to determine whether or not the manufacturer has followed its GMP requirements, which are required for the manufacture of medical devices. Additionally, the FDA requires reporting of certain product defects and prohibits the domestic sale or exportation of devices that do not comply with the law. The Company's manufacturing facility was inspected by the FDA in September 2008 and no deficiencies in the Company's compliance with the FDA's requirements were cited by the FDA. The Company believes it is currently in compliance in all material respects with these regulatory requirements, and expects that the processes and procedures in place will satisfy the FDA, although such cannot be assured.

STATE REGULATION

Federal law preempts states or their political subdivisions from regulating medical devices. Upon application, the FDA may permit state or local regulation of medical devices which is either more stringent than federal regulations or is required because of compelling local conditions. To date, and to the best of the Company's knowledge, only California has filed such an application. On October 5, 1980, the FDA granted partial approval to such application, effective December 9, 1980. The California requirements which have been exempted from preemption have not had a materially adverse effect on the Company.

INSURANCE REIMBURSEMENT

To permit the users of the Company's products to obtain reimbursement under Federal health care programs such as Medicare, the Company may be required to demonstrate, in an application to the Centers for Medicare and Medicaid Services ("CMS"), at either the local or federal level or both, the safety and efficacy of its products and the benefit to patients there from which justify the cost of such treatment. Criteria for demonstrating such benefits are in the process of being defined by CMS, and there does not yet exist a clear method or requirement to receive approval for

reimbursement. There is no assurance that such an application, if made, will be approved by CMS. Most private health insurance companies and state health care programs have standards for reimbursement similar to those of CMS. If an application for reimbursement of a product is not approved by CMS, private insurers and/or health care programs, marketing of such product would be adversely affected.

COST OF COMPLIANCE WITH FDA AND OTHER APPLICABLE REGULATIONS

The costs of complying with FDA and other governmental regulations prior to the sale of approved products are reflected mainly in the Company's R&D expenditures. The cost of first obtaining an IDE for a product and, after having developed a product which in the Company's view is safe and effective, obtaining a PMA approval therefore, as well as making the necessary application to CMS in order to establish insurance reimbursability for treatments utilizing such product, adds significantly to the cost of developing and bringing a product to market over what such cost would have been if such regulatory requirements did not exist.

Such regulatory requirements also lengthen the time which is required to develop and commence marketing a product. These delays increase the Company's R&D costs by (a) lengthening the time during which the Company must maintain and bear the carrying costs of a given research and development effort and (b) delaying the time when the Company can commence realizing revenues from sales of a product, during which time, however, the Company must nevertheless continue to bear administrative and overhead costs. It is, however, not possible for the Company to quantify or estimate in advance the direct and indirect costs of complying with such regulatory requirements, particularly since the expense and difficulty of such compliance can vary greatly, depending upon the nature of the product, its intended use, the technological success of the R&D effort and the results of clinical testing of its products.

To the extent applicable regulations require more rigorous testing than might otherwise be deemed necessary by the Company, the costs entailed in conducting testing of its products by such institutions (and fees or royalties, if any, payable to them) may be deemed in part a cost to the Company of compliance with such regulatory requirements.

EMPLOYEES

On September 30, 2010, the Company had 53 full-time employees, of whom 13 were employed by MST. Of the remainder, 29 were engaged in production and engineering, two in sales and marketing, and nine in general and administrative functions. On September 30, 2010, the Company had two part-time employees of whom one was engaged in production and R&D, and one in general and administrative functions.

The Company may require additional employees in the areas of administration, product development, research, production, regulatory affairs, quality control, sales and marketing in the future. There is intense competition for capable, experienced personnel in the medical device and laser fields, and there is no assurance the Company will be able to obtain new qualified employees when required.

Management believes its relations with its employees are good.

PATENTS

As of September 30, 2010, the Company owned or had licenses to 19 U.S. Patents and two foreign Patents, four U.S. patent applications and two foreign patent applications.

There is no assurance that (a) any patents will be issued from the pending applications, (b) any issued patents will prove enforceable, (c) the Company will derive any competitive advantage therefrom or (d) that the Company's products may not infringe patents owned by others, licenses to which may not be available to the Company. To the extent that pending patent applications do not issue, the Company may be subject to more competition. There can also be no assurance that the already patented products, methods and processes will be medically useful or commercially viable. The issuance of patents on some but not all aspects of a product may be insufficient to prevent competitors from essentially duplicating the product by designing around the patented aspects. The Company is obligated, under certain of its patent licenses, to make royalty payments. Part of the Company's R&D activities will be directed towards obtaining additional patent rights, which may entail future royalty and minimum payment obligations.

COMPETITION

The Company faces competition from a number of both small and large companies in the medical field. The larger companies include Medtronic, Inc., Johnson & Johnson, Boston Scientific, Inc., Lumenis Ltd., American Medical Systems Holdings, Inc., Olympus, Inc., and others, all of which have greater financial resources, R&D and manufacturing facilities, technical skills, management staffs and/or sales and marketing organizations than the Company's.

Among the smaller companies with which the Company competes are: Dornier, Inc., Lisa Lasers, Convergent, Inc. and others, certain of which are publicly held.

INSURANCE

The Company has a commercial general liability insurance policy, including an umbrella policy, providing coverage in the aggregate amount of $5,000,000 and a products liability insurance policy providing coverage in the amount per

occurrence of $5,000,000. There is no assurance that such amounts of insurance will be sufficient to protect the Company's assets against claims by users of its products. Although there have been no successful claims against the Company, there is no assurance the Company will be able to maintain such liability insurance in force in the future at an acceptable cost, or at all, in which case the Company's assets would be at risk in the event of successful claims against it. Successful claims in excess of the amount of insurance then in force could have a serious adverse effect upon the Company's financial condition and its future viability. The Company does not carry director and officer liability insurance, but does have indemnification agreements covering its officers and directors.

