TRIMEDYNE INC
Form 10-K
January 13, 2009

SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

FORM 10-K

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

FOR THE FISCAL YEAR ENDED SEPTEMBER 30, 2008
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 (ADDRESS OF PRINCIPAL EXECUTIVE OFFICES)	92630 (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 [_] 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 [_] 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 [_]

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. [_]

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	|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 [X] No [_]

Issuer's revenues for the most recent fiscal year were: $5,871,000.

The aggregate market value of voting stock held by non-affiliates of registrant on January 12, 2009 based upon the closing price of the common stock on such date was approximately $1,169,955

As of January 12, 2009, there were outstanding 18,365,960 shares of registrant's Common Stock.

TABLE OF CONTENTS

PART I

ITEM 1. DESCRIPTION OF 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 Plan of Operation". 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 Securities and Exchange Commission, including the Quarterly Reports on Form 10-QSB filed by the Company in fiscal year 2008.

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. Most 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. MST's revenues and those of our field service department represented about 35% of our revenues in the fiscal year ended September 30, 2008.

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. 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 UROLOGY MARKET

While our Lasers and Fibers are presently used in urology to fragment stones in the kidney, ureter and bladder, we have developed two, new, proprietary, Side Firing Laser Fibers for use with our Holmium Lasers and others to vaporize a portion of the prostate to treat benign prostatic hyperplasia or "BPH", commonly called an enlarged prostate.

One of these new Fibers is for use with our 80 watt Holmium Lasers and the other is designed for use with 80 and 100 watt Holmium Lasers manufactured by Lumenis, Ltd. of Yokneam, Isreal ("Lumenis"). Lumenis is one of the world's largest manufacturers of medical lasers, has revenues exceeding 250 million per year and has a large worldwide sales force.

The Side Firing Fibers we will be manufacturing for Lumenis will be marketed in the U.S. and Japan under Lumenis' DuraMAX trademark by Boston Scientific Corporation (NYSE:BSX) and by Lumenis' sales organization elsewhere throughout the world, when BSX has completed its quality review and testing of the new Fiber.

We will market the other Side Firing Fiber under our VaporMAX registered trademark through a limited number of commission sales representatives in the United States and by distributors in certain foreign countries.

Both of these Side Firing Fibers are designed to be used with our and Lumenis' Holmium Lasers to vaporize a portion of the prostate gland to treat BPH. This condition, in which excessive growth of the prostate causes difficulty in urination, affects about 50% of men over age 55, and a higher percentage of men at advanced ages. While drugs are used to treat BPH, when they are no longer able to adequately treat this condition, removal of a portion of the prostate is needed to open a channel to permit proper urine flow.

About 200,000 men in the United States and an estimated one million men in foreign countries are treated with a procedure each year to remove a portion of the prostate to open a channel for urine flow. While radio frequency ("RF")

energy is also used to do this, laser vaporization or resection of the prostate is becoming increasingly popular, as the laser procedure typically reduces procedural bleeding and can be performed on an outpatient basis, whereas the RF procedure usually entails a hospital stay, potentially significant bleeding, a variety of adverse effects and a recuperation period of days to weeks.

As a result, when Boston Scientific and Lumenis begin marketing the new Fiber for use with Lumenis' Holmium Lasers, we believe the treatment of BPH will become the largest segment of our business.

The development of our new Side Firing Fiber for use with our 80 watt Holmium Lasers and Lumenis' 80 and 100 watt Holmium Lasers has been delayed due to obstacles imposed by the high peak powers and other characteristics of Holmium Lasers, which make them excellent at vaporizing tissue, but also make them very hard on the glass components of the Fibers. The new Side Firing Fibers we are developing have been shown in our bench testing on animal tissue to vaporize tissue faster and to be significantly more durable than the side firing fibers presently being manufactured by Lumenis and marketed by Boston Scientific and Lumenis.

Our new Side Firing Fibers have been cleared for sale by the FDA.

In mid December 2008, we delivered a number of DuraMax Side Firing Fibers to Lumenis for bench testing on animal tissue, and we plan to deliver a number of these devices to an independent laboratory for bench testing on animal tissue in early 2009 and expect to receive the results of this testing in February 2009.

If the results of this testing confirms our results, we anticipate Boston Scientific may commence its quality audit of Trimedyne in the first calendar quarter of February or March of 2009, which could take four or more months to complete.

The problems we faced in developing our new Side Firing Fibers are detailed in the following description of the lasers and impact of their laser energy on the Fibers.

Holmium Lasers emit very short pulses of laser energy. At 80 watts, our Holmium Lasers emit pulses of energy with a duration or pulse width of about 700 microseconds, with a peak pulse power level of up to 9,000 watts. The laser energy is transmitted from the laser through optical fibers to a tip designed to emit the energy to the side at an angle of about 80 to 90 degrees.

Holmium Laser energy is highly absorbed by water. When tissue is struck by the laser beam, water in the cells is almost instantly turned to steam, vaporizing the tissue. As a result, Holmium Lasers vaporize tissue more efficiently than most other lasers whose energy can be transmitted through conventional optical fibers, such as KTP Lasers, whose energy is highly absorbed by hemoglobin in blood, and Diode lasers, whose energy is moderately absorbed in both hemoglobin and water.

KTP and Diode lasers, at very high power, can vaporize tissue, but can also cause significant charring and thermal damage to the remaining tissue. Charred tissue is removed from the body by macrophages and other mechanisms. Macrophages emit harsh chemicals to dissolve char and other foreign matter, which causes the patient to experience irritation at the vaporization site in the prostate for a week or two.

Holmium lasers are able to vaporize tissue better than the above mentioned lasers, with little or no charring or damage to the remaining tissue. However, the very high power energy pulses of Holmium Lasers cause a steam bubble to almost instantly be formed in a sort of explosion. These explosions of steam typically occur at a rate of about 25 times per second with our Holmium Lasers

and at a rate of about 50 times per second with Lumenis' Holmium Lasers.

Also, when the steam bubble collapses between pulses, it causes an acoustic shock, which can damage the glass components in the tip of the Fibers. And, the water and steam heated by the laser energy can act as a catalyst for erosion of the glass surface at the tip of the optical fiber, which can cause damage to the Fiber's tip. Further, when the laser energy strikes the tissue, some of the laser energy is reflected back into the tip of the optical fiber, which can cause thermal damage that can affect the integrity of the Fiber's tip.

The combination of the above described steam explosions and the shock waves from the collapse of the steam bubbles can fracture the glass enclosure of the Fiber's tip and, with the degradation of the fiber tip by laser energy reflected from the target tissue, reduce the Side Firing Fiber's useful lifetime.

As a result of the above described problems, it took us much longer than anticipated to develop a durable, fast vaporizing, Side Firing Fiber for use with our 80 watt Holmium Lasers. We expect, barring any unforeseen problems in manufacturing, to begin marketing our VaporMAX(R) Side Firing Fiber for use with our Holmium Lasers by late March 2009.

We encountered a more difficult problem in developing the Side Firing Fiber for use with Lumenis' 100 watt Holmium Lasers. At 100 watts of power, Lumenis' Holmium Laser produces 25% more laser energy than our 80 watt Holmium Laser, and its pulse width or duration is about 250 microseconds at this power level, with a peak pulse power of up to 11,000 watts.

In addition to the optical fiber's tip having to emit 25% more energy per pulse, since the pulse width is about one-half that of our 80 watt Holmium Laser, 25% more power must be transmitted through the tip of the optical fiber at about twice the number of pulses per second as with our 80 watt Holmium Laser. The steam explosions at the surface of the tip of the Fiber are more powerful, the acoustic shocks caused by the collapse of the steam bubble are more intense and the amount of laser energy reflected from the tissue, which can damage the tip of the Fiber, is more powerful.

As a result, developing a fast vaporizing, durable, Side Firing Fiber for use with Lumenis' Holmium Lasers proved to be a formidable challenge. A very significant portion of our management and R & D efforts over the past year were devoted to the development of the new Side Firing Laser Fiber for use with Lumenis' Holmium Lasers and our Holmium Lasers.

Before Boston Scientific and Lumenis will commence marketing our new Side Firing Fiber, Boston Scientific must conduct a quality review of the new Fiber and our manufacturing and quality systems, as well as conducting limited physician feedback testing in humans to assure that it functions within customer expectations. No clinical studies of the new Fiber are expected to be required, as we have already received FDA clearance to market the new Fiber.

While we plan to commence marketing our new VaporMAX(R) Side Firing Fiber to the owners of our Holmium Lasers by late March 2009, the quality review and testing of our DuraMax Side Firing Fiber for use with Lumenis' 80 and 100 watt Holmium Lasers by Boston Scientific and Lumenis is expected to take four months or longer from the time we provide supplies of the new fiber to Boston Scientific and Lumenis, which is presently anticipated to commence, barring unforeseen

delays, in late March 2009. As a result, we expect to commence shipments of the new Fibers to Boston Scientific and Lumenis early in the third calendar quarter of 2009, assuming Boston Scientific begins its quality audit in February or March of 2009 and physician feedback testing of the new fiber in April 2009.

We settled our patent litigation against Lumenis, Ltd., and in September 2005 entered into an OEM Agreement, under which Lumenis agreed to purchase 100% of its side firing (75 to 90 degree emitting) laser fibers and 75% of its angled firing (60 to 75 degree emitting) laser fibers from us. Lumenis presently markets its laser fibers through Boston Scientific in the U.S. and Japan and markets them elsewhere throughout the world through its own sales organization. Our Side Firing Laser Fiber will replace Lumenis' side firing laser fibers in these markets when Boston Scientific completes its quality audit and testing of the new Fiber and validates us as a supplier (vendor).

Side firing laser fibers to treat an enlarged prostate typically sell for about $750 or more and, due to their exposure to blood, are labeled "single use" and should be discarded after one use, although some illicit re-use of these fibers occurs in the United States and Europe and is common throughout the rest of the world, where government reimbursement, insurance plans and self-pay patients cannot afford such expensive devices.

Our Lasers and plain, straight-ahead firing Fibers are used in urology to fragment stones in the kidney, ureter or bladder in "lithotripsy" procedures. However, our plain, straight-ahead firing Fibers are reusable and are used an average of about 20-30 times. As a result, revenues from the sale of $500 plain Fibers to fragment stones do not result in as significant sales as those expected from single use, disposable Side Firing Fibers to treat enlarged prostates.

THE ORTHOPEDIC MARKET

Our Side Firing Laser Needles are used with our Lasers to treat herniated or ruptured lumbar, thoracic or cervical discs in the spine in minimally invasive procedures, most of which are performed on an outpatient basis in about 30-40 minute procedures, typically with only local anesthesia. The lower back, leg and neck pain usually disappears on the operating table, and the patient usually walks out with only 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 disc procedures, published in medical journals, show success rates (good or excellent results, based on pain scores) of 85% to 94%.

Approximately 400,000 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, some bleeding, post-operative pain and a recovery period of a month or longer. 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%.

