# FORM 10-K

Annual report pursuant to section 13 and 15(d)

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## FILER

**TRIMEDYNE INC**

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SECURITIES AND EXCHANGE COMMISSION
WASHINGTON, D.C. 20549

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# 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, 1996 COMMISSION FILE NO. 0-10581

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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.) |
| 2801 BARRANCA ROAD, P.O. BOX 57001<br>IRVINE, CALIFORNIA 92619-7001<br>(ADDRESS OF PRINCIPAL EXECUTIVE OFFICES) | 92619-7001<br>(ZIP CODE) |

REGISTRANT'S TELEPHONE NUMBER, INCLUDING AREA CODE:
(714) 559-5300

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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)

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INDICATE BY CHECK MARK WHETHER THE REGISTRANT (1) HAS FILED ALL REPORTS REQUIRED TO BE FILED BY SECTION 13 OR 15(D) OF THE SECURITIES EXCHANGE ACT OF 1934 DURING THE PRECEDING 12 MONTHS (OR FOR SUCH SHORTER PERIOD THAT THE REGISTRANT WAS REQUIRED TO FILE SUCH REPORTS, AND (2) HAS BEEN SUBJECT TO THE FILING REQUIREMENTS FOR THE PAST 90 DAYS. YES X NO _____

THE AGGREGATE MARKET VALUE OF VOTING STOCK HELD BY NON-AFFILIATES OF REGISTRANT ON DECEMBER 23, 1996, BASED UPON THE CLOSING PRICE OF THE COMMON STOCK ON SUCH DATE WAS $32,997,000.

AS OF DECEMBER 23, 1996, THERE WERE OUTSTANDING 10,890,347 SHARES OF REGISTRANT'S COMMON STOCK.

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 REGISTRANT'S 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._____



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PART I

ITEM I. BUSINESS

GENERAL

Trimedyne, Inc. (the "Company") is engaged in the development, manufacturing and marketing of Holmium "cold" pulsed lasers, Nd:YAG "thermal" lasers and proprietary, disposable fiber-optic laser delivery devices for use in orthopedics, urology and other medical specialties.

The Company's principal efforts from its inception in 1980 until 1991 were devoted to the manufacturing and marketing of cardiovascular lasers for vaporizing plaque (fatty deposits) in blood vessels. As a result of significant declines in sales of its cardiovascular laser products, in 1991 the Company shifted its focus to laser and proprietary delivery system technologies for use in selected "less invasive" surgical applications in orthopedics, urology and other medical specialties. In the year ended September 30, 1996, the Company derived approximately 64% of its sales from the orthopedic field, where the Company believes its laser products may have advantages over conventional surgical devices.

Net revenue of the Company in fiscal 1996 decreased 4% to $12,488,000 from $13,041,000 for the prior year. The Company incurred a net loss of $4,729,000 or $0.47 per share during fiscal 1996, compared to a net loss of $5,290,000 or $0.56 per share in fiscal 1995. The loss in fiscal 1996 was lower than in 1995 due to the Company's cost reduction efforts and lower warranty and service costs. The decline in sales in the year ended September 30, 1996 was due to lower sales of plastic fiber optics which declined $298,000 or 9% and sales of urology products which declined $345,000 or 33%.

Despite United States Food and Drug Administration ("FDA") clearance to market the Company's lasers and side-firing laser devices for the treatment of BPH in March 1996, sales of these products have been less than anticipated, due to the introduction of new, lower priced electrovaporization devices and the incursion of a variety of side-firing laser devices made by competitors into the U.S. market when C.R. Bard Inc. ("Bard") ceased marketing the Company's sidefiring laser device. As of September 30, 1996, the Company increased it's reserves totalling $1,000,000 for the write down of inventories and write-off of prepaid royalties related to its urology products. (See "Agreement with Bard", "FDA Status and Pending Litigation" and "Litigation" herein.)

The Company believes its future lies in expanding its orthopedic business, the development of the new products in neurology, gynecology, urology, dermatology and cosmetic surgery described herein and the Company's investment in a newly established cardiovascular laser subsidiary, Cardiodyne, Inc. (See "New Products", "Cardiodyne" and "License Agreements" for a description of the new devices the Company and Cardiodyne are developing).