FOREIGN OPERATIONS

In fiscal 2010 and 2009, sales of products in foreign countries accounted for approximately 15.1% and 25.2%, respectively, of the Company's total sales. See "Marketing" herein for information on the marketing of the Company's products in foreign countries.

ITEM 2. PROPERTIES

The Company currently occupies approximately 28,700 sq. ft, office, R&D, manufacturing and warehouse facility at 25901 Commercentre Drive, Lake Forest, CA 92630. Our present lease was amended and became effective June 1, 2010 expires on May 31, 2013, and contains two sixty-month options to extend the lease at the then prevailing market rent. The rent for the first year is at $24,108 per month, with the first four months at $12,054. The lease contains two increases occuring at the end of 12 months and 24 months, for $29,561 and $30,422, respectively, with the first increase including a month's free rent.

The Company's subsidiary, MST, currently occupies approximately 1,500 square feet of office space in Dallas, Texas, which it leases at a rental of $1.688 per month through August 31, 2011.

Management considers all of its facilities to be well maintained and adequate for its purposes.

ITEM 3. LEGAL PROCEEDINGS

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.

The Company had no product liability lawsuits commenced against it during the year ended September 30, 2010. 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 coverage 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 $5,000,000 insurance coverage. In such case, Trimedyne would be liable for any liability in excess of $5,000,000.

In February, 2008, we and six other laser manufacturers were sued in the district court of Massachusetts by CardioFocus, Inc., alleging infringement of three of their now expired U.S. Patents.

To avoid the cost and uncertainty of litigation, as of November 24, 2010, we settled the litigation with CardioFocus, paid them $175,000, entered into mutual releases and the lawsuit was dismissed.

ITEM 4. [REMOVED AND RESERVED]

PART II

ITEM 5. MARKET FOR REGISTRANT'S COMMON EQUITY, RELATED STOCKHOLDER MATTERS AND ISSUER PURCHASES OF EQUITY SECURITIES

A. MARKET INFORMATION

Since November 18, 2003, the Company's Common Stock has been quoted on the Over-The-Counter Bulletin Board under the symbol "TMED." The following table sets forth the high and low closing sales prices for the Common Stock for each quarterly period within the Company's two most recent fiscal years:

2009		High		Low
Quarter ended:				
December 31, 2008	$	0.22	$	0.08
March 31, 2009		0.29		0.13
June 30, 2009		0.26		0.18
September 30, 2009		0.49		0.20

2010		High		Low
Quarter ended:				
December 31, 2009	$	0.51	$	0.37
March 31, 2010		0.53		0.36
June 30, 2010		0.44		0.24
September 30, 2010		0.29		0.14

Such over-the-counter market quotations reflect inter-dealer prices, without retail mark-up, mark-down or commission and may not necessarily represent actual transactions.

B. HOLDERS OF COMMON STOCK

As of September 30, 2010, there were approximately 1,000 holders of record of the Company's Common Stock and an estimated 9,000 additional holders who maintain the beneficial ownership of their shares in "Street Name".

C. DIVIDENDS

The Company has never paid cash dividends on its Common Stock, and does not anticipate paying cash dividends in the foreseeable future. Any future determination as to the payment of cash dividends will be dependent upon the Company's financial condition and results of operations and other factors then deemed relevant by the Board of Directors.

D. SECURITIES AUTHORIZED FOR ISSUANCE UNDER EQUITY COMPENSATION PLANS

The following table provides information as of September 30, 2010 with respect to shares of the Company's common stock that may be issued through its employee compensation plans:

PLAN CATEGORY	NUMBER OF SECURITIES TO BE ISSUED UPON EXERCISE OF OUTSTANDING OPTIONS, WARRANTS AND RIGHTS (a)	WEIGHTED-AVERAGE EXERCISE PRICE OF OUTSTANDING OPTIONS, WARRANTS AND RIGHTS (b)	NUMBER OF SECURITIES REMAINING AVAILABLE FOR FUTURE ISSUANCE UNDER EQUITY COMPENSATION PLANS (EXCLUDING SECURITIES REFLECTED IN COLUMN(a)) (c)
Equity compensation plans approved by security holders	100,629	$ 0.98	--
Equity compensation plans not approved by security holders	1,162,950	$ 0.90	1,076,600
Total	1,263,579	$ 0.91	1,076,600

Recent Sales of Unregistered Securities

On August 20, 2010, Marvin P. Loeb, the Company's Chairman and CEO, loaned the Company $500,000 through the purchase of a 6% Senior Secured Convertible Note (the "Note"), which is secured by all of the assets of the Company and is due August 19, 2015. However, the Note contains a provision whereby the CEO can redeem the Note at any time. The CEO agreed to not redeem the Note, without the Company's consent for a period of two years from September 30, 2010. The Note is reflected as a long-term obligation of the Company as of September 30, 2010 on the accompanying consolidated balance sheet. The funds received from the purchase of the Note is to be used for operations. The Note can be converted at any time into shares of the Company's common stock at a conversion price of $0.21 per share. The conversion price equaled the fair market value of the Company's common stock on the date of the purchase of the Note, and no beneficial conversion feature was recorded. However, the Note contains an anti-dilution provision whereby the price resets in the event of any future financing in the Note. The sale of the Note is exempt from registration under the Securities Act of 1933 (the "Act") pursuant to Section 4(2) of the Act.

Purchases of Equity Securities by the Issuer and Affiliated Purchasers

None.