While our laser procedures to treat herniated or ruptured spinal discs compare very favorably to the conventional surgical procedures to treat these conditions and are less costly to third party payors, before surgeons can perform our laser procedures, they must attend a one or more training courses in which they

practice the procedure on cadavers. 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 2-3 hour conventional disc surgery than for our 30-40 minute, outpatient laser procedures, reducing their desire to take time away from their practice to attend a training course.

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.

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.

In August 2008, we entered into a non-binding Letter of Interest with FemSuite LLC of San Francisco, California to explore the use in the field of gynecology of fiber-optic devices, including side firing laser fibers, covered by seven of our issued U.S. Patents and two pending U.S. Patent Applications. There is no assurance this arrangement will result in a License Agreement or an OEM Supply Agreement with FemSuite.

Developing new medical devices for untested applications entails considerable risk. While we have more than ten years of experience in designing, developing, manufacturing and marketing lasers, conventional optical fibers and side firing laser devices, we cannot assure that any new devices we attempt to develop for FemSuite or other new Side Firing Fibers for use with our Holmium lasers and Holmium lasers 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 $55,000 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 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.

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.

In November 2003, the Company settled its patent litigation against Lumenis, Inc. ("Lumenis"). Under the settlement agreement, Lumenis agreed to pay a 7.5% royalty to us on their sales of certain side-firing and angled-firing devices manufactured by Lumenis or purchased by Lumenis from third-party suppliers. In addition, Lumenis agreed to purchase 75% of its Angled-Firing (60 degree to 75 degree firing) and 100% of its Side-Firing (75 degree to 90 degree) Devices from the Company under an OEM Supply Agreement. The OEM Agreement was executed on September 8, 2005, and the Company is developing a special version of its VaporMAX(TM) Side-Firing Device exclusively for Lumenis, under Lumenis' DuraMAX trademark, for use with Lumenis' Holmium lasers for their cleared indications for use, which include the treatment of benign prostatic hyperplasia or "BPH", commonly referred to as an enlarged prostate.

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 new expired U.S. Patents, which limits their claim for royalties to six years from their date of expiration. We and two other laser companies joined in a petition to the U.S. Patent & Trademark Office ("USPTO") to re-examine these patents and declare them invalid. The other four defendants likewise individually requested a re-examination of these patents and a declaration of invalidity by the USPTO. The USPTO agreed to re-examine these patents and the lawsuit has been stayed by the court for one year and may be stayed for an additional year. We have not established a reserve for any damages under this lawsuit.

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, 2008, an aggregate of $51,811,000 has been

expended by the Company for research and development ("R&D"), including clinical and regulatory activities, of which $1,311,000 and $1,220,000 was expended during the fiscal years ended September 30, 2008 and 2007, respectively. As it has in the past, the Company expects to contract with unaffiliated hospitals and research institutions for the clinical testing of its developmental products.

MANUFACTURING AND SUPPLY AGREEMENTS

The Company believes that it has adequate engineering, design and manufacturing facilities (see "DESCRIPTION OF PROPERTIES" 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, 2008, the Company had marketing arrangements for the sale of its Lasers, Fibers, Needles and Tips with 4 salesmen on a straight commission basis, who devote only a part of their time to the Company's products, in the United States. Outside the United States, the Company sells its products through 23 independent distributors who sell various medical products in approximately 25 foreign countries. The Company presently employs a Vice President of Sales who directs the Company's sales activities in the United States and elsewhere.

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 Fiber, its Side Firing Needles for treating spinal discs 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 therefrom 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, 2008, the Company had 61 full-time employees, of whom 11 were employed by MST. Of the remainder, 39 were engaged in production and engineering, one in sales and marketing, and 10 in general and administrative functions. On September 30, 2008, the Company had five part-time employees of whom four were engaged in production and engineering, 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 AND PATENT APPLICATIONS

As of September 30, 2008, the Company owned or had licenses to 19 U.S. Patents 2 foreign and 4 U.S. patent applications. The validity of one of the U.S. Patents covering the Company's 80 watt Holmium Laser was challenged by a competitor in the U.S. in an action before the U.S. Patent and Trademark Office ("USPTO"). In December 1996, the USPTO upheld the validity of all of the claims of this Patent.

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, Inc., 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., PhotoMedex, 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 2008 and 2007, sales of products in foreign countries accounted for approximately 24.6% and 22.9%, 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. DESCRIPTION OF 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. The lease became effective April 1, 2006, and has a five-year term with two five-year renewal options. The lease agreement provides for rent of $29,251 per month through July 2009, and then for a 4% rental increase effective on August 2009.

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 2010.

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

ITEM 3. LEGAL PROCEEDINGS

The Company no liability lawsuits during the prior or current year. 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.

The Company is 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 of the Company's existing and future litigation may adversely affect the Company.

In February 2008, the Company and other manufacturers of lasers were named as defendants in a lawsuit in the State Court of Massachusetts by CardioFocus, Inc. as allegedly infringing three of their now expired patents in 2002 -2006. The Company and two of the other defendants submitted a petition to the U.S. Patent and Trademark Office ("USPTO") to re-examine the patents to determine if they are valid, as did several of the other defendants. The Company and the other defendants were successful in petitioning the Court to stay the action, which is commonly done in patent cases, to save the court time in conducting a case on patents which may be later invalidated by the USPTO. The USPTO usually takes two to three years to reach a decision on the validity of patents. If the USPTO should find any of the patents to be valid, the Company has other defenses that we believe will enable it to successfully defend against any claims by CardioFocus, Inc.

ITEM 4. SUBMISSION OF MATTERS TO A VOTE OF SECURITY HOLDERS

During the Company's fiscal year ended September 30, 2008, no matters were submitted to a vote of securities holders.

PART II

ITEM 5. MARKET FOR COMMON EQUITY AND RELATED STOCKHOLDER MATTERS

A. MARKET INFORMATION

Since November 18, 2003, the Company's Common Stock has been quoted on the NASDAQ 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:

2007	High	Low
Quarter ended:		
December 31, 2006	$ 1.69	$ 1.31
March 31, 2007	1.65	1.35
June 30, 2007	1.47	0.93
September 30, 2007	1.04	0.64

2008	High	Low
Quarter ended:		
December 31, 2007	$ 0.89	$ 0.60
March 31, 2008	0.62	0.33
June 30, 2008	0.48	0.33
September 30, 2008	0.33	0.21

B. HOLDERS OF COMMON STOCK

As of September 30, 2008, 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, 2008 with respect to shares of the Company's common stock that may be issued through its employee compensation plans:

	NUMBER OF SECURITIES TO BE ISSUED UPON EXERCISE OF	WEIGHTED-AVERAGE EXERCISE PRICE OF	NUMBER OF SECURITIES REMAINING AVAILABLE FOR FUTURE ISSUANCE UNDER EQUITY COMPENSATION PLANS

PLAN CATEGORY	OUTSTANDING OPTIONS, WARRANTS AND RIGHTS (a)	OUTSTANDING OPTIONS, WARRANTS AND RIGHTS (b)	(EXCLUDING SECURITIES REFLECTED IN COLUMN (a)) (c)
Equity compensation plans approved by security holders	199,029	$ 1.37	--
Equity compensation plans not approved by security holders	1,439,450	$ 1.08	772,550
Total	1,638,479	$ 1.12	772,550

ITEM 6. MANAGEMENT'S DISCUSSION AND ANALYSIS OR PLAN OF OPERATION

OFF-BALANCE SHEET ARRANGEMENTS

We have no off-balance sheet arrangements, as defined by Regulation S-B Section 303.

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.

In accordance with Staff Accounting Bulletin 104, "Revenue Recognition," 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, 2008 and 2007, 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 2008 and 2007, 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

Goodwill represents the excess of the cost over the acquired assets of MST. On

October 1, 2002, the Company adopted the provisions of Statement of Financial Accounting Standards ("SFAS") No. 142, "Goodwill and Other Intangible Assets." As a result of adoption SFAS No. 142, the Company's goodwill is no longer amortized, but is subject to an annual impairment test, or whenever events or changes in circumstances indicate that the carrying value may not be recoverable. There was no impairment loss recognized on goodwill during the fiscal years ended September 30, 2008 and 2007.

IMPAIRMENT OF LONG-LIVED ASSETS

SFAS No. 144, "Accounting for Impairment or Disposal of Long-Lived Assets", requires that long-lived assets, such as property and equipment and purchased intangibles subject to amortization, be 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 management's best estimate based on currently available information and reasonable and supportable assumptions. Any impairment recognized in accordance with SFAS No. 144 is permanent and may not be restored. To date, the Company has not recognized any impairment of long-lived assets in connection with SFAS No. 144.

DEFERRED TAXES

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

STOCK-BASED COMPENSATION

Effective October 1, 2006, the Company adopted SFAS No. 123(R), "Share Based Payment," which establishes standards for the accounting of all transactions in which an entity exchanges its equity instruments for goods or services, including transactions with non-employees and employees. SFAS No. 123(R) requires a public entity to measure the cost of non-employee and employee services received in exchange for an award of equity instruments, including

stock options, based on the grant date fair value of the award, and to recognize it as compensation expense over the period service is provided in exchange for the award, usually the vesting period. The value of the portion of the award that is ultimately expected to vest is recognized as expense over the requisite service periods in the Company's consolidated statement of income. SFAS No. 123(R) supersedes the Company's previous accounting under APB No. 25. In March 2005, the SEC issued SAB No. 107, "Share-Based Payment," relating to SFAS No. 123(R). The Company has applied the provisions of SAB No. 107 in its adoption of SFAS No. 123(R).

The Company adopted SFAS No. 123(R) using the modified prospective transition method. Accordingly, the Company's consolidated financial statements as of and for the fiscal year ended September 30, 2007 reflect the impact of adopting SFAS No. 123(R). The Company's consolidated financial statements for the fiscal year prior to the adoption of SFAS No. 123(R) have not been restated to reflect, and do not include, the impact of SFAS No. 123(R).

RESULTS OF OPERATIONS

The statements contained in this Annual Report on Form 10-K 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.

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 2008 AND 2007

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, 2008 and 2007:

	Year Ended September 30,	
	2008	2007
Net revenues	100.0%	100.0%
Cost of sales	70.9	57.8
Selling, general and administrative expenses	40.4	37.4
Research and development expenses	22.3	22.3
Interest expense	0.6	0.2
Other income, net	7.4	11.9
Income taxes	0.2	0.1
Net income	(27.0)	(5.9)

NET REVENUES

Net revenues increased $401,000 or 7.3% in fiscal 2008 to $5,871,000 from $5,470,000 in fiscal 2007. Net sales from Lasers and accessories increased by $438,000 or 65.1% to $1,111,000 during the fiscal year ended September 30, 2008 from $673,000 during the prior fiscal year, primarily due to international customers taking advantage of existing lower pricing for lasers before a scheduled price increase. Net sales from Fibers, Needles and Tips decreased by $383,000 or 12.3% to $2,721,000 during the current fiscal year ended September 30, 2008 from $3,104,000 during the prior fiscal year. The decreases in sales was primarily due to domestic customers and international distributors awaiting the introduction of the Company's new VaporMax(R) Fiber, which will be used with the Company's Holmium Laser for the treatment of benign prostatic hyperplasia ("BPH"). International export revenues increased $191,000 or 15.2% to $1,444,000 for fiscal 2008 from $1,253,000 for fiscal 2007 primarily due to international customers taking advantage of existing lower pricing for lasers before a scheduled price increase. Net revenues from service and rental increased by $346,000 or 20.4% in fiscal 2008 to $2,039,000 from $1,693,000 in fiscal 2007, primarily due to an increase in revenue from MST as a result of its expansion of services.