The Company's working capital on September 30, 1996 was $13,919,000. (See "Management's Discussion and Analysis of Results of Operations and Consolidated Financial Condition" herein).

The Company was incorporated in Nevada on May 1, 1980, and adopted its present name on December 31, 1980. The Company has a 90% owned subsidiary, Poly-Optical Products, Inc. ("Poly-Optical"), which manufactures plastic optical fibers for use in automotive, consumer, industrial and medical products. In November 1996, the Company entered into a letter of intent to sell its 90% interest in Poly-Optical, subject to the buyer obtaining financing therefor. Unless the context otherwise requires, all references to the Company shall be to Trimedyne, Inc. and its subsidiaries. The Company's principal executive offices are located at 2801 Barranca Road, Irvine, California 92606, and its telephone number is (714) 559-5300.

COLD LASER USE IN ORTHOPEDICS AND OTHER SURGICAL APPLICATIONS

Cold lasers, which generate very short, extremely powerful pulses of laser energy, are able to cut and vaporize tissue without significant thermal damage to surrounding areas. Such lasers are expected to have advantages over continuous wave "thermal" lasers in certain surgical applications, particularly when used in tissues such as cartilage, which can be irreparably damaged by heat, or heat sensitive blood vessels or nerves. In March 1991, the Company received FDA clearance of its 510(k) Premarket Notification (see "Government Regulation") to market its OmniPulse(TM)





Holmium "cold" pulsed laser and a variety of disposable optical fiber delivery devices for use in orthopedic surgery in soft tissues. Orthopedic tissues, such as cartilage in the joints, do not regenerate (re-grow) if damaged by heat. Also, tiny optical fibers permit laser energy to be delivered into spaces in joints too small to accommodate conventional surgical tools. While an estimated 1,200,000 arthroscopic surgeries are performed annually in the United States, the proportion in which a laser might be used cannot presently be predicted.

In December 1991, the Company received FDA clearance of its 510(k) Premarket Notification to market its OmniPulse(TM) Holmium laser for use in herniated lumbar spinal disks to treat lower back pain. In a laser discectomy procedure, a needle containing an optical fiber is inserted into the spinal disk, either under x-ray guidance or through an endoscope, and the laser is used to vaporize a portion of the nucleus of the disk, relieving the pressure of the disk on the nerves of the spinal column. In June, 1993, the Company received FDA clearance of its 510(k) Premarket Notification to market its proprietary SideFire(TM) Laser Needle for use with its Holmium laser in herniated spinal disks. According to published studies, Holmium Laser use in discectomy was successful in relieving the pain in up to 90% of the cases treated. While more than 20 million people in the United States suffer from lower back pain, the number of these whose back pain is sufficiently serious to warrant a laser discectomy procedure cannot presently be ascertained.

In September 1991, the Company received FDA clearance of its 510(k) Premarket Notification to market its OmniPulse(TM) Holmium Laser in general surgery. In March 1994, the Company received FDA clearance under a 510(k) Premarket Notification to market its Holmium laser for use in urology and endoscopic sinus surgery, an ear, nose and throat ("ENT") specialty. In July, 1995, the Company received FDA clearance to market this laser under a 510(k) Premarket Notification for use in gynecology and lithotripsy (to fragment urinary stones). The Company plans to file similar applications with the FDA for the use of its Holmium Laser in a variety of other surgical applications.

THERMAL LASERS AND SIDE-FIRING LASER DEVICES IN UROLOGY

In certain surgical applications, such as the treatment of benign prostatic hyperplasia (enlarged prostate or "BPH"), deep coagulation of tissues is desired. Laser light, which penetrates tissue to a predictable depth based upon the wavelength being used, offers the unique ability to create coagulation zones in tissue of almost any desired depth or shape. The coagulated tissues die, due to lack of blood flow, and are partially absorbed by the body. The remainder is sloughed off by the body in a mucous-like effusion, resulting in a shrinkage of the mass.