ITEM 6. SELECTED FINANCIAL DATA - N/A

ITEM 7. MANAGEMENT'S DISCUSSION AND ANALYSIS OF FINANCIAL CONDITION AND RESULTS OF OPERATIONS

OFF-BALANCE SHEET ARRANGEMENTS

None.

CRITICAL ACCOUNTING POLICIES

REVENUE RECOGNITION AND ALLOWANCE FOR DOUBTFUL ACCOUNTS

The Company's revenues include revenues from the sale of delivery and disposable devices, the sale and rental of laser equipment and accessories, and service contracts for lasers manufactured by the Company.

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 Lasers, Fibers, Needles and Tips 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. In general, the Company does not have any post shipment obligations such as installation or acceptance provisions. All domestic Lasers are sold with a one year warranty which includes parts and labor. All international Lasers are sold with a one year parts only warranty. As each Laser sale is recognized, a liability is accrued for estimated future warranty costs.

The Company utilizes distributors for international sales only. All Lasers sales are non-returnable. Our international distributors typically locate customers for Lasers before ordering and in general do not maintain inventories. The Company's return policy for Laser accessories, delivery and disposable devices sold to distributors is as follows: 1) The Company will accept returns of any unopened, undamaged, standard catalogue items (except laser systems) within sixty (60) days of invoice date. Acceptable returned products will be subject to a 20% restocking fee, 2) A return authorization number is required for all returns. The number can be obtained by contacting the Customer Service Department, and 3) Should a product be found defective at the time of initial use, the Company will replace it free of charge.

The Company offers service contracts on its Lasers. These service contracts are offered at different pricing levels based on the level of coverage, which include periodic maintenance and different levels of parts and labor to be provided. Since the service contracts have a twelve-month term, the revenue of each service contract is deferred and recognized ratably over the term of each service contract.

Trimedyne rents its Lasers for a flat monthly charge for a period of years or on a month-to-month basis, or on a fee per case basis, sometimes with a minimum monthly rental fee. During the fiscal years ended September 30, 2010 and 2009, two Lasers, respectively, were being rented by Trimedyne, each on a month-to-month basis. For these lasers, rental revenue is recorded ratably over the rental period. MST generally enters into rental service contracts with customers for a two year period which, unless cancelled, are renewed on an annual basis after the initial period. During the rental service contract period customers do not maintain possession of any rental equipment unless it is for the Company's convenience. Customers are billed on a fee per case basis for rentals, which includes the services of the laser operator and, in some cases, the use of a reusable or single use laser delivery device. Revenue from these rental service contracts is recognized as the cases are performed.

Allowances for doubtful accounts are estimated based on estimates of losses related to customer receivable balances. Estimates are developed based on historical losses, adjusting for current economic conditions and, in some cases,

evaluating specific customer accounts for risk of loss. The establishment of reserves requires the use of judgment and assumptions regarding the potential for losses on receivable balances. Though we consider these balances adequate and proper, changes in economic conditions in specific markets in which we operate could have a material effect on reserved balances required. Our credit losses in 2010 and 2009, were less than one percent of revenues.

INVENTORIES

Inventories consist of raw materials and component parts, work in process and finished Lasers. Inventories are recorded at the lower of cost or market, cost being determined principally by use of the average-cost method, which approximates the first-in, first-out method. Cost is determined at the actual cost for raw materials, and at production cost (materials, labor and indirect manufacturing overhead) for work-in-process and finished goods.

Laser units located at medical facilities for sales evaluation and demonstration purposes or those units used for development and medical training are included in inventory since the lasers will ultimately be sold. These units are written down to reflect their net realizable values.

We write-down our inventory for estimated obsolescence equal to the net realizable value of the obsolete inventory. Product obsolescence may be caused by changes in technology discontinuance of a product line, replacement products in the marketplace or other competitive situations. We maintain a reserve on inventories that we consider to be slow moving or obsolete, to reduce the inventory to their net estimated realizable value. Once specific inventory is written-down, the write-down is permanent until the inventory is physically disposed of.

GOODWILL

We account for goodwill and acquired intangible assets in accordance with ASC No. 350 "Intangible Goodwill and Other", whereby goodwill is not amortized, and is tested for impairment at the reporting unit level annually during the fourth quarter and in interim periods if certain events occur indicating that the carrying value of goodwill may be impaired. A reporting unit is an operating segment for which discrete financial information is available and is regularly reviewed by management. We have one reporting unit, our service and rental group, to which goodwill is assigned.

ASC No. 350 requires a two-step approach to test goodwill for impairment for each reporting unit. The first step tests for impairment by applying fair value-based tests to a reporting unit. The second step, if deemed necessary, measures the impairment by applying fair value-based tests to specific assets and liabilities within the reporting unit. Application of the goodwill impairment tests require judgment, including identification of reporting units, assignment of assets and liabilities to each reporting unit, assignment of goodwill to each reporting unit, and determination of the fair value of each reporting unit. The determination of fair value for a reporting unit could be materially affected by changes in these estimates and assumptions.

As part of the first step, we generally estimates the fair value of the reporting unit based on market prices (i.e., the amount for which the assets could be bought by or sold to a third party), when available. When market prices are not available, we estimate the fair value of the reporting unit using the income approach. The income approach uses cash flow projections. Inherent in our development of cash flow projections are assumptions and estimates derived from a review of our historical operating results, future business plans, expected growth rates, cost of capital, future economic conditions, etc. Many of the factors used in assessing fair value are outside the control of management, and these assumptions and estimates can change in future periods. During the fourth quarter of the year ended September 30, 2010, we conducted a goodwill impairment test for its service and rental group using a combination of the market and income approach. As a result of the first step analysis, the expected cash flows to be generated by the service and rental were sufficient enough to support the carrying value of the goodwill. Thus, we determined there was no impairment of the goodwill as of September 30, 2010.