COST OF GOODS SOLD

Cost of sales in fiscal 2008 was approximately 71% of net revenues, compared to 58% in fiscal 2007. Gross profit from the sale of lasers and accessories was 6% in the fiscal year ended September 30, 2008 as compared to 20% for the prior year fiscal period. Gross profit from the sale of Fibers, Needles and Tips during the fiscal year ended September 30, 2008 was 41% as compared to 52% for the prior fiscal year period. The lower gross profit during the current fiscal year as compared to the previous fiscal year was due to increases in cost of raw materials for Fibers, Needles and Tips, increases in expense incurred for quality control, and a non-recurring year end adjustment of $127,000 to reserve obsolete and slow moving inventory. Gross profit from revenue received from service and rentals was 26% in the current fiscal year ended September 30, 2008 as compared to 34% for the prior fiscal year period. The decrease in gross profit was due to a decrease in billable services for the service department while maintaining necessary overhead and staff and higher costs of maintaining new equipment purchased for the expansion of services by MST.

SELLING, GENERAL AND ADMINISTRATIVE EXPENSES

Selling, general and administrative ("SG&A") expenses increased 16% to $2,373,000 in fiscal 2008, compared to $2,046,000 in fiscal 2007. The $327,000 increase in fiscal 2008 was primarily the result of $72,000 in commission expense, $105,000 in administrative payroll expense, $55,000 in legal expense, which was primarily related to an accused patent infringement, $43,000 in insurance expense, $33,000 in temporary administrative staff, $26,000 in audit related expense, $17,000 in travel expense, and $12,000 in repairs and maintenance expense. The above expenses were offset by decreases in marketing and recruiting expense of $24,000 and $12,000, respectively.

RESEARCH AND DEVELOPMENT (R&D) EXPENSES

R&D expenses increased $91,000 or 7.5% to $1,311,000 in fiscal 2008, compared to $1,220,000 in fiscal 2007. R&D as a percentage of net revenues decreased to

21.8% of net revenues in fiscal 2008 as compared to 22.3% in fiscal year 2007. R&D spending in fiscal 2008 was higher as the Company is nearing the completion of its product development efforts and staff in readying its new Side-Firing Fibers for use with its Lasers and Lumenis' Holmium Lasers.

OTHER INCOME AND EXPENSE

Total other income, net decreased $242,000 or 38% to $399,000 in fiscal 2008 from $641,000 in fiscal 2007. Interest income decreased by $81,000 or 60% to $53,000 in fiscal 2008 compared to $134,000 in fiscal 2007. The levels of cash available for investment in interest bearing securities were $2,007,000 and $3,179,000 as of September 30,2008 and 2007, respectively. The decrease in interest income was due to the Company's decrease in the levels of cash available for investment in interest bearing securities due to negative cash flows along with lower interest rates paid by institutions during fiscal 2008. Income from royalties decreased $113,000 or 23% to $374,000 in fiscal 2008 from $487,000 in fiscal 2007. This decrease was due to royalties received from Lumenis based on a percentage of Lumenis' sales of side-firing and angled-firing devices manufactured by Lumenis, as stipulated in the settlement agreement entered into on November 17, 2003 between the Company and Lumenis, Inc. During the year ended September 30, 2008, the Company incurred a loss form the sales of assets of $17,000. During the fiscal year ended September 30, 2007, the Company received refunds from the state of California and the state of Texas for and $21,000, respectively, for the overpayment of use tax, and $2,000 in insurance settlements, offset by interest expense due on Senior Secured Notes due to an officer.

NET LOSS

As a result of the above, the net loss in fiscal 2008 was $1,590,000, compared to a net loss of $324,000 in fiscal 2007.

LIQUIDITY AND CAPITAL RESOURCES

Cash flows

In fiscal 2008, net cash used in operating activities was $895,000, as compared to net cash used of $368,000 in fiscal 2007. Net cash used in investing activities was $126,000 in fiscal 2008, compared to net cash used of $229,000 in fiscal 2007. The decrease in cash used in investing activities in fiscal 2008 as compared to fiscal 2007 was primarily due to the prior fiscal year's purchasing of upgraded equipment. The net cash used in financing activities during fiscal 2008 of $151,000 for payments on debt as compared to net cash provided of $2,974,000 during the prior fiscal year, which was the result of proceeds from the Company's sale of 2,915,000 shares of common stock along with the exercise of stock options, net of payments on debt.

Liquidity

At September 30, 2008, the Company had working capital of $4,625,000 compared to $6,285,000 at the end of the previous fiscal year ended September 30, 2007. Cash decreased by $1,172,000 to $2,007,000 at September 30, 2008 from $3,179,000 at the fiscal year ended September 30, 2007.

Managements' Plans

The Company has incurred losses from operations for the past two years. However, the Company believes that existing cash flows are sufficient enough to fund operations through September 30, 2009. 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 months may be required. If necessary, the Company will raise

additional debt and/or equity capital, reduce its costs by eliminating certain personnel positions and reducing certain overhead costs in order to fund operations. There is no assurance that management's plans will be successful.

ITEM 7. FINANCIAL STATEMENTS

The financial statements required by Item 7 of this Annual Report are set forth in the index on page F-1.

ITEM 8. CHANGES IN AND DISAGREEMENTS WITH ACCOUNTANTS ON ACCOUNTING AND FINANCIAL DISCLOSURE

Not applicable.

ITEM 8A. CONTROLS AND PROCEDURES

a) Evaluation of Disclosure Controls and Procedures. Regulations under the Securities Exchange Act of 1934 require public companies to maintain "disclosure controls and procedures," which are defined to mean a company's controls and other procedures that are designed to ensure that information required to be disclosed in the reports that it files or submits under the Securities Exchange Act of 1934 is recorded, processed, summarized and reported, within the time periods specified in the Commission's rules and forms. Our Chief Executive Officer ("CEO"), President and our Chief Accounting Officer ("CAO") carried out an evaluation of the effectiveness of our disclosure controls and procedures as of September 30, 2008. Based on those evaluations, as of the evaluation date, our CEO, President and CAO believe:

   i) That our controls and procedures are designed to ensure that information required to be disclosed by us in the reports we file under the Securities Exchange Act of 1934 is recorded, processed, summarized and reported in the time periods specified in the SEC's rules and forms and that such information is accumulated and communicated to our management, including the CEO, President and CAO, as appropriate to allow timely decisions regarding required disclosures; and

   ii) That our disclosure controls and procedures are effective.

b) Changes in Internal Controls. There were no significant changes in our internal controls or, to our knowledge, in other factors that could significantly affect our internal controls subsequent to the evaluation date.

LIMITATIONS ON THE EFFECTIVENESS OF INTERNAL CONTROL

Our management, including the CEO, does not expect that our disclosure controls and procedures or our internal control over financial reporting will necessarily prevent all fraud and material errors. An internal control system, no matter how well conceived and operated, can provide only reasonable, not absolute, assurance that the objectives of the control system are met. Further, the design of a control system must reflect the fact that there are resource constraints, and the benefits of the controls must be considered relative to their costs.

Because of the inherent limitations on all internal control systems, no evaluation of controls can provide absolute assurance that all control issues and instances of fraud, if any, within the Company have been detected. These inherent limitations include the realities that judgments in decision-making can be faulty, and that breakdowns can occur because of simple errors or mistakes. Additionally, controls can be circumvented by the individual acts of some persons, by collusion of two or more people, and/or by management override of control. The design of any system of internal control is also based in part upon certain assumptions about the likelihood of future events, and there can be no assurance that any design will succeed in achieving its stated goals under all potential future conditions. Over time, controls may become inadequate because of changes in circumstances, and/or the degree of compliance with the policies and procedures may deteriorate. Because of the inherent limitations in a cost-effective internal control system, financial reporting misstatements due to error or fraud may occur and not be detected on a timely basis.

ITEM 8B. OTHER INFORMATION

Not applicable.

PART III

ITEM 9. DIRECTORS, EXECUTIVE OFFICERS, PROMOTERS AND CONTROL PERSONS

MANAGEMENT

The following persons served as our officers and directors in fiscal 2008.

Name	Age	Position
Marvin P. Loeb	82	Chairman and CEO
Glenn D. Yeik	41	President, COO, and Director
Brian T. Kenney	52	V.P. - Global Sales and Marketing
Donald Baker	79	Director

Richard Horowitz, Secretary and Director of the Company, died in September, 2008, and has not been replaced as a Director. Don Baker now serves as Secretary of the Company.

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 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 Cadiomedics, 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.

RICHARD F. HOROWITZ was a director of our Company from April 1983 to his death in September, 2008, and Secretary from July 2001 to his death. He was also a director of Cardiodyne, Inc. (formerly Trioptic Laser, Inc.) since May 1992. He was a director of Automedix Sciences, Inc. (now COMC, Inc.) from November 1988 until 1999 and was a director of Cardiomedics, Inc. since 1992. Mr. Horowitz was a practicing attorney in New York City for the past 41 years. He was a member of the firm of Heller, Horowitz & Feit, P.C. (formerly Heller, Horowitz & Feit) since January 1979. Mr. Horowitz was a graduate of Columbia College and held a J.D. degree from Columbia Law School. He was a member of the Association of the Bar of the City of New York and the New York State Bar Association.

DONALD BAKER has been a director of our Company since May 1983. He also has been a director of Cardiodyne, Inc. since August 1996. Mr. Baker retired after 39 years as a 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.

Compliance With Section 16(A) of the Exchange Act

Not applicable.

ITEM 10. EXECUTIVE COMPENSATION

All executives enter into employment 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, 2008.

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, 2008 and September 30, 2007 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 2008:

Name and Principal Position	Year	Salary ($)	Option Awards ($)(2)	All Other Compensation ($)(3)	Total ($)
Marvin P. Loeb.....	2008	$ 121,257	0	$ 6,996	$ 128,253
CEO and Chairman	2007	$ 120,373	0	$ 17,344	$ 137,717
Glenn D. Yeik.....	2008	$ 159,135	14,110	$ 18,240	$ 195,035
COO, President, and Director	2007	$ 157,976	16,579	$ 21,334	$ 195,889
Brian T. Kenney, V.P.....	2008	$ 120,000	0	$ 86,234	$ 206,234
	2007	$ 99,696	1,256	$ 55,516	$ 156,468

(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 2008 and 2007 fiscal year for the fair value of stock options granted to the named executive officers in accordance with SFAS 123R. We did not grant awards to named executive officers in fiscal 2008 or 2007. For additional information on the valuation assumptions used by the Company 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 2008 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.