The Company's Neodymium:YAG ("Nd:YAG") Lasers, which produce continuous wave "thermal" light energy at a wavelength of 1064 nanometers, can create a greater depth of coagulation in tissue (approximately 4,000 microns or 4mm) than any other wavelength of laser light. Heat conduction can increase the coagulation zone in tissue up to approximately 1.4cm (0.55 inches). In 1988, the Company acquired an exclusive, worldwide license to a side-firing fiber optic device consisting of a specially designed, reflectively coated metal tip which is mounted on the end of an optical fiber. In March 1992, the license was determined to be non-exclusive. Two U.S. Patents covering such devices have since issued. The Company also holds an exclusive license to a U.S. Patent which issued in August 1995 and covers the method of use of side-firing laser devices in urology, gynecology, gastroenterology and other medical specialties.

In June 1991, the Company's side-firing laser device was cleared for sale by the U.S. Food and Drug Administration ("FDA") under a 510(k) Premarket Notification for ablation and hemostasis (coagulation) of urologic tissues. In November 1994, the Company received clearance from the FDA under a 510(k) Premarket Notification to market a new, improved version of its side-firing laser device, which has greater durability, and a new, more versatile version which has the ability to both coagulate and ablate tissue. However, sales of these products have not been substantial (See "Agreement with Bard, FDA Status and Pending Lawsuit").

AGREEMENT WITH BARD, FDA STATUS AND PENDING LAWSUIT

In June 1991, the Company entered into a Development, Supply and License Agreement with C.R. Bard, Inc. ("Bard"), under which Bard was granted exclusive, worldwide rights to market the Company's side-firing laser devices (under Bard's Urolase(R) trademark), certain other laser delivery devices and improvements thereto in urology, gynecology and gastroenterology. Bard also agreed, at its expense, to conduct a prospective, randomized, controlled clinical study of the Urolase(R) Fiber at a number of medical centers in the United States in the treatment of benign prostatic hyperplasia ("BPH") or enlarged prostate, a condition affecting an estimated 50% of all men over age 55.





Bard's clinical study was begun in 1991. In April 1992, Bard commenced a limited marketing release of the Urolase(R) Fiber for urologic use in the United States and commenced marketing these devices in Europe, the Far East and a number of other countries in early 1993. Although cleared for sale by the FDA for ablation and hemostasis (coagulation) of urologic tissues, in January 1993, the FDA announced that side-firing laser devices were investigational and not cleared for sale for the treatment of BPH. Although the FDA stated that side-firing laser devices cleared for sale for ablation and coagulation of urologic tissues could be used by a urologist for the treatment of BPH if he felt it was in the best interest of the patient, Bard ceased promoting the Urolase(R) Fiber in the United States.

In June 1993, the FDA announced that a Pre-Market Approval ("PMA") Application (see "Government Regulation") and a controlled, prospective clinical trial, with a one-year follow-up period, would be required for approval to market a side-firing laser device for the treatment of BPH. The Company filed its PMA Application for the treatment of BPH in July 1993. In October 1995, the FDA changed its position and advised the Company and other laser manufacturers that side-firing laser devices could be cleared for sale for the treatment of BPH under the less stringent 510(k) Premarket Notification process, with appropriate clinical study data. In October 1995, the Company withdrew its PMA Application and filed its 510(k) Premarket Notification with the FDA. The Company's 510(k) Premarket Notification Application to market its side-firing laser devices for the treatment of BPH was cleared by the FDA in March 1996.

The Company believes that Bard's ceasing to promote the sale of the Company's side-firing laser devices in the U.S. for more than two years enabled competitors to fill the void created by Bard's withdrawal from the U.S. market. Since Bard had not advised the Company of any plan for it to re-enter the market, on October 6, 1995, the Company filed a lawsuit against Bard claiming damages of at least $72 million for Bard's failure to perform its obligations as Trimedyne's exclusive distributor under the Agreement. The Company has taken actions to mitigate its damages, produce revenues and attempt to regain sales in urology. However, for the reasons described above, and other market factors, the Company has not been able to generate any significant sales of its side-firing laser devices in the urology field.

NEW PRODUCTS

The Company is developing a new type of laser for use in plastic surgery, cosmetic surgery and dermatology. This new laser will have the capability to perform procedures that cannot be done with conventional lasers. The Company plans to commence testing its new laser in March 1997 and expects to commence commercial sales, subject to FDA clearance, in 1997. Since cosmetic surgery lasers are sold directly to plastic and cosmetic surgeons, dermatologists and other physicians, the Company does not expect that sales of its new laser will be inhibited by limited capital equipment funds, as is the case in sales of conventional lasers to hospitals.