IMPAIRMENT OF LONG-LIVED ASSETS

Long-lived assets, such as property and equipment and purchased intangibles subject to amortization, are reviewed for impairment whenever events or changes in circumstances indicate that the carrying amount of an asset may not be recoverable. Recoverability of the asset is measured by comparison of its carrying amount to undiscounted future cash flows the asset is expected to generate. If such assets are considered to be impaired, the impairment to be recognized is measured as the amount by which the carrying amount of the asset exceeds its fair market value. Estimates of expected future cash flows represent our best estimate based on currently available information and reasonable and supportable assumptions. Any impairment recognized is permanent and may not be restored. To date, we have not recognized any impairment of long-lived assets.

We record a valuation allowance to reduce the deferred tax assets to the amount that is more likely than not to be realized. We have 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 our deferred tax assets have been reserved. If actual results differ favorably from those estimates used, we may be able to realize all or part of our net deferred tax assets. Such realization could positively impact our operating results and cash flows from operating activities.

DEFERRED TAXES

We record a valuation allowance to reduce the deferred tax assets to the amount that is more likely than not to be realized. We have 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 our deferred tax assets have been reserved. If actual results differ favorably from those estimates used, we may be able to realize all or part of our net deferred tax assets. Such realization could positively impact our operating results and cash flows from operating activities.

STOCK-BASED COMPENSATION

We account for equity based compensation under the provisions of ASC No. 718, "Compensation, Stock Compensation" ("ASC 718"). ASC 718 requires the recognition of the fair value of equity-based compensation in operations. The fair value of our stock option awards are estimated using a Black-Scholes option valuation model. This model requires the input of highly subjective assumptions and elections including expected stock price volatility and the estimated life of each award. In addition, the calculation of equity-based compensation costs requires that we estimate the number of awards that will be forfeited during the vesting period. The fair value of equity-based awards is amortized over the vesting period of the award and we elected to use the straight-line method for awards granted after the adoption of ASC 718.

DERIVATIVE LIABILITIES

Effective October 1, 2009, the Company adopted the provisions of Emerging Issues Task Force 07-5, "Determining Whether an Instrument (or Embedded Feature) is Indexed to an Entity's Own Stock" ("EITF 07-5"), which has been codified into ASC 815 . The guidance applies to any freestanding financial instruments or embedded features that have the characteristics of a derivative, as defined by SFAS No. 133, "Accounting for Derivative Instruments and Hedging Activities," which was codified into ASC 815) and to any freestanding financial instruments that are potentially settled in an entity's own common stock. The guidance had an impact on the Company's financial statements and position due to certain warrants and the senior secured convertible note payable to related party in which the exercise/conversion price resets upon capital raised at lower effective rates. See Notes 4 and 5 for the impact of such transactions on the consolidated financial statements.

Our issued and outstanding common stock purchase warrants and embedded conversion features are recorded at their fair value upon issuance and at each reporting period. The common stock purchase warrants were not issued with the intent of effectively hedging any future cash flow, fair value of any asset, liability or any net investment in a foreign operation. The warrants do not qualify for hedge accounting, and as such, all future changes in the fair value of these warrants will be recognized currently in earnings until such time as the warrants are exercised or expire. These common stock purchase warrants do not trade in an active securities market, and as such, we estimate the fair value of these warrants using the Black-Scholes option pricing model. The value of the embedded conversion feature is determined using the Lattice model. All future changes in the fair value of the embedded conversion feature will be recognized currently in earnings until the note is converted or redeemed.

CONVERTIBLE DEBT

If a conversion feature of conventional convertible debt is not accounted for as a derivative instrument and provides for a rate of conversion that is below market value, this feature is characterized as a beneficial conversion feature (“BCF”). A BCF is recorded by the Company as a debt discount. In those circumstances, the convertible debt will be recorded net of the discount related to the BCF. The Company amortizes the discount to interest expense over the life of the debt using the effective interest method.

RISKS AND UNCERTAINTIES

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.

CONSOLIDATED RESULTS OF OPERATIONS FOR FISCAL YEARS 2010 AND 2009

The following table sets forth certain items in the consolidated statements of income as a percentage of net revenues for the years ended September 30, 2010 and 2009:

	Year Ended September 30,	
	2010	2009
Net revenues	100.0%	100.0%
Cost of sales	65.6	62.5
Selling, general and administrative expenses	40.4	36.1
Research and development expenses	16.6	17.7
Interest expense	0.6	0.6
Other income, net	32.7	4.5
Income taxes	0.2	0.4
Net income (loss)	10.3	(12.2)

NET REVENUES

Net revenues decreased $1,021,000 or 13.8% in fiscal 2010 to $6,401,000 from $7,422,000 in fiscal 2009. Net sales from Lasers and accessories decreased by $879,000 or 55.0% to $720,000 during the fiscal year ended September 30, 2010 from $1,599,000 during the prior fiscal year, primarily due to a decrease in international sales. Sales from Fibers,

Needles and Tips decreased by $295,000 or 9.5% to $2,823,000 during the current fiscal year ended September 30, 2010 from $3,119,000 during the prior fiscal year. The decrease in sales from Fibers, Needles and Tips was primarily due to a decrease in international sales. International export revenues decreased $904,000 or 48.4% to $965,000 during fiscal 2010 from $1,869,000 during fiscal 2009. Net revenues from "per case" rentals and field service and rental increased by $154,000 or 5.7% in fiscal 2010 to $2,858,000 from $2,704,000 in fiscal 2009, primarily due to an increase in per case revenues from MST as a result of the addition of sales personnel and the expansion of its service business.