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 Underlying Unexercised Unearned Options (#)	Option Exercise Price ($)	Option Expiration Date
Marvin P. Loeb	72,000			0.50	8/13/2009
	30,000			1.25	4/04/2011
	48,000			2.75	4/18/2010
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
	80,000			0.92	3/31/2016
	25,000			1.25	4/04/2011
	48,000			3.84	3/20/2010
Brian T. Kenney	20,000			0.50	4/15/2012
	15,000			1.06	3/08/2009
	50,000			1.25	4/04/2011
	15,000			2.75	4/18/2010

None of Messrs. Loeb, Yeik, or Kenney exercised any options during fiscal year 2008.

DIRECTOR COMPENSATION IN FISCAL YEAR 2008

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. No such grants were given during the fiscal year ended September 30, 2008.

DIRECTOR COMPENSATION

Name	Fees Earned or Paid in Cash ($)	Stock Awards ($)	Option Awards ($) (1)	Non-Equity Incentive Plan Compensation ($)	Change in Pension Value and Nonqualified Deferred Compensation Earnings ($)	All Other Compensatio ($)
Donald Baker			10,172			

Richard F. Horowitz (2)	--

None of Messrs. Baker or Horowitz exercised any options during fiscal year 2007

1) This column represents the dollar amount recognized for financial statement reporting purposes with respect to the 2008 fiscal year for the fair value of stock options granted to directors, in 2008 as well as prior years, in accordance with SFAS 123R. Portions of awards granted over several years are included. For additional information on the valuation assumptions used by the Company in calculating these amounts refer to Note 2 to Consolidated Financial Statements incorporated by reference in this Form 10-KSB. The amounts reported in the Summary Compensation Table for these awards may not represent the amounts the directors will actually realize from the awards. Whether and to what extent, a director realizes value will depend on stock price fluctuations and the director's continued service on the Board.

2) Deceased September 2008; all unvested options cancelled.

ITEM 11. 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, 2008 and the percent of the class so owned. 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
	MAJOR SHAREHOLDERS	
Common Stock $.01 Par Value	Marvin P. Loeb, Chairman & CEO (1) 25901 Commercentre Drive Lake Forest, CA 92630	2,486,028
	Corsair Capital, LLC. (6) 717 Fifth Avenue, 24 Floor New York, NY 10022	1,140,000
	Seth Hamot and his associates c/o Costa Brava Partnership III L.P. 420 Boylston Street Boston, MA 02116	1,013,536
	Bruce J. Haber and his associates 145 Huguenot Street, Suite 405	931,653

New Rochelle, NY 10801	
OTHER DIRECTORS AND EXECUTIVE OFFICERS	
Donald Baker, Director (2) 544 Earlston Road Kenilworth, IL 60043	110,000
Richard F. Horowitz, Secy. & Dir. (2)(7) Heller, Horowitz & Feit, P.C. 292 Madison Avenue New York, New York 10017	90,000
Glenn D. Yeik, Pres. COO (3)(5)	580,351
Brian T. Kenney, V.P. (4)(5)	135,000
All Directors and Executive Officers as a Group (5 persons)	3,421,375

---

* Indicates less than 1%

(1) Consists of 2,486,028 Shares owned by Mr. Loeb and his wife, adult children, grandchildren and trusts for their benefit, of which Mr. Loeb is not a beneficiary, and Options to purchase 150,000 Shares.
(2) Consists of 50,000 Shares and Options to purchase 40,000 Shares.
(3) Consists of 230,351 Shares, and Options to purchase 350,000 Shares.
(4) Consists of 35,000 Shares and Options to purchase 100,000 Shares.
(5) Address is 25901 Commercentre Drive Lake Forest, CA 92630
(6) Consists of Shares owned by funds managed by Corsair Capital, LLC.
(7) Deceased September 2008

ITEM 12. CERTAIN RELATIONSHIPS AND RELATED TRANSACTIONS

During the year ended September 30, 2008, the Company incurred $7,600 of legal services with a Director, of which $3,800 was paid during the fiscal year. During the prior fiscal year ended September 30, 2007, the Company incurred $14,800 of legal services with a Director, of which $12,600 was paid during the prior fiscal year.

ITEM 13. EXHIBITS

(a) Financial Statements.

See "Index to Consolidated Financial Statements" included in this report at Page F-1.

(b) Exhibits

Filed Previously:

10(b) Development, Supply and License Agreement with C.R. Bard,

Inc., dated June 28, 1991.

10(c) Industrial Lease (for Barranca Parkway headquarters) with Griswold Controls dated June 19, 1991, and Addendum thereto dated July 1, 1991.

10(d) Patent Licensing Agreement with Royice B. Everett, M.D. (covering the Lateralase Catheter) dated April 1, 1988 as amended.

10(f) Addendum to Industrial Lease with Griswold Controls dated September 14, 1993

10(i)* Amendment to Development Supply and License Agreement with C.R. Bard dated June 14, 1994.

10(j) Industrial Lease (for Bake Parkway headquarters) with Buckhead Industrial Properties, Inc, dated October 25, 2000.

10(k) Industrial Lease effective July 26, 2005

* The Company requested and received confidential treatment for portions of those exhibits marked with an asterisk (*).

ITEM 14. PRINCIPAL ACCOUNTANT FEES AND SERVICES

Principal Accountant Fees And Services

The following table sets forth fees billed to us by our Independent Registered Public Accounting Firm during the fiscal years ended September 30, 2008 and September 30, 2007 for: (i) services rendered for the audit of our annual financial statements and the review of our quarterly financial statements, (ii) services by our auditors that are reasonably related to the performance of the audit or review of our financial statements and that are not reported as Audit Fees, (iii) services rendered in connection with tax compliance, tax advice and tax planning, and (iv) all other fees for services rendered. "Audit Related Fees" consisted of consulting regarding accounting issues. "All Other Fees" consisted of fees related to the issuance of consents for our Registration Statements and this Annual Report.

		September 30, 2008	2007
(i)	Audit Fees	42,900	60,500
(ii)	Audit Related Fees	30,750	8,650
(iii)	Tax Fees	7,250	8,665
(iv)	All Other Fees	37,622	3,460

POLICY ON AUDIT COMMITTEE PRE-APPROVAL OF AUDIT AND PERMISSIBLE NON-AUDIT SERVICES OF INDEPENDENT AUDITOR

The audit committee is responsible for pre-approving all audit and permitted non-audit services to be performed for us by our independent registered public accounting firm.

SIGNATURES

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

Trimedyne, Inc.

Date: January 12, 2009

/s/ Marvin P. Loeb

Marvin P. Loeb,
Chairman, and
Chief Executive Officer

Pursuant to the requirements of the Securities Exchange Act of 1934, this report has been signed below by the following persons on behalf of the registrant and in the capacities and on the dates indicated.

Signature	Title	Date
/s/ Marvin P. Loeb Marvin P. Loeb	Chairman of the Board of Directors & CEO	January 12, 2009
/s/ Glenn D. Yeik Glenn D. Yeik	President, COO Director	January 12, 2009
/s/ Donald Baker Donald Baker	Director	January 12, 2009
/s/ Richard F. Horowitz Richard F. Horowitz	Secretary & Director	January 12, 2009
/s/ Jeffrey S. Rudner Jeffrey S. Rudner	Treasurer & Chief Accounting Officer	January 12, 2009

TRIMEDYNE, INC.

INDEX TO CONSOLIDATED FINANCIAL STATEMENTS

Consolidated Financial Statements:

REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

To the Board of Directors and Stockholders
Trimedyne, Inc.

We have audited the accompanying consolidated balance sheet of Trimedyne, Inc. and its subsidiaries (the "Company") as of September 30, 2008, and the related consolidated statements of operations, stockholders' equity and cash flows for the year then ended. These consolidated financial statements are the responsibility of the Company's management. Our responsibility is to express an opinion on these consolidated financial statements based on our audit.

We conducted our audit in accordance with standards of the Public Company Accounting Oversight Board (United States). Those standards require that we plan and perform the audit to obtain reasonable assurance about whether the consolidated financial statements are free of material misstatement. The Company is not required to have, nor were we engaged to perform, an audit on its internal control over financial reporting. Our audit included consideration of internal control over financial reporting as a basis for designing audit procedures that are appropriate in the circumstances, but not for the purpose of expressing an opinion on the effectiveness of the Company's internal control over financial reporting. Accordingly, we express no such opinion. An audit includes examining, on a test basis, evidence supporting the amounts and disclosures in the consolidated financial statements. An audit also includes assessing the accounting principles used and significant estimates made by management, as well as evaluating the overall consolidated financial statement presentation. We believe that our audit provide a reasonable basis for our opinion.

In our opinion, the consolidated financial statements referred to above present fairly, in all material respects, the consolidated financial position of Trimedyne, Inc. and its subsidiaries as of September 30, 2008, and the consolidated results of its operations and its cash flow the year then ended, in conformity with accounting principles generally accepted in the United States of America.

/s/ McKennon Wilson & Morgan LLP
Irvine, California

January 13,2009

REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

To the Board of Directors and Stockholders Trimedyne, Inc.

We have audited the accompanying consolidated balance sheet of Trimedyne, Inc. and its subsidiaries (the "Company") as of September 30, 2007, and the related consolidated statements of operations, stockholders' equity and cash flows for the year then ended. These consolidated financial statements are the responsibility of the Company's management. Our responsibility is to express an opinion on these consolidated financial statements based on our audit.

We conducted our audit in accordance with the standards of the Public Company Accounting Oversight Board (United States). Those standards require that we plan and perform the audit to obtain reasonable assurance about whether the consolidated financial statements are free of material misstatement. The Company is not required to have, nor were we engaged to perform, an audit on its internal control over financial reporting. Our audit included consideration of internal control over financial reporting as a basis for designing audit procedures that are appropriate in the circumstances, but not for the purpose of expressing an opinion on the effectiveness of the Company's internal control over financial reporting. Accordingly, we express no such opinion. An audit includes examining, on a test basis, evidence supporting the amounts and disclosures in the consolidated financial statements. An audit also includes assessing the accounting principles used and significant estimates made by management, as well as e valuating the overall consolidated financial statement presentation. We believe that our audit provides a reasonable basis for our opinion.

In our opinion, the consolidated financial statements referred to above present fairly, in all material respects, the consolidated financial position of Trimedyne, Inc. and its subsidiaries as of September 30, 2007, and the consolidated results of its operations and its cash flows for the year then ended, in conformity with accounting principles generally accepted in the United States of America.