As discussed under "License Agreements" below, the Company has acquired U.S. Patents covering proprietary devices for delivering and releasing coils in brain aneurisms and treating menhorragia (excessive uterine bleeding). The Company is developing products covered by these patents for use in neurology, gynecology and urology. In order to market these products, the Company is attempting to negotiate distribution agreements with established companies with large sales forces in these medical specialties. There is no assurance the Company's efforts to do so will be successful.

CARDIODYNE

In October 1996, the Company agreed to invest $2,000,000 in Cardiodyne, Inc. ("Cardiodyne"), a wholly-owned subsidiary of Trimedyne, which plans to develop a proprietary laser system for use in transmyocardial revascularization or "TMR". Trimedyne also agreed to transfer to Cardiodyne, its design for a TMR Laser System, several lasers, testing and production equipment and supplies. Trimedyne agreed to grant Cardiodyne an exclusive license to all of Trimedyne's present and future patents, patent applications and technology in the cardiovascular field. Trimedyne also agreed to supply all of Cardiodyne's requirements for lasers on a cost-plus basis.

TMR is a new procedure for treating severe coronary artery disease. Cardiodyne's proprietary TMR Laser System, which is presently in development, consists of its SuperPulse(TM) Holmium laser, the most powerful laser of this type presently available, as well as Cardiodyne's proprietary AutoFire(TM) automated firing system and its proprietary, disposable Channel Maker(TM) optical fiber devices. Cardiodyne's TMR System will be used to create 15 to 50 channels through the heart wall between heartbeats, triggered by the patient's electrocardiogram (ECG), in less than one-half



second. The channels enable blood from the heart chamber to reach and nourish areas of the myocardium (heart muscle) that have been deprived of blood by blockages in the patient's coronary arteries.

In early 1997, Cardiodyne plans to apply to the FDA for approval to commence clinical trials of its TMR System in the treatment of so-called "no option" angina patients, who have already failed bypass surgery and/or balloon angioplasty or are not suitable candidates for such procedures. In a second clinical trial, Cardiodyne plans to perform TMR as an adjunct or "back-up" to coronary bypass surgery, to provide an alternate source of blood to the heart muscle if one or more of the grafted vessels or an unbypassed artery fails. At about the same time, Cardiodyne also plans to request FDA approval to commence clinical trials of its TMR System in humans in a minimally invasive TMR procedure, through a needle puncture between the ribs. In this procedure, the placement of the Channel Maker(TM) optical fiber will be observed by the surgeon through an endoscope, which is inserted into the chest cavity through a separate puncture beneath the rib cage.

In late 1997, Cardiodyne plans to request FDA approval to commence a clinical trial of its patented Spectraprobe(TM) optical fiber percutaneously through a catheter, which would be inserted into a puncture in the patient's femoral artery in the groin and moved through the arterial system into the left ventricle, the main pumping chamber of the heart. In this procedure, the TMR channels will be made part way through the heart wall "from the inside", eliminating the risk of bleeding from the heart's surface.

Extensive, controlled clinical trials, demonstrating the safety and efficacy of Cardiodyne's TMR System versus conventional therapies, will be required before Cardiodyne can submit a Pre-Market Approval ("PMA") application to the FDA to market its TMR System for use in TMR. This process could take two to three years, or longer, and will require Cardiodyne's raising additional funds. Until U.S. marketing approval is obtained, Cardiodyne plans to market its TMR Systems overseas, particularly in countries whose health care budgets cannot afford the high cost of coronary bypass surgery or balloon angioplasty.

E. Phillip Palmer recently joined Cardiodyne as its President and Chief Operating Officer. Mr. Palmer was formerly Vice President-Corporate Development of St. Jude Medical, Inc. Prior thereto, he was Vice President-Global Sales and Marketing of Pacesetter, Inc., a $400 million manufacturer of cardiac pacemakers and cardiac rhythm devices. Earlier, he was Director of Operations in Europe, Africa and the Middle East for Medtronic, Inc.