COST OF GOODS SOLD

Cost of sales in fiscal 2010 was approximately 63.9% of net revenues, compared to 62.5% in fiscal 2009. Gross profit from the sale of lasers and accessories was 0.0% in the fiscal year ended September 30, 2010 as compared to 23% for the prior year fiscal period. The lower gross profit during the fiscal year ended September 30, 2010 was the result of a volumizing difference due to a lower production of units created by the 55% decrease in international sales of laser systems and accessories and a non-recurring year-end adjustment of $103,000 primarily to reserve obsolete and slow moving inventory. Gross profit from the sale of Fibers, Needles and Tips during the fiscal year ended September 30, 2010 was 34% as compared to 43% for the prior fiscal year period. The decrease in gross profit was primarily the result of a volumizing difference due to a lower production of units created by the 9.5% decrease in sales of delivery systems during the current year and a non-recurring year-end adjustment of $138,000 primarily to reserve obsolete and slow moving inventory. Gross profit from revenue received from service and per case rentals was 45% in the current fiscal year as compared to 41% for the prior fiscal year period. The higher gross profit for the current year was primarily attributable to a lower cost of sales for our subsidiary, MST, which was the result of decreased repairs to MST's laser fleet combined with higher margins received from increases in procedures which have a higher per case rate.

SELLING, GENERAL AND ADMINISTRATIVE EXPENSES

Selling, general and administrative ("SG&A") expenses decreased $98,000 or 3.7% to $2,585,000 in fiscal 2010, compared to $2,683,000 in fiscal 2009. The $98,000 decrease in fiscal 2010 was primarily the result of decreases in commission expense of $115,000, outside services of $54,000, audit and tax preparation of $29,000, travel expenses of $21,000, and $18,000 in bad debt expense, offset by increases in taxes and license expense of $14,000, sales and use tax expense of $25,000 resulting from a Texas sales tax audit performed at MST, marketing expense of $45,000 and legal expense of $57,000.

RESEARCH AND DEVELOPMENT (R&D) EXPENSES

R&D expenses decreased $256,000 or 19.3% to $1,060,000 in fiscal 2010, compared to 1,316,000 in fiscal 2009. R&D as a percentage of net revenues decreased to 16.6% of net revenues in fiscal 2010 as compared to 17.7% in fiscal year 2009. R&D spending in fiscal 2009 was higher as during fiscal 2010 we were nearing the completion of our product development efforts in readying our new Side-Firing Fibers for use with Holmium Lasers.

OTHER INCOME AND EXPENSE

Total other income, net increased $1,762,000 or 529% to $2,095,000 in fiscal 2010 from $333,000 in fiscal 2009.

Income from royalties decreased $29,000 or 10% to $266,000 in fiscal 2010 from $295,000 in fiscal 2009. This decrease was due to of the continued decrease of Lumenis' sales of side-firing and angled-firing devices in which we receive royalties on.

In addition, Lumenis paid us $2,000,000 under a Settlement Agreement (see SETTLEMENT WITH LUMENIS). While the Settlement Agreement was executed at a later date, the Settlement Agreement is dated as of August 23, 2010, the date of expiration of the OEM Agreement. As a result, the $2 million payment by Lumenis is reflected in the Company’s financial statements as other income for the fiscal year ended September 30, 2010.

To avoid the cost and uncertainty of litigation, as of November 24, 2010, we settled the lawsuit filed against us and others by CardioFocus. We paid CardioFocus $175,000, entered into mutual releases and the lawsuit was dismissed.

This settlement expense was accrued and included in other expense for the year ended September 30, 2010.

During the current fiscal year, we accrued a provision for state income tax of $15,000 due to the net income apportioned to MST. During the fiscal year ended September 30, 2009, we accrued a provision for state income tax of $20,000

NET INCOME (LOSS)

As a result of the above, the net income in fiscal 2010 was $639,000, compared to a net loss of $909,000 in fiscal 2009. The primary change in our financial position for the current period was due to the $2 million paid to us by Lumenis under the Settlement Agreement.

LIQUIDITY AND CAPITAL RESOURCES

Cash flows

In fiscal 2010, net cash provided by operating activities was $644,000, as compared to net cash used of $54,000 in fiscal 2009. The primary reason for the cash provided in fiscal 2010 was due to $2 million in proceeds received in connection with a settlement with Lumenis. Net cash used in investing activities was $49,000 in fiscal 2010, compared to net cash used of $136,000 in fiscal 2009. The Company continues to conserve capital for operations and thus only incurs capital expenditures on an as needed basis. Net cash provided by financing activities during fiscal 2010 was $312,000 compared to cash used of $196,000 in fiscal 2009. In fiscal 2010, we continued to make payments on capital leases. In addition, we received $500,000 from the sale of a 6% senior secured convertible note to our Chief Executive Officer.

Liquidity and Management's Plans

At September 30, 2010, we had working capital of $5,025,000 compared to $3,772,000 at the end of the previous fiscal year ended September 30, 2009. Cash increased by $907,000 to $2,258,000 at September 30, 2010 from $1,621,000 at the fiscal year ended September 30, 2009. We believe that existing cash flows are sufficient to fund operations through September 30, 2011; however, we have incurred losses from operations for the past three years. There can be no assurance that we will be able to maintain or achieve sales growth in the next 12 months, or that the Company will be profitable. Thus, it is possible that additional working capital in the next 12 to 24 months may be required. If necessary, we will raise additional debt and/or equity capital, sell some of our assets, reduce our costs by eliminating certain personnel positions and reducing certain overhead costs in order to fund operations. There is no assurance that our efforts to do so will be successful.