/s/ KMJ Corbin & Company LLP
Irvine, California
January 15, 2008

TRIMEDYNE, INC. AND SUBSIDIARIES
CONSOLIDATED BALANCE SHEET

ASSETS

	For The Years Ended September 30	
	2008	2007
Current assets:		
Cash and cash equivalents	$ 2,007,000	$ 3,179,000
Trade accounts receivable, net of allowance for doubtful accounts of $12,000 and $12,000, respectively	954,000	574,000
Inventories	2,584,000	2,991,000
Note due from related party	--	9,000
Other current assets	171,000	245,000
Total current assets	5,716,000	6,998,000
Property and equipment, net	1,382,000	920,000
Other	83,000	41,000
Goodwill	544,000	544,000
	7,725,000	$ 8,503,000

LIABILITIES AND STOCKHOLDERS' EQUITY

Current liabilities:		
Accounts payable	$ 256,000	$ 212,000
Accrued expenses	469,000	427,000
Deferred revenue	75,000	45,000
Accrued warranty	54,000	27,000
Current portion of note payable and capital leases	237,000	2,000
Total current liabilities	1,091,000	713,000
Note payable and capital leases, net of current portion	400,000	--
Deferred rent	73,000	91,000
Total liabilities	1,564,000	804,000
Commitments and contingencies		
Stockholders' equity:		
Preferred stock - $0.01 par value, 1,000,000 shares authorized, none issued and outstanding		--
Common stock - $0.01 par value; 30,000,000 shares authorized, 18,467,569 shares issued, 18,365,960 shares outstanding at September 30, 2008 and 2007	186,000	186,000
Additional paid-in capital	51,425,000	51,373,000
Accumulated deficit	(44,737,000)	(43,147,000)
	6,874,000	8,412,000
Treasury stock, at cost (101,609 shares)	(713,000)	(713,000)
Total stockholders' equity	6,161,000	7,699,000
	$ 7,725,000	$ 8,503,000

See accompanying notes to consolidated financial statements

TRIMEDYNE, INC. AND SUBSIDIARIES
CONSOLIDATED STATEMENTS OF OPERATIONS

	For The Years Ended September 30,	
	2008	2007
Net revenues:		
Products	$ 3,832,000	$ 3,777,000
Service and rental	2,039,000	1,693,000
	5,871,000	5,470,000
Cost of sales:		
Products	2,657,000	2,039,000
Service and rental	1,506,000	1,122,000
	4,163,000	3,161,000
Gross profit	1,708,000	2,309,000
Selling, general and administrative expenses	2,373,000	2,046,000
Research and development expenses	1,311,000	1,220,000
Loss from operations	(1,976,000)	(957,000)
Other income (expense):		
Interest income	53,000	134,000
Royalty income	374,000	487,000
Interest expense	(38,000)	(10,000)
Creditor settlements and recoveries	27,000	30,000
Loss on disposal of equipment	(17,000)	--
Total other income, net	399,000	641,000
(Loss) before provision for income taxes	(1,577,000)	(316,000)
Provision for income taxes	13,000	8,000
Net (loss)	$ (1,590,000)	$ (324,000)
Basic net (loss) per share	$ (0.09)	$ (0.02)

Basic weighted average common shares outstanding:	18,365,960	17,594,668
Diluted net (loss) per share	$ (0.08)	$ (0.02)
Diluted weighted average common shares outstanding:	18,365,960	17,594,668

See accompanying notes to consolidated financial statements

TRIMEDYNE, INC. AND SUBSIDIARIES
CONSOLIDATED STATEMENTS OF STOCKHOLDERS' EQUITY

	Common Stock		Additional Paid-In	Accumulated	Treasur
	Shares	Amount	Capital	Deficit	Stock
Balances at October 1, 2006	14,770,511	149,000	47,979,000	(42,823,000)	(713,
Issuance of common stock	2,915,000	29,000	3,005,000	--	
Conversion of convertible related-party notes and accrued interest into common stock	763,958	8,000	314,000	--	
Exercise of stock options	18,100	--	11,000	--	
Share-based compensation expense	--	--	64,000	--	
Net loss	--	--	--	(324,000)	
Balances at September 30, 2007	18,467,569	$ 186,000	$ 51,373,000	$(43,147,000)	$ (713,
Share-based compensation expense	--	--	52,000	--	
Net loss	--	--	--	(1,590,000)	
Balances at September 30, 2008	18,467,569	$ 186,000	$ 51,425,000	$(44,737,000)	$ (713,

See accompanying notes to consolidated financial statements

TRIMEDYNE, INC. AND SUBSIDIARIES
CONSOLIDATED STATEMENTS OF CASH FLOWS

	For The Years Ended September 30,	
	2008	2007
Cash flows from operating activities:		
Net (loss)	$(1,590,000)	$ (324,000)
Adjustments to reconcile net (loss) to net cash (used in) provided by operating activities:		
Stock-based compensation	52,000	64,000
Accrued interest on senior secured notes	--	11,000
Depreciation and amortization	315,000	234,000
Loss on disposal of equipment	--	--
Changes in operating assets and liabilities:		
Trade accounts receivable	(380,000)	168,000
Inventories	407,000	(395,000)
Other assets	167,000	(63,000)
Accounts payable	44,000	(111,000)
Note from related party	9,000	29,000
Accrued expenses	42,000	28,000
Deferred revenue	30,000	(3,000)
Accrued warranty	27,000	4,000
Income tax payable	--	(4,000)
Deferred rent	(18,000)	(6,000)
Net cash (used in)operating activities	(895,000)	(368,000)
Cash flows from investing activities:		
Purchase of property and equipment	(143,000)	(229,000)
Loss on disposal of fixed assets	17,000	--
Net cash used in investing activities	(126,000)	(229,000)
Cash flows from financing activities:		
Proceeds from the exercise of stock options	--	11,000
Proceeds from the sale of common stock	--	3,034,000
Principal payments on debt	(151,000)	(71,000)
Net cash (used in) provided by financing activities	(151,000)	2,974,000
Net (decrease) increase in cash and cash equivalents	(1,172,000)	2,377,000
Cash and cash equivalents at beginning of year	3,179,000	802,000
Cash and cash equivalents at end of year	$ 2,007,000	$ 3,179,000

During the fiscal year ended September 30, 2007, the Company issued 763,958

shares of common stock to its Chief Executive Officer in connection with the conversion of senior convertible notes of $200,000 and accrued interest of $122,000 thereon owed to the officer. There were no such issuances in during the fiscal year ended September 30, 2008.

Cash paid for income taxes in the years ended September 30, 2008 and 2007 was $13,000 and $7,000, respectively. Cash paid for interest in the years ended September 30, 2008 and 2007 was $38,000 and $10,000, respectively.

Supplemental disclosure of non-cash investing activity:

During the fiscal year ended September 30, 2008, the Company financed the purchase of equipment with $651,000 in note and lease agreements.

During the fiscal year ended September 30, 2008, the Company financed the purchase of certain insurance policies with a $134,000 note.

See accompanying notes to consolidated financial statements

TRIMEDYNE, INC. AND SUBSIDIARIES
NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

NOTE 1. ORGANIZATION AND BUSINESS

Trimedyne, Inc. ("Trimedyne") and its subsidiaries (collectively "the Company") are engaged primarily in the manufacture and sale of lasers, and disposable and reuseable fiber-optic laser devices in the medical field. The Company's operations include the provision of services and rental of lasers and other medical equipment to hospitals and surgery centers on a "fee-per-case" basis in the Southwestern United States, through its wholly owned subsidiary Mobile Surgical Technologies, Inc. ("MST"), located in Dallas, Texas. The Company's operations are primarily located in Southern California with distribution of its products worldwide (see Note 9).

Managements' Plans

The Company has incurred losses from operations for the past two years. However, the Company believes that existing cash flows are sufficient enough to fund operations through September 30, 2009. 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 months may be required. If necessary, the Company will raise additional debt and/or equity capital, reduce its costs by eliminating certain personnel positions and reducing certain overhead costs in order to fund operations. There is no assurance that management's plans will be successful.

NOTE 2. SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES

Principles of Consolidation

The accompanying consolidated financial statements include the accounts of Trimedyne, Inc., its wholly owned subsidiary, MST, Inc., and its 90% owned and inactive subsidiary, Cardiodyne, Inc. ("Cardiodyne") (collectively, the

"Company"). All intercompany accounts and transactions have been eliminated in consolidation.

Concentration of Credit Risk and Customer Concentration

The Company generates revenues principally from sales of products in the medical field. As a result, the Company's trade accounts receivable are concentrated primarily in this industry. As of September 30, 2008 two customers accounted for 24% and 12% of the Company's receivables. During the year ended September 30, 2007, one customer accounted for 13% of the Company's receivables. The Company performs limited credit evaluations of its customers and generally does not require collateral. The Company maintains reserves for potential credit losses. The Company considers the following factors when determining if collection of a fee is reasonably assured: customer credit-worthiness, past transaction history with the customer, current economic industry trends and changes in customer payment terms. In some cases in regards to new customers, management requires payment in full or letters of credit before goods are shipped or services are performed. If these factors do not indicate collection is reasonably assured, revenue is deferred until collection becomes reasonably assured, which is generally upon receipt of cash. During fiscal 2008 and 2007, credit losses were not significant.

At September 30, 2008, the Company had cash balances in excess of federally insured limits of $100,000 in the amount of $1,861,648.

Inventories

Inventories consist of raw materials and component parts, work-in-process and finished good lasers and dispensing systems. 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. Writedowns are considered permanent reductions at cost basis of the related inventories.

Goodwill

Goodwill represents the excess of the cost over the acquired assets of MST. On October 1, 2002, the Company adopted the provisions of Statement of Financial Accounting Standards ("SFAS") No. 142, "Goodwill and Other Intangible Assets." As a result of adoption SFAS No. 142, the Company's goodwill is no longer amortized, but is subject to an annual impairment test, or whenever events or changes in circumstances indicate that the carrying value may not be recoverable. There was no impairment loss recognized on goodwill during the fiscal years ended September 30, 2008 and 2007.

Impairment of Long-Lived Assets

SFAS No. 144, "Accounting for Impairment or Disposal of Long-Lived Assets", requires that long-lived assets, such as property and equipment and purchased intangibles subject to amortization, be 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 net 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 management's best estimate based on currently available information and reasonable and supportable assumptions. Any impairment recognized in accordance with SFAS No. 144 is permanent and may not be restored. To date, the Company has not recognized any impairment of long-lived assets in connection with SFAS No. 144.