LICENSE AND PATENT AGREEMENTS

The Company acquired an exclusive license to a U.S. Patent covering a device and method for depositing a tiny coil of platinum wire in an aneurysm in a blood vessel in the brain. An aneurysm occurs when a portion of the wall of a blood vessel becomes weakened and balloons out, like a bubble on an automobile tire. Depositing platinum coils in the aneurysm causes a clot to form, filling the aneurysm and taking the pressure off the weakened vessel wall. An estimated 90,000 brain aneurysms are diagnosed annually in the United States. In 1995 the Company filed a U.S. Patent application on an improved device for delivering and releasing coils in brain aneurysms. (See "New Products" above).

In 1996, the Company acquired an exclusive license to a U.S. Patent covering a unique laser device for use in gynecology for the treatment of menhorragia (excessive uterine bleeding). An estimated 200,000 surgeries are performed annually in the United States to treat this condition. This device may also be useful in urology for the treatment of BPH. The Company believes this patent, which has also issued in the United Kingdom and Germany, may enable the

Company to enter the gynecology field and , possibly in the urology field, although such cannot be assured.
(See "New Products" above.)

In 1995, the Company acquired sole ownership of a U.S. Patent covering the therapeutic use in the heart of a laser or any other source of energy synchronized with the movement of the heart, triggered from the patient's ECG. The use of lasers not properly synchronized with the patient's ECG has been shown to increase the incidence of life threatening arrhythmia (irregular, sometimes uncontrollable heartbeats). The Company believes this patent, which was issued in 1988, is the basic patent covering ECG synchronization in the TMR field. This patent was exclusively licensed to Cardiodyne. (See "Cardiodyne" above.)

In 1993, the Company acquired sole ownership of a U.S. Patent covering an expandable laser angioplasty catheter. In November, 1995, the Company was issued a U.S. Patent covering an improved, expandable laser




angioplasty catheter. Since coronary arteries are almost always larger in diameter than conventional catheters, it is necessary to follow the laser procedure with balloon angioplasty to widen the channel, which can result in reclosure of the vessel. These U.S. Patents may enable the Company to develop an expandable laser catheter able to create a channel significantly larger than the catheter's original diameter and restore normal blood flow, without the need to follow the laser procedure with balloon angioplasty. These patents have been exclusively licensed to Cardiodyne. (See "Cardiodyne" above.)

In 1994, the Company acquired an exclusive, worldwide license to a U.S. Patent (pending in several foreign countries) covering a temporary, removable stent and coronary infusion catheter for relieving abrupt reclosure (generally due to spasm of the vessel) or dissection (separation of the plaque from the vessel wall), a condition which occurs in approximately 5% and 9%, respectively, of the estimated 400,000 coronary balloon angioplasty procedures performed each year in the United States. This patent has been exclusively licensed to Cardiodyne. (See "Cardiodyne" above.)

The Company also has license agreements with a number of universities and inventors, under which royalties on sales, if any, are payable, and one license agreement with a competitor under which an annual maximum royalty is payable. U.S. Patents covering certain of the Company's products have also been issued to officers and employees of the Company and have been assigned to the Company without royalty. In addition, patent applications by officers and employees of the Company are on file with the U.S. Patent Office (and in a number of foreign countries) and have been assigned to the Company without royalty. These 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.

PLASTIC OPTICAL FIBERS

In 1983, the Company acquired Poly-Optical Products, Inc. ("Poly-Optical"), a manufacturer of fiber-optic lighting and viewing devices. Poly-Optical owns several U.S. Patents and pending U.S. Patent applications, certain of which cover products the Company believes have potential for backlighting membrane switches and liquid crystal displays. In December 1986, the Company sold 10% of the outstanding stock of Poly-Optical to Mitsubishi-Rayon Limited, Inc. ("Mitsubishi").

Poly-Optical's product line consists of both high and low loss polymeric (plastic) optical fibers. These products sell for a wide range of prices, depending upon the size, shape and manufacturing complexity involved. Current customers include the automotive and truck manufacturing industry, scientific instrument manufacturers, the aircraft industry and medical device firms. For the fiscal year ended September 30, 1996, Poly-Optical had sales of $3,105,000 and income from operations of $252,000, compared to sales of $3,403,000 and income from operations of $373,000 in the prior year.

The Company has entered into an agreement, subject to, among other significant matters, the availability of financing, for the sale of Poly-Optical. In the event that the proposed sale of Poly-Optical is not consummated, the Company plans to continue operating Poly-Optical as a subsidiary.