MATERIAL TRANSACTION WITH RELATED PARTY

On August 20, 2010, Marvin P. Loeb, the Company's Chairman and CEO, loaned the Company $500,000 evidenced by a 6% Senior Secured Convertible Note with a principal amount of $500,000 (the "Note"), which is secured by all of the assets of the Company, and is due August 19, 2015. However, the Note contained a provision whereby the CEO can redeem the note at any time. The CEO agreed not to redeem the Note, without the written consent of the Company, for a period of two tears from September 30, 2010. Thus, the Note is reflected as a long-term obligation as of September 30, 2010 on the accompanying consolidated balance sheet. The funds provided under the Note are to be used for operations. The Note can be converted at any time into shares of the Company’s common stock at a conversion price of $0.21 per share. The conversion price equaled the fair market value of the Company’s common stock on the date of the purchase of the Note, and no beneficial conversion feature was recorded. However, the Note contains an anti-dilution provision whereby the price resets in the event of the sale or issuance of shares at a conversion price lower than the conversion price set forth in the Note.

ITEM 8. FINANCIAL STATEMENTS AND SUPPLEMENTARY DATA

The financial statements required by Item 8 of this Annual Report are set forth in the index on page F-1.

ITEM 9. CHANGES IN AND DISAGREEMENTS WITH ACCOUNTANTS ON ACCOUNTING AND FINANCIAL DISCLOSURE

None

ITEM 9A(T). CONTROLS AND PROCEDURES

Disclosure Controls and Procedures

Our management has evaluated, under the supervision and with the participation of our chief executive officer and chief 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 chief executive officer and chief 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 within the time periods specified in the Securities and Exchange Commission's rules and forms, and (2) accumulated and communicated to our management, including our chief executive officer and chief financial officer, as appropriate to allow timely decisions regarding required disclosure.

Management's Annual Report on Internal Control Over Financial Reporting

Our management is responsible for establishing and maintaining adequate internal control over financial reporting, as such term is defined in Exchange Act Rule 13a-15(f). Under the supervision and with the participation of our management, including our principal executive officer and principal financial officer, we conducted an evaluation of the effectiveness of our internal control over financial reporting as of September 30, 2010, based on the criteria set forth in "Internal Control - Integrated Framework" issued by the Committee of Sponsoring Organizations of the Treadway Commission. Based on our evaluation under such criteria, our management concluded that our internal control over financial reporting was effective as of the fiscal year ended September 30, 2010.

This Annual Report does not include an attestation report of our independent registered public accounting firm regarding internal control over financial reporting. We were not required to have, nor have we engaged our independent registered public accounting firm to perform, an audit on our internal control over financial reporting pursuant to the rules of the Securities and Exchange Commission that permit us to provide only management's report in this Annual Report.

Changes in Internal Control Over Financial Reporting

There were no changes in our internal control over financial reporting during the fourth quarter of fiscal 2010 that have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

ITEM 9B. OTHER INFORMATION

Not applicable.

PART III

ITEM 10. DIRECTORS, EXECUTIVE OFFICERS AND CORPORATE GOVERNANCE

DIRECTORS AND EXECUTIVE OFFICERS

The following persons served as our officers and directors in fiscal 2010.

Name	Age	Position
Marvin P. Loeb	84	Chairman and CEO
Glenn D. Yeik	43	President, COO, and Director
Brian T. Kenney	54	V.P. - Global Sales and Marketing
Donald Baker	81	Director

MARVIN P. LOEB has been a director of our Company since 1980, Chairman of the Board since March 1981, Chief Executive Officer from April 1991 to November 2000 and since July 2001. He has been the Chairman of the Board of Cardiodyne, Inc. (formerly Trioptic Laser, Inc., a 90% owned, inactive subsidiary of the Company) since May 1992. Since May 1986, he has been Chairman, CEO and a director of Cardiomedics, Inc., a privately held company which developed and is marketing a circulatory assist device. Since November 1988, he has been Chairman of Ultramedics, Inc., a privately held company whose principal interest is its investment in Cardiomedics, Inc. Mr. Loeb has been President of Master Health Services, Inc., a family held medical consulting firm, since 1973, and Marvin P. Loeb and Company, a family held patent licensing firm, since 1983. Mr. Loeb holds an honorary Doctor of Science Degree from Pacific States University and a Bachelor of Science Degree from the University of Illinois.

GLENN D. YEIK has been our President, Chief Operating Officer, and Director since September 2003. Since October 2004, he has been a Director of Cardiomedics, Inc., a privately held company which developed and is marketing a circulatory assist device. Before September 2003, he was our Executive Vice President from April 2002 to September 2003 and Vice President Product Development from March 2000 to April 2002 to September 2003. Mr. Yeik was Manager and Director of Electronic Systems at AngioTrax, Inc. from May 1998 to March 2000. He was our Manager, Laser Engineering from May 1994 to May 1998 and our Senior Electrical Engineer from July 1992 to May 1994. Before joining Trimedyne, Mr. Yeik was a Software Engineer at Cardiac Science, Inc. from June 1991 to July 1992. Mr. Yeik received a Bachelor of Science of Engineering Degree in Electrical Engineering from LeTourneau University. Mr. Yeik is Mr. Loeb's son-in-law.

BRIAN T. KENNEY has been our Vice President of Sales and Marketing since January 2000. Mr. Kenney had been our Director of International Sales from January 1999 to January 2000. Before joining Trimedyne, Mr. Kenney held sales and sales management positions with Exogen, a division of Smith & Nephew from April 1996 to November 1999, U.S. Surgical Corporation from January 1982 to December 1984, Stryker Corporation/Endoscopy Division from May 1988 to December 1992, and Surgical Laser Technologies from January 1993 to February 1996. Mr. Kenney is a graduate of the University of Oklahoma with a Bachelors Degree in Business Administration in Marketing and Finance.