Stock-Based Compensation

Effective October 1, 2006, the Company adopted SFAS No. 123(R), "Share Based Payment," which establishes standards for the accounting of all transactions in which an entity exchanges its equity instruments for goods or services, including transactions with non-employees and employees. SFAS No. 123(R) requires a public entity to measure the cost of non-employee and employee services received in exchange for an award of equity instruments, including stock options, based on the grant date fair value of the award, and to recognize it as compensation expense over the period service is provided in exchange for the award, usually the vesting period. The value of the portion of the award that is ultimately expected to vest is recognized as expense over the requisite service periods in the Company's consolidated statement of income. SFAS No. 123(R) supersedes the Company's previous accounting under APB No. 25. In March 2005, the SEC issued SAB No. 107, "Share-Based Payment," relating to SFAS No. 123(R). The Company has applied the provisions of SAB No. 107 in its adoption of SFAS No. 123(R).

The Company adopted SFAS No. 123(R) using the modified prospective transition method. Accordingly, the Company's consolidated financial statements as of and for the fiscal year ended September 30, 2008 and 2007 reflect the impact of adopting SFAS No. 123(R).

Stock-based compensation expense recognized in the Company's consolidated statements of operations for the fiscal year ended September 30, 2008 and 2007 includes compensation expense for share-based payment awards granted prior to, but not yet vested as of September 30, 2006 based on the grant date fair value estimated in accordance with the pro forma provisions of SFAS No. 123 and compensation expense for the share-based payment awards granted subsequent to September 30, 2006 based on the grant date fair value estimated in accordance with the provisions of SFAS No. 123(R). As stock-based compensation expense recognized in the consolidated statements of operations for the fiscal year ended September 30, 2008 and 2007 is based on awards ultimately expected to vest, it has been reduced for estimated forfeitures. SFAS No. 123(R) requires forfeitures to be estimated at the time of grant and revised, if necessary, in subsequent periods if actual forfeitures differ from those estimates. The estimated average forfeiture rate for fiscal years ended September 30, 2008 and 2007 of approximately 5% is based on historical forfeiture experience and estimated future employee forfeitures. The estimated term of option grants for the fiscal year ended September 30, 2008 was five years.

TRIMEDYNE, INC. AND SUBSIDIARIES
NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

The fair value of stock-based awards is calculated using the Black-Scholes option pricing model. The Black-Scholes model requires subjective assumptions regarding future stock price volatility and expected time to exercise, which greatly affect the calculated values. The expected term of options granted is derived from historical data on employee exercises and post-vesting employment termination behavior. The risk-free rate selected to value any particular grant is based on the U.S. Treasury rate that corresponds to the pricing term of the grant effective as of the date of the grant. The expected volatility for the fiscal year ended September 30, 2008 is primarily based on the Company's historical volatilities of its common stock. These factors could change in the future, affecting the determination of stock-based compensation expense in future periods. The assumptions used for options granted during the fiscal years ended September 30, 2008 and 2007, are as follows:

	Fiscal Years Ended September 30,	
	2008	2007
Expected term	5 years	5 years
Expected stock volatility	94%	93%
Risk free rate	3.07%	4.71%
Dividend yield	--%	--%

The weighted-average grant date fair value of options granted during the fiscal years ended September 30, 2008 and 2007 was $0.29 and $0.94 per option, respectively. There were no options exercised during the fiscal year ended September 30, 2008. The total intrinsic value of options exercised during the fiscal year ended September 30, 2007 was $13,370.

As of September 30, 2008, there was approximately $135,604 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 four years, which is consistent with the vesting period.

The following table summarizes stock-based compensation expense related to employee and director stock options under SFAS No. 123(R) for the fiscal years ended September 30, 2008 and 2007, which was allocated as follows:

	Fiscal Years Ended September 30,	
	2008	2007
Stock-based compensation included in:		
Cost of revenues	$ 10,000	$ 9,000
Research and development expenses	5,000	7,000
Selling, general, and administrative expenses	37,000	48,000
	$52,000	$ 64,000

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, losses for contingencies and certain accrued liabilities.

Fair Value of Financial Instruments

The Company's financial instruments consist primarily of cash and cash equivalents, accounts receivable, note due from related party, accounts payable, accrued expenses and long-term debt. The carrying amounts of the Company's financial instruments generally approximate their fair values as of September 30, 2008 and 2007.

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 year ended September 30, 2008 and 2007, outstanding options of 60,842 and 368,418, respectively, were excluded from the diluted net loss per share as the effects would have been anti-dilutive.

Revenue Recognition

The Company's revenues include revenues from the sale of reusable and disposable Fibers, Needles, and Tips, the sale and rental of Lasers and accessories, and service contracts for Lasers manufactured by the Company.

In accordance with Staff Accounting Bulletin 104, "Revenue Recognition," 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 fibers, needles, and tips and lasers 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 laser systems are sold with a one year warranty which

includes parts and labor. All international lasers systems 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 laser system 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, fibers, needles, and tips 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, which 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 the 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, which sometimes includes a minimum monthly rental fee. During both fiscal years ended September 30, 2008 and 2007, two lasers were 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 Fiber, Needle, and Tip. Revenue from these rental service contracts is recognized as the cases are performed.

Shipping and Handling Costs

Costs incurred for shipping and handling are included in cost of equipment and services revenues at the time the related revenue is recognized. Amounts billed to a customer for shipping and handling are reported as an offset to cost of goods sold.

Product Warranty Costs

The Company provides warranties for certain products and maintains warranty reserves for estimated product warranty costs at the time of sale. In estimating its future warranty obligations, the Company considers various relevant factors, including the Company's stated warranty policies and practices, the historical frequency of claims and the cost to replace or repair its products under warranty. The following table provides a summary of the activity related to the Company's accrued warranty expense:

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

	For The Years Ended September 30,	
	2008	2007
Balance at beginning of period	$ 27,000	$ 23,000
Charges to costs and expenses	74,000	46,000
Costs incurred	(47,000)	(42,000)
Balance at end of period	$ 54,000	$ 27,000

Research and Development Costs

All research and development costs, including licensing costs, are charged to expense as incurred. In accordance with this policy, all costs associated with the design, development and testing of the Company's products have been expensed as incurred.

Income Taxes

The Company uses the asset and liability method of SFAS No. 109 "Accounting for Income Taxes," which requires the recognition of deferred tax liabilities and assets for expected future tax consequences of temporary differences between the carrying amounts and tax bases of assets and liabilities. Management provides a valuation allowance for deferred tax assets when it is more likely than not that all or a portion of such assets will not be recoverable based on future operations.

In July 2006, the Financial Accounting and Standards Board (FASB) issued Interpretation No. 48, "Accounting for Uncertainty in Income Taxes-- an interpretation of FASB Statement No. 109 ("FIN 48")". FIN 48 clarifies the accounting for uncertainty in income taxes recognized in an enterprise's financial statements in accordance with SFAS No. 109, Accounting for Income Taxes. FIN 48 describes a recognition threshold and measurement attribute for the recognition and measurement of tax positions taken or expected to be taken in a tax return and also provides guidance on derecognition, classification, interest and penalties, accounting in interim periods, disclosure and transition. FIN 48 is effective for fiscal years beginning after December 15, 2006. The cumulative effect of adopting FIN 48 was required to be reported as an adjustment to the opening balance of retained earnings (or other appropriate components of equity) for that fiscal year, presented separately. The adoption of FIN 48 did not have a material impact to the Company's financial statements.

Property and Equipment

Property and equipment is recorded at cost. Depreciation of property and equipment is calculated on a straight-line basis over the estimated useful lives of the assets ranging from three to ten years. Leasehold improvements are amortized on a straight-line basis over the lesser of the useful lives or the term of the lease. Depreciation expense for the years ended September 30, 2008 and 2007, was $315,000 and $234,000, respectively.

Segment Information

The Company reports information about operating segments, as well as disclosures about products and services, geographic areas and major customers (see Note 9). Operating segments are defined as revenue-producing components of the

enterprise, which are generally used internally for evaluating segment performance.

Recently Issued Accounting Pronouncements

In September 2006, the FASB issued SFAS No. 157, "Fair Value Measurements" ("SFAS 157"). SFAS 157 provides accounting guidance on the definition of fair value and establishes a framework for measuring fair value and requires expanded disclosures about fair value measurements. SFAS 157 is effective for financial statements issued for fiscal years beginning after November 15, 2007. We plan to adopt the provisions of SFAS 157 on October 1, 2008 with limited impact on our financial statements and on our results of operations and financial condition.

In February 2007, the FASB issued SFAS No. 159, "The Fair Value Option for Financial Assets and Financial Liabilities--Including an amendment of FASB Statement No. 115" ("SFAS 159"). SFAS 159 permits entities to choose to measure financial instruments and certain other items at fair value. The objective is to improve financial reporting by providing entities with the opportunity to mitigate volatility in reported earnings caused by measuring related assets and liabilities differently without having to apply complex hedge accounting provisions. SFAS 159 is effective for financial statements issued for fiscal year beginning after November 15, 2007. We plan to adopt the provisions of SFAS 159 on October 1, 2008 with limited impact on our financial statements and on our results of operations and financial condition.

In December 2007, the FASB issued SFAS No. 141(R), "Business Combinations" ("SFAS 141(R)"), which replaces FAS 141. SFAS 141(R) establishes principles and requirements for how an acquirer in a business combination recognizes and measures in its financial statements the identifiable assets acquired, the liabilities assumed, and any controlling interest; recognizes and measures the goodwill acquired in the business combination or a gain from a bargain purchase; and determines what information to disclose to enable users of the financial statements to evaluate the nature and financial effects of the business combination. SFAS 141(R) is to be applied prospectively to business combinations.

In May 2008, the FASB issued FAS 162, "The Hierarchy of Generally Accepted Accounting Principles". FAS 162 is intended to improve financial reporting by identifying a consistent framework, or hierarchy, for selecting accounting principles to be used in preparing financial statements that are presented in conformity with GAAP for nongovernmental entities. FAS 162 is effective 60 days following the SEC's approval of the Public Company Accounting Oversight Board amendments to AU Section 411, "The Meaning of Present Fairly in Conformity with Generally Accepted Accounting Principles." We do not expect the adoption of this statement to have a material impact on our results of operations, financial position or cash flows.

In April 2008, the FASB issued FSP No. 142-3, "Determination of the Useful Life of Intangible Assets". FSP 142-3 amends the factors that should be considered in developing renewal or extension assumptions used to determine the useful life of a recognized intangible asset under Financial Accounting Standard No. 142, "Goodwill and Other Intangible Assets". FSP 142-3 is effective for fiscal years

beginning after December 15, 2008. Therefore, we will be required to adopt FSP 142-3 for the fiscal year beginning October 1, 2009. We are currently evaluating the impact of FSP No. 142-3 on our consolidated financial position and results of operations.