RESEARCH AND DEVELOPMENT

From its inception to September 30, 1996, an aggregate of $27,720,000 has been expended by the Company for research and development ("R&D"), including clinical and regulatory activities, of which $2,378,000 was expended during the fiscal year ended September 30, 1996. As it has in the past, the Company intends to continue to contract with unaffiliated hospitals and research institutions for the clinical testing of its developmental products.

MANUFACTURING, SUPPLY AGREEMENTS

Trimedyne and Poly-Optical believe that each has adequate engineering, design and manufacturing facilities (see "Properties" herein).

The Company has supply agreements with several vendors for components and materials used in the production of its products. 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 there is 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 products are hospitals with orthopedic, urology, and other surgical operating room facilities, as well as outpatient surgery facilities. In the United States, this market represents approximately 5,500 hospitals, as well as a number of outpatient surgery centers. There is no assurance as to the extent to which the Company will be able to penetrate this market. The Company anticipates marketing only those products which are customarily sold to the same customer groups that currently use its lasers and related devices.

At September 30, 1996, the Company had marketing arrangements for the sale of its lasers and certain of its disposable products on a straight commission basis with 23 independent sales representatives and organizations employing an estimated 44 sales persons specializing in the sale of medical devices in the United States. Outside the United States, the Company sells its products through 60 independent distributors who sell various medical products in approximately 60 foreign countries. The Company presently employs two Regional Sales Directors, a Vice President - International Sales, an International Sales Manager, a Marketing Director and a Clinical Education Director.

The Company hopes in the future to increase the number of domestic sales representatives and to appoint additional distributors in foreign countries for the purpose of expanding sales of the Company's products. There is no assurance that the Company will be able to enter into marketing arrangements with any or all of the persons or organizations with which it is presently negotiating 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 likely 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 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.

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.

Pre-Market 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 anticipates the majority of its cardiovascular products will be classified as Class III devices and that a PMA approval from the FDA will be required before the sale of each of such products commences. 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 new products can be obtained or that PMA approvals or 510(k) clearances for the Company's present products can be maintained. The failure to maintain PMA approvals and 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 upon the Company's future operations.

GMP Requirements

In October 1996, the FDA published a revision to its Good Manufacturing Practice ("GMP") regulations. Compliance with the new GMP regulations is required by June 1, 1997.

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 believes it is 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 Health Care Financing





Administration ("HCFA"), at either the state 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 definition by HCFA, 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 HCFA. Most private health insurance companies and state health care programs have standards for reimbursement similar to those of HCFA. If an application for reimbursement of a product is not approved by HCFA, 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 therefor, as well as making the necessary application to HCFA 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 market 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, 1996, the Company and Poly-Optical had 101 and 38 full-time employees, respectively, a total of 139, of whom 76 were engaged in production, 32 in R&D, 14 in sales and marketing, and 17 in general and administrative functions.

The Company may require additional employees in the areas of administration, product development, research, production, regulatory affairs, 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.

The Company believes its relations with its employees are good.

PATENTS AND PATENT APPLICATIONS

As of September 30, 1996, the Company had been assigned or obtained exclusive or non-exclusive , worldwide licenses to 15 issued U.S. Patents and 4 patent applications on file with the U.S. Patent Office. Several of such patents have issued as foreign patents and several corresponding patent applications have been filed in up to 7 foreign countries.

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 royalty and minimum payment obligations.

COMPETITION

The Company faces competition from a number of both young and established companies in the medical field. The larger of such established companies include Coherent, Inc., Bristol Myers, Inc., Smith & Nephew, Inc., Boston Scientific, Inc. and others, all of which have greater financial resources, engineering and manufacturing facilities, technical skills, management staffs and/or marketing organizations than the Company's.

Among the younger companies with which the Company may compete are Laserscope, Inc., Surgical Laser Technologies, Inc., Sharplan Lasers, Inc., PLC Systems, Inc., CardioGenesis, Inc., Eclipse Surgical Technologies, 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 $7,000,000 and a products liability insurance policy providing coverage in the aggregate amount 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 with its officers and directors.

INDUSTRY SEGMENT INFORMATION

Information about the industry segments in which the Company is engaged is provided in Note 1 and Note 13 of the Notes to Consolidated Financial Statements herein.