DONALD BAKER has been a director of our Company since May 1983 and Audit Committee Chairman since September 2008. He also has been a director of Cardiodyne, Inc. since August 1996. Mr. Baker retired after 39 years as a Managing Partner of the law firm of Baker & McKenzie. He holds a J.D.S. degree from the University of Chicago

Law School. Mr. Baker was a Director of the management committee of the Mid-America Committee of Chicago for many years, a director of various medical technology companies and is currently on the board of Cardiomedics, Inc., of Irvine, CA. He is a member of the Chicago and American Bar Associations.

Family Relationships

Our director Glenn Yeik is the son-in-law of our Chairman Marvin Loeb. Other then the foregoing, there are no family relationships among the individuals comprising our board of directors, management and other key personnel.

Involvement in Certain Legal Proceedings

During the past five years, none of the following have occurred that are material to an evaluation of the ability or integrity of any director, person nominated to become a director, executive officer, promoter or control person of the Company:

1. Any bankruptcy petition filed by or against any business of which such person was a general partner or executive officer either at the time of the bankruptcy or within two years prior to that time;

2. Any conviction in a criminal proceeding or being subject to a pending criminal proceeding (excluding traffic violations and other minor offenses);

3. Being subject to any order, judgment, or decree, not subsequently reversed, suspended or vacated, of any court of competent jurisdiction, permanently or temporarily enjoining, barring, suspending or otherwise limiting his involvement in any type of business, securities or banking activities; and

4. Being found by a court of competent jurisdiction (in a civil action) , the Commission or the Commodity Futures Trading Commission to have violated a federal or state securities or commodities law, and the judgment has not been reversed, suspended, or vacated.

Compliance With Section 16(a) of the Exchange Act

Section 16(a) of the Exchange Act requires "insiders," including our executive officers, directors and beneficial owners of more than 10% of our common stock, to file reports of ownership and changes in ownership of our common stock with the Securities and Exchange Commission and to furnish us with copies of all Section 16(a) forms they file. Based solely on our review of the copies of such forms received by us, or written representations from reporting persons, we believe that our insiders complied with all applicable Section 16(a) filing requirements during fiscal 2010.

Changes to Nominating Process

There have been no changes to the nominating process or adoption of procedures by which security holders may recommend nominees to our board of directors.

Audit Committee

Don Baker is our Audit Committee Chairman and Director. Mr. Baker is an "audit committee financial expert" in accordance with SEC rules. Because we are not a listed issuer, members of our Audit Committee are not subject to the independence requirements of any national securities exchange or association.

REPORT OF THE AUDIT COMMITTEE

The following Report of the Audit Committee does not constitute soliciting material and should not be deemed filed or incorporated by reference into any other Company filing under the Securities Act of 1933 or the Securities Exchange Act of 1934, except to the extent we specifically incorporate this Report by reference therein.

The Audit Committee of the Board of Directors operates pursuant to a written charter. The Committee met once and acted by unanimous written consent during fiscal 2010 to fulfill its responsibilities. To ensure independence, the Audit Committee also meets separately with the Company's independent registered public accounting firm and members of management. The sole member of the Audit Committee is a non-employee, non-board member and satisfies the SEC requirements with respect to independence, financial sophistication and experience.

The role of the Audit Committee is to oversee the Company's financial reporting process on behalf of the Board of Directors. Management of the Company has the primary responsibility for the Company's consolidated financial statements as well as the Company's financial reporting process, principles and internal controls. The independent registered public accounting firm is responsible for performing an audit of the Company's financial statements and expressing an opinion as to the conformity of such consolidated financial statements with generally accepted accounting principles.

In this context, the Audit Committee has reviewed and discussed the audited financial statements of the Company as of and for the year ended September 30, 2010, with management and the independent registered public accounting firm. These reviews included discussion with the outside independent registered public accountants of matters required to be discussed pursuant to Statement on Auditing Standards No. 61 (Communication with Audit Committees). In addition, the Audit Committee has received the written disclosures required by PCAOB Rule 3526, and it has discussed with the independent registered public accountants its independence with respect to the Company.

Based on the reports and discussions described above, the Audit Committee recommended to the Board of Directors that the audited financial statements be included in the Company's Annual Report on Form 10-K for the fiscal year ended September 30, 2010, for filing with the Securities and Exchange Commission.

/s/ Don Baker
January 18, 2011

Other Committees

The Board intends to appoint such persons and form such committees as are required to meet the corporate governance requirements imposed by the national securities exchanges. Therefore, we intend that a majority of our directors will eventually be independent directors and at least one director will continue to qualify as an "audit committee financial expert." Additionally, the Board is expected to appoint a nominating committee and compensation committee, and to adopt charters relative to each such committee. Until further determination by the Board, the full Board will undertake the duties of the compensation committee and nominating committee.

Code of Ethics

We have formally adopted a written code of ethics that applies to our board of directors, principal executive officer, principal financial officer and employees; it can be found on our website at www.trimedyne.com.

Compliance With Section 16(A) of the Exchange Act

Not applicable.

ITEM 11. EXECUTIVE COMPENSATION

Compensation Discussion and Analysis

All executives are employed as salaried employees on an "at-will" basis. The issuance of all bonuses, stock and option awards are discretionary and are approved by the Board of Directors. No bonuses, stock, or option awards were granted to executive officers during the fiscal year ended September 30, 2010.

Our company does not provide its executives with perquisites and does not have any deferred compensation programs or retirement programs other than our 401(k) plan, which is generally available to all employees. All of our full-time employees are eligible to enroll in our health, dental and life and disability insurance programs.