NOTE 3. COMPOSITION OF CERTAIN BALANCE SHEET CAPTIONS

Inventories consist of the following:

	For The Years Ended September 30,	
	2008	2007
Raw materials	$ 1,036,000	$ 1,129,000
Work-in-process	722,000	940,000
Finished goods	826,000	922,000
	$ 2,584,000	$ 2,991,000

For the fiscal years ended September 30, 2008 and 2007, 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:

	For The Years Ended September 30,	
	2008	2007
Royalty receivable	$ 58,000	$ 132,000
Prepaid insurance	86,000	86,000
Deposits	9,000	6,000
Prepaid income tax	5,000	4,000
Other	13,000	17,000
Total other current assets	$ 171,000	$ 245,000

Property and equipment, net consists of the following:

	For The Years Ended September 30,	
	2008	2007
Furniture and equipment	$ 3,216,000	$ 2,513,000
Leasehold improvements	619,000	619,000
Other	282,000	216,000
	$ 4,117,000	$ 3,348,000
Less accumulated depreciation and amortization	(2,735,000)	(2,428,000)
	$ 1,382,000	$ 920,000

As of September 30, 2008, equipment purchased under capital leases had a cost of $692,000 and an accumulated depreciation of $66,000.

Accrued expenses consist of the following:

	For The Years Ended September 30,	
	2008	2007
Accrued vacation	187,000	$ 149,000
Accrued salaries and wages	130,000	103,000
Sales and use tax	67,000	66,000
Accrued professional fees	4,000	43,000
Customer deposits	13,000	10,000
Commissions	51,000	34,000
Accrued payroll tax	8,000	8,000
Other	9,000	14,000
Total accrued expenses	$ 469,000	$ 427,000

NOTE 4. ACQUISITION OF CPT

On August 6, 2008, the Company, through its subsidiary MST, acquired certain assets and assumed certain liabilities of CPT Services, Inc. ("CPT") for an aggregate cash purchase price of $21,000. CPT provided laser service and repair services similar to the MST. The acquisition is expected to assist the MST in the expansion of its services.

Since the assets acquired constituted a business, the acquisition has been accounted for using the purchase method of accounting in accordance with SFAS No. 141, whereby the estimated purchase price has been allocated to tangible and intangible net assets acquired based upon their fair values at the date of acquisition.

The purchase price of CPT has been allocated to assets acquired and liabilities assumed based on their estimated fair values determined by management as follows:

Property and equipment	$ 129,000
Intangible asset - customer list	30,000
Notes and leases payable	(138,000)
Cash paid	$ 21,000

The customer relationships are considered an intangible asset and are being amortized over the estimated useful live of five years from the date of the acquisition. The estimated useful life was determined based upon the historical lives of the customer base. The pro-forma financial statements have not been provided as they are insignificant to the Company's financial statements.

NOTE 5. NOTES PAYABLE AND CAPITAL LEASES

SENIOR CONVERTIBLE SECURED NOTES DUE TO OFFICER

During the fiscal year ended September 30, 2007, the Company had two senior convertible secured notes (the "Convertible Notes") in the amounts of $150,000 and $50,000 to its Chief Executive Officer. The Convertible Notes accrued interest at 12%, per annum, with maturity dates of February 27, and April 15,

2007, respectively, and were convertible, including accrued interest thereon, into common stock, based on $0.40 per share and $0.50 per share (the "Conversion Price"), respectively. The Notes and the accrued interest thereon of $122,000, were converted into 763,958 shares of common stock on their respective maturity dates. Their were no such Notes during issued during the fiscal year ended September 30,2008.

TRIMEDYNE, INC. AND SUBSIDIARIES
NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

NOTES PAYABLE AND CAPITAL LEASES

Notes payable and capital leases consists of the following at September 30, 2008:

Capital lease agreement in connection with the purchasing of equipment bearing an effective interest rate of 8.69% per annum. The lease requires monthly payments of $3,147 through September 2012.	99,000
Capital lease agreement in connection with the purchasing of equipment bearing an effective interest rate of 9.25% per annum. The lease requires monthly payments of $4,979 through January 2013.	213,000
Capital lease agreement in connection with the purchasing of ERP software bearing an effective interest rate of 9.23% per annum. The lease requires monthly payments of $526 through February 2013.	23,000
Capital lease agreement in connection with the purchasing of equipment bearing an effective interest rate of 8.82% per annum. The lease requires monthly payments of $2,403 through March 2012.	87,000
Capital lease agreement in connection with the purchasing of equipment bearing an effective interest rate of 8.66% per annum. The lease requires monthly payments of $2,386 through October 2010.	52,000
Capital lease agreement in connection with the purchasing of ERP software bearing an effective interest rate of 8.51% per annum. The lease requires monthly payments of $3,195 through April 2011.	89,000
Finance agreement issued in connection with the purchasing of certain insurance policies. The note bears interest at 6.8% per annum and require monthly principal and interest payments of $12,631 through March 2009.	74,000
	637,000
Less: current portion	(237,000)
	$ 400,000

The Company leases certain equipment under capital leases with terms ranging from three to five years. Future annual minimum lease payments are as follows as of September 30:

2009	$ 200,000
2010	200,000
2011	157,000
2012	80,000
2013	17,000
Total minimum lease payments	654,000
Less amount representing interest	(91,000)
Present value of future minimum lease payments	563,000
Less current portion of capital lease payments	163,000
Capital lease obligations, net of current portion	$ 400,000

NOTE 6. INCOME TAXES

The deferred income tax balances at September 30, 2008, are comprised of the following:

Deferred income tax assets (liabilities):	
Net operating loss carry forwards	$ 12,422,000
Inventories	139,000
Reserves and accruals	252,000
Research and development credits	2,591,000
Depreciation and amortization	(72,000)
Other	4,000
Valuation allowance	(15,336,000)
	$ --

The valuation allowance for deferred tax assets decreased approximately $504,000 during the year ended September 30, 2008 and approximately $475,000 during the year ended September 30. 2007, primarily due to a portion of the Company's net operating loss carryforwards ("NOLS") for federal and state income tax reporting, as well as research and development tax credits that expired. For the years ended September 30, 2008 and 2007, the Company recorded a current provision for state income taxes of $13,000 and $8,000, respectively. There was not a provision for federal income taxes.

The Company's effective income tax rate differs from the statutory federal income tax rate as follows for the years ended September 30, 2008 and 2007:

September 30,

	2008	2007
Statutory federal income tax rate	(34.00) %	(34.00) %
Increase (decrease) in tax rate resulting from:		
State tax benefit, net of federal benefit	(5.80) %	(5.80) %
Other	(0.03) %	0.50 %
Valuation Allowance	40.63 %	41.80 %
Effective income tax rate	0.80 %	2.50 %

At September 30, 2008, the Company had NOL carry forwards for Federal and California income tax purposes totaling approximately $35.6 million and $5.0 million, respectively. Federal and California NOL's have begun to expire and fully expire in 2020 and 2011, respectively. The Tax Reform Act of 1986 includes provisions which may limit the new operating loss carry forwards available for use in any given year if certain events occur, including significant changes in stock ownership. In addition, the Company has R & D credits that have begun to expire and fully expire in 2028 for federal tax purposes.

NOTE 7. COMMITMENTS AND CONTINGENCIES

Lease Commitments

The Company has two non-cancelable operating leases, which include a lease for MST's facility in Dallas, Texas, which expires in August 2010, and a lease for the Company's corporate office and manufacturing facility in Lake Forest, California, which expires in March 2011.

Future annual minimum lease payments under the above lease agreements, at September 30, 2008 are as follows:

Years ending September 30,	
2009	$ 374,000
2010	385,000
2011	183,000
Total	$ 942,000

Rent expense for the years ended September 30, 2008 and 2007 was approximately $358,000 and $356,000, respectively.

In accordance with SFAS No. 13 "Accounting for Leases" and Financial Accounting Standards Board Technical Bulletin 85-3, "Accounting for Operating Leases with Scheduled Rent Increases", rent expense on the leases are recognized on a straight-line basis over the term of the lease. Therefore, rent expense on the leases does not correspond with the actual rent payments due. Additionally, as part of the Company's lease agreement of its facility in Lake Forest, California, the Company received $100,000 from the lessor as an allowance for leasehold improvements contributed by the Company. In accordance with Financial Accounting Standards Board Technical Bulletin No. 88-1, the unamortized portion of the $100,000 payment received is being recognized on a straight-line basis over the term of the lease as reduction to rent expense and the unamortized portion is included in deferred rent. The difference between the cumulative rent payments, net of the $100,000 allowance on leasehold improvements versus the cumulative rent expense on a straight-line basis is recorded as a deferred rent liability. As of September 30, 2008, this liability was $75,000.

The Company is subject to various claims and actions which arise in the ordinary course of business. The litigation process is inherently uncertain, and it is possible that the resolution of any of the Company's existing and future litigation may adversely affect the Company. Management is unaware of any matters which are not reflected in the condensed consolidated statements of operations that may have material impact on the Company's financial position, results of operations or cash flows.

See Note 5 regarding capital leases.

TRIMEDYNE, INC. AND SUBSIDIARIES
NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

Settlement and OEM Agreement

Under the terms of a settlement agreement with Lumenis, Inc. ("Lumenis"), Lumenis has agreed to pay a 7.5% royalty on their sales of certain side-firing and angled-firing devices manufactured by Lumenis. In addition, Lumenis agreed to purchase 75% of its Angled-Firing (60 to 75 degree firing) and 100% of its Side-Firing (75 to 90 degree) Fibers from the Company under an OEM agreement ("OEM Agreement"). The OEM Agreement was executed on September 8, 2005, under which the Company agreed to manufacture a special version of its VaporMAX(TM) Side-Firing Device exclusively for Lumenis, for use with Lumenis' Holmium lasers for their cleared indications for use, which include the treatment of benign prostatic hyperplasia or "BPH", commonly referred to as an enlarged prostate.

For the years ended September 30, 2008 and 2007 the Company recognized as income $374,000 and $487,000, respectively, in royalties from Lumenis. These amounts are all included as other income in the accompanying statements of operations.

Product Liability

The Company is subject to various claims and actions which arise in the ordinary course of business. The litigation process is inherently uncertain, and it is possible that the resolution of any of the Company's existing and future litigation may adversely affect the Company. Management is unaware of any matters which are not reflected in the consolidated financial statements that may have material impact on the Company's financial position, results of operations or cash flows.

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 lessors for certain claims arising from the use of the facilities. 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 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, recently announced a proposed decision to deny reimbursement for thermal intradiscal procedures (TIPs). Thermal procedures to treat spinal discs typically entail the use of electrothermal (ET) or radiofrequency (RF) energy to heat or coagulate the nucleus of the disc, a spongy, gelatinous material that absorbs shocks when people run, jump or are injured, to prevent damage to the vertebra.

CMS, however, included the use of laser energy in its proposed denial of reimbursement, as the early lasers used in spinal disc treatment, Nd:YAG and KTP lasers, emit continuous wave (CW) energy at a constant level, which is thermal, like ET or RF energy.

The Company's pulsed Holmium Lasers emit pulsed energy, which is highly absorbed by water. Each pulse of Holmium laser energy is absorbed by the water in the cells, which is rapidly turned to steam, vaporizing the tissue. The tissue cools between the pulses, which last a few hundred microseconds (millionths of a second), and only a small amount of heating or coagulation occurs. That is why our Holmium lasers are commonly referred to as "cold" vaporizing lasers.

The Company filed an objection to CMS' lumping our pulsed Holmium Lasers with ET, RF and older, thermal Nd:YAG and KTP lasers, few of which lasers are still in use in the treatment of spinal discs. We explained the different mechanisms of action, tissue effects and improved patient outcomes of pulsed Holmium laser energy, compared to those of ET, RF, Nd:YAG and KTP laser energy, and we attached ten (10) published papers on clinical studies of Holmium laser energy that support our position.

The Company believes its objection makes a convincing argument to avoid including our pulsed Holmium Lasers with other thermal devices in CMS' proposed decision. The Company expects it will take until October or later before CMS makes a final decision to either deny or approve reimbursement for TIPS or take no action, leaving the decision on what to reimburse or not to its 30 or so local reimbursement bodies. If CMS makes a final decision to deny reimbursement for the use of our pulsed Holmium Lasers in TIPS, our spinal business would be adversely affected.

TRIMEDYNE, INC. AND SUBSIDIARIES
NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

NOTE 8. STOCKHOLDERS' EQUITY

During the first quarter of 2007, the Company sold 2,650,000 shares of its common stock through J. H. Darbie & Co., Inc. ("Darbie") and First Island Capital, Inc. ("FIC"). The Company sold 2,600,000 shares and 212,000 warrants through Darbie to four institutional investors and a related accredited individual at a price of $1.25 per share for an aggregate of $3,250,000, and 50,000 shares through FIC at a price of $1.25 per share for $62,500 to an accredited individual. In addition, as part of the sale of the common stock, the Company also issued warrants, exercisable to purchase 208,000 and 4,000 shares of common stock to Darbie and FIC, respectively, at a price of $1.25 per share, with a customary anti-dilution provision. The Company paid a commission of

$260,000 to Darbie and incurred $18,500 in legal expenses and other costs.

In January 2007, the Company and the investors renegotiated the terms of the offering above, and the Company issued 265,000 additional shares of common stock to the investors without cost, bringing the total number of shares issued to 2,915,000 at an average cost of $1.136 per share.

In fiscal 2007, the Chief Executive Officer converted two Senior Convertible Secured Notes in the amounts of $150,000 and $50,000, and their respective accrued interest, totaling $122,000, into 763,958 shares of common stock based on their conversion price of $0.40 and $0.50 per share, respectively, upon their respective maturity dates.

During the first quarter of fiscal 2007, the Company issued 212,000 warrants in connection with a stock sale.

	Shares of Common Stock Issuable Upon Exercise of Warrants	Weighted Average Exercise Price Per Share	Range o Exercis Prices
Outstanding, at September 30, 2006	--	$ --	$
Issued	212,000	$ 1.25	$
Outstanding, at September 30, 2007	212,000	$ 1.25	$
Issued	--	--	
Outstanding, at September 30, 2008	212,000	$ 1.25	$

Stock Options

The Company has adopted stock option plans that authorize the granting of options to key employees, directors, and consultants to purchase unissued common stock subject to certain conditions, such as continued employment. Options are generally granted at the fair market value of the Company's common stock at the date of grant, become exercisable over a period of five years from the date of grant, and generally expire in six or ten years specific to their respective plan. Forfeitures of stock options are returned to the Company and become available for grant under the respective plan.

During fiscal 2007, the board of directors authorized the grant of non-qualified stock options to purchase 172,000 shares as follows:

Number of Options(1)	Option Exercise Price Per Share(2)
36,000	$0.64
35,000	$1.20
16,000	$1.40
25,000	$1.52
60,000	$1.53

(1) These options vest over five years and expire ten (10) years from the date of grant.
(2) Exercise price per share is based on the closing price of the Company's

common stock on the date of grant.

During fiscal 2008, the Board of Directors authorized the grant of non-qualified stock options to purchase 96,500 shares as follows:

Number of Options(1)	Option Exercise Price Per Share(2)
41,500	$0.38
30,000	$0.35
25,000	$0.77

(1) These options vest over five years and expire ten (10) years from the date of grant.
(2) Exercise price per share is based on the closing price of the Company's common stock on the date of grant.

Stock Options Outstanding:

	Shares	Weighted-Average Exercise Price	Weighted-Average Remaining Contractual Term (Years)	Aggreg Intrin Valu
Options outstanding at October 1, 2006	1,425,979	$ 1.16		
Options granted	172,000	$ 1.26		
Options exercised	(18,100)	$ 0.49		
Options forfeited	(152,900)	$ 1.53		
Options outstanding at September 30, 2007	1,426,979	$ 1.14		
Options granted	96,500	$ 0.47		
Options exercised	--	--		
Options forfeited	(97,000)	$ 1.04		
Options outstanding at September 30, 2008	1,426,479	$ 1.10	4.0	$ 4
Options exercisable at September 30, 2008	1,244,229	$ 1.13	3.4	$ 4

The following table summarizes information concerning outstanding and exercisable options at September 30, 2008:

	OPTIONS OUTSTANDING		OPTIONS EXERCI

Range of Exercise Prices	Outstanding as of 9/30/2008	Weighted-Average Remaining Contractual Life (years)	Weighted-Average Exercise Price	Exercisable as of 9/30/2008	We A Exer
$0.14 - $0.38	151,500	4.3	$0.27	121,500	
$0.39 - $0.94	586,679	5.0	$0.61	509,029	
$0.95 - $1.88	523,400	3.5	$1.30	448,800	
$1.89 - $2.61	16,000	1.7	$2.29	16,000	
$2.62 - $3.38	100,900	1.5	$2.75	100,900	
$3.39 - $4.25	48,000	1.5	$3.84	48,000	
	1,426,479	4.0	$1.10	1,244,229	

The weighted-average grant date fair value of options granted during the fiscal years ended September 30, 2008 and 2007 was $0.29 and $0.94 per option, respectively. There were no options exercised during the fiscal year ended September 30, 2008. The total intrinsic value of options exercised during the fiscal year ended September 30, 2007 was $13,370.

NOTE 9. EMPLOYEE BENEFIT PLAN

The Company has a 401(k) retirement savings plan (the "Retirement Plan"). Under the terms of the Retirement Plan, employees may, subject to certain limitations, contribute up to 15% of their total compensation. The Company contributes an additional $0.50 for each dollar of employee contributions up to 4% of eligible employee compensation. Employees become vested in the Company's contribution at 20% per year over five years. The Company's annual contributions to the Retirement Plan for the fiscal years ended September 30, 2008 and 2007 totaled $32,000 and $31,000, respectively.

NOTE 10. SEGMENT INFORMATION:

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

	For the year ended September 30, 2008:			For the year en	
	Product	Service and Rental	Total	Product	Serv Re

Revenues	$ 3,832,000	$2,039,000	$ 5,871,000	$ 3,777,000	$1,
Cost of sales	2,657,000	1,506,000	4,163,000	2,039,000	1,
Gross profit	1,175,000	533,000	1,708,000	1,738,000	
Expenses:					
Selling, general and administrative	1,877,000	496,000	2,373,000	1,676,000	
Research and development	1,311,000	--	1,311,000	1,220,000	
(Loss) income from operations	$(2,013,000)	$ 37,000	(1,976,000)	$(1,158,000)	$
Other income (expense):					
Interest income			53,000		
Royalty income			374,000		
Interest expense			(38,000)		
Creditor settlements and recoveries			27,000		
Loss on disposal of equipment			(17,000)		
(Loss) before provision for income taxes			(1,577,000)		
Provision for income taxes			13,000		
Net (loss)			$(1,590,000)		

Sales in foreign countries in fiscal 2008 and 2007 accounted for approximately 24.6% and 22.9%, respectively, of the Company's total sales. The breakdown by geographic region is as follows:

	2008	2007
Asia	$ 802,000	$ 675,000
Europe	224,000	224,000
Latin America	118,000	138,000
Middle East	80,000	1,000
Australia	121,000	6,000
Africa	--	--
Other	99,000	209,000
	$1,444,000	$1,253,000

Sales and gross profit to customers by similar products and services for the fiscal year ended September 30, 2008 and September 30, 2007 were as follows:

	For the year ended September 30, 2008	2007
By similar products and services:		
Sales		
Products:		
Lasers and accessories	$ 1,111,000	$ 673,000
Fibers, Needles and Tips	2,721,000	3,104,000
Service and rental	2,039,000	1,693,000
Total	$ 5,871,000	$ 5,470,000
Gross profit		
Products:		
Lasers and accessories	$ 66,000	$ 137,000
Fibers, Needles and Tips	1,109,000	1,601,000
Service and rental	533,000	571,000
Total	$ 1,708,000	$ 2,309,000

All the Company's long-lived assets were located in the United States at September 30, 2008.

NOTE 11. RELATED PARTY TRANSACTIONS

During the fiscal years ended September 30, 2008 and 2007, the Company incurred $6,900 and $14,800 of legal services rendered by a Director, respectively, of which $1,000 was still outstanding and included in accounts payable as of September 30, 2008.

The Company entered into a service agreement with Cardiomedics, Inc. ("Cardiomedics"), a privately held corporation in which the Chairman/CEO of Trimedyne, Inc. holds a majority interest and is a member of the Board of Directors. The COO/President of the Company is also a board member of Cardiomedics. Under the agreement, Trimedyne agreed to provide warranty service, periodic maintenance, and repair on Cardiomedics' heart assist devices for which Trimedyne billed Cardiomedics $40,000 on account and recorded as service income, including $29,000 during the year ended September 30, 2006. During the quarter ended March 31, 2006 Cardiomedics' account with Trimedyne, Inc. became delinquent and the Company ceased providing services to Cardiomedics. Cardiomedics also entered into a reimbursement agreement with the Company for business expenses incurred by the CEO/Chairman of the Company on behalf of Cardiomedics in the amount of $11,000.

The above balances due were consolidated and converted into a $51,000 promissory note (the "Note"). The Note bears interest at 8.0% per annum, and matured on March 31, 2008. During the fiscal year ended September 30, 2008 the Note was paid in full. During the fiscal year ended September 30, 2007, the Company received $29,000 in principal reduction payments from Cardiomedics, reducing the principal balance of the Note to $9,000 and recorded $2,000 in interest income in connection with the above agreement.

In connection with the above service agreement with Cardiomedics, the Company received $33,000 in service income during the fiscal year ended September 30, 2008.

On April 7, 2006, the Company entered into an agreement to employ Cardiomedics as a consultant to provide graphics arts services, since the Company had no employee with experience in the design and production of brochures and other marketing materials. Under this agreement, Cardiomedics provides the services of a graphics art specialist at a rate comparable to those presently prevailing in the market in the design and production of marketing materials. During the years ended September 30, 2008 and 2007, the Company incurred $36,000 and $38,000, respectively, in expense for the services provided under the agreement, which was recorded to marketing expense, of which $4,000 was included in the balance of accounts payable at September 30, 2008.