The following table sets forth the information required by Securities and Exchange Commission Regulation S-B Item 402 as to the compensation paid or accrued by us for the years ended September 30, 2010 and 2009 for services rendered in all capacities, by all persons who served as our executive officers who earned more than $100,000 in combined salary, stock option awards and other compensation in fiscal 2010 and 2009:

Name and Principal Position	Year	Salary ($)	Option Awards ($) (2)	All Other Compensation ($) (3)	Total ($)
Marvin P. Loeb	2010	$ 121,257	0	$ 9,320	$ 130,557
CEO and Chairman	2009	$ 121,257	0	$ 6,996	$ 128,253
Glenn D. Yeik	2010	$ 160,000	0	$ 17,991	$ 177,991
COO, President, and Director	2009	$ 159,135	0	$ 21,421	$ 180,556
Brian T. Kenney, V.P.	2010	$ 120,000	0	$ 82,923	$ 202,923
	2009	$ 120,000	0	$ 105,954	$ 225,954

(1) Amounts shown include cash and non-cash compensation earned and received by our executive officers.

(2) This column represents the dollar amount recognized for financial statement reporting purposes with respect to the 2010 and 2009 fiscal year for the fair value of stock options granted to the named executive officers in accordance with ASC 718. We did not grant awards to named executive officers in fiscal 2010 or 2009. For additional information on the valuation assumptions used by us in calculating these amounts refer to Note 2 to Consolidated Financial Statements incorporated by reference in this Form 10-K. The amounts reported in the Summary Compensation Table for these awards may not represent the amounts the named executive officers will actually realize from the awards. Whether and to what extent, a named executive officer realizes value will depend on stock price fluctuations and the named executive officer's continued employment. Additional information on all outstanding awards is reflected in the Outstanding Equity Awards at 2010 Fiscal Year-End table.

(3) Amounts of Other Compensation shown for the above listed officers include the cost of (i) car allowances and expenses and (ii) costs to us of 401(k)matching contributions (iii) accrued vacation and (iv)commissions and (v) company paid medical benefits.

OUTSTANDING EQUITY AWARDS AT FISCAL YEAR END

	Option Awards				
Name	Number of Securities Underlying Unexercised Options (#) Exercisable	Number of Securities Underlying Unexercised Options (#) Unexercisable	Equity Incentive Plan Awards: Number of Securities Unexercised Uneared Options (#)	Option Exercise Price ($)	Option Expiration Date
Marvin P. Loeb	30,000			1.25	4/04/2011
Glenn D. Yeik	50,000			0.14	1/14/2013
	22,000			0.50	8/13/2013
	30,000			0.50	4/15/2012
	75,000			0.60	4/15/2015
	100,000			0.92	3/31/2016
	25,000			1.25	4/04/2011
Brian T. Kenney	20,000			0.50	4/15/2012
	50,000			1.25	4/04/2011

None of Messrs. Loeb, Yeik, or Kenney exercised any options during fiscal year 2010.

DIRECTOR COMPENSATION IN FISCAL YEAR 2010 AND 2009

Each non-employee director who is appointed to the committee to administer our 2003 Non-Qualified Stock Option Plan (the "Committee") is entitled to a grant of 30,000 options to purchase shares every three years, beginning the day the director is so appointed, for so long as he or she serves on the Committee. The options vest in equal amounts over three years.

During the fiscal years ended September 30, 2010 and 2009, no such grants were given and no options were exercised.

Compensation Committee Interlocks and Insider Participation

During 2010, we did not have a compensation committee or another committee of the board of directors performing equivalent functions. Instead the entire board of directors performed the function of compensation committee. Our board of directors approved the executive compensation, however, there were no deliberations relating to executive officer compensation during 2010.

Compensation Committee Report

None.

ITEM 12. SECURITY OWNERSHIP OF CERTAIN BENEFICIAL OWNERS AND MANAGEMENT AND RELATED STOCKHOLDER MATTERS

The following table sets forth the name of and address of each beneficial owner of more than five percent of the Company's Common Stock known to the Company, each director of the Company, each named executive officer, and all directors and executive officers as a group, the number of shares beneficially owned by such persons as of September 30, 2010 and the percent of the class so owned. In computing the number of shares beneficially owned by a person and the percentage of ownership of that person, shares of common stock subject to options held by that person that are currently exercisable, as appropriate, or will become exercisable within 60 days of the reporting date are deemed outstanding, even if they have not actually been exercised. Those shares, however, are not deemed outstanding for the purpose of computing the percentage ownership of any other person.

Each person named in the table has sole investment and sole voting power with respect to the shares of Common Stock set forth opposite his name, except as otherwise indicated. All shares are directly owned or are held for the stockholder in street name, except as otherwise indicated.

Each person named in the table has sole investment and sole voting power with respect to the shares of Common Stock set forth opposite his name, except as otherwise indicated. All shares are directly owned or are held for the stockholder in street name, except as otherwise indicated.

TITLE OF CLASS	NAME AND ADDRESS OF BENEFICIAL OWNER	AMOUNT AND NATURE OF BENEFICIAL OWNERSHIP	PERCENT OF CLASS OUTSTANDING*
	MAJOR SHAREHOLDERS		
Common Stock	Marvin P. Loeb, Chairman & CEO (1)	4,935,980	26.9%
$.01 Par Value	25901 Commercentre Drive		
	Lake Forest, CA 92630		
	Corsair Capital, LLC. (6)	1,140,000	6.2%
	717 Fifth Avenue, 24 Floor		
	New York, NY 10022		
	Seth Hamot and his associates	1,013,536	5.5%
	c/o Costa Brava Partnership III L.P.		
	420 Boylston Street		
	Boston, MA 02116		
	Bruce J. Haber and his associates	931,653	5.1%
	145 Huguenot Street, Suite 405		
	New Rochelle, NY 10801		