FOREIGN OPERATIONS

In fiscal 1996, sales of products in foreign countries accounted for approximately 20% of the Company's total sales. See "Marketing" herein for information on the marketing of the Company's products in foreign countries.

ITEM 2. PROPERTIES

The Company occupies approximately 40,000 square feet of office, manufacturing and warehouse space in Irvine, California, which it sub-leases at a monthly rent of approximately $17,830 per month. The sub-lease expires in December 1998. The Company also has an option to renew the sublease for one period of 30 months. This facility serves as the Company's headquarters, where research, regulatory, sales, marketing and administrative activities, as well as manufacturing and warehousing, are conducted.

Poly-Optical Products Inc. leases a 19,700 square foot one-story office and manufacturing building in Irvine, California, under a thirty month lease expiring in October, 1998 at a monthly rent of approximately $8,100, with one 30 month renewal option. As described under "Plastic Optical Fibers" herein, the Company has entered into an agreement, subject to financing, for the sale of Poly- Optical. The agreement for the sale of Poly-Optical includes a provision requiring the buyer to assume responsibility for Poly-Optical's facility lease.

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




ITEM 3. LITIGATION

In connection with the June 9, 1994 settlement of litigation with the co-inventor of the Urolase(R) fiber, the Company amended and restated its licensing agreement with the co-inventor. The Company paid $90,000 of the settlement amount for royalties owed on past Urolase(R) fiber sales and $585,000 of the settlement amount as a non-refundable prepayment of future royalties which otherwise would be owed to the co-inventor on future sales of the Urolase(R) fiber. In addition, the Company is required to pay a royalty on sales

of Urolase(R) fibers over the term of the agreement. At the end of fiscal 1996, the Company had a balance of $355,000 in prepaid royalties. On September 30, 1996, the Company established a reserve for the remaining prepaid royalty balance due to the uncertainty of future urology revenues..

In early 1995, the Company filed a lawsuit against Surgical Laser Technologies, Inc. (SLT) charging infringement of the Company's U.S. Patents No. 4,646,737 and 5,380,317, which are owned by the Company, and U.S. Patent No. 5,380,317, which is owned jointly by the Company and a co-inventor. The Court granted SLT's motion for summary judgment that all three U.S. Patents are not infringed by SLT's laser devices. The Company believes that the Court's granting SLT's motions for summary judgment is incorrect, and the Company has decided, upon advice of its counsel, to appeal the Court's decision on the latter two of the above patents.

As described above, on October 6, 1995, the Company filed a lawsuit against Bard claiming damages of at least $72 million for Bard's failure to perform its obligations as Trimedyne's exclusive distributor under the Agreement and pay certain amounts due under the agreement.

The Company has been named as a defendant in one product liability lawsuit which is being handled by the Company's insurance carrier. The Company believes this lawsuit will not have a material effect upon its finances and is expected to be either settled or dismissed in 1997. At the end of the fiscal year, the Company was not involved in any other lawsuits which are believed to have a material adverse effect on the Company's results of operations or financial position.

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

No matters were submitted to a vote of stockholders during the fourth quarter of the fiscal year ended September 30, 1996.



PART II

ITEM 5. MARKET FOR REGISTRANT'S COMMON STOCK AND RELATED STOCKHOLDER MATTERS

A. Market Information

The Company's Common Stock has been traded in the over-the-counter market since April 13, 1982, and has been quoted on the NASDAQ system since the commencement of trading under the symbol "TMED". On August 12, 1986, the Common Stock was approved for trading in the NASDAQ National Market System. 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 on the National Market System.

<TABLE>
<CAPTION>

| 1995 | HIGH | LOW |
|---|---|---|
| <S> | <C> | <C> |
| Quarter ended: | | |
| December 31, 1994 | 4 5/8 | 2 3/4 |
| March 31, 1995 | 3 5/8 | 2 1/4 |
| June 30, 1995 | 3 5/8 | 1 11/16 |
| September 30, 1995 | 5 1/8 | 2 |

<CAPTION>

| 1996 | HIGH | LOW |
|---|---|---|
| <S> | <C> | <C> |
| Quarter ended: | | |
| December 31, 1995 | 4 | 1 15/16 |
| March 31, 1996 | 16 1/4 | 2 9/32 |
| June 30, 1996 | 9 1/4 | 5 |
| September 30, 1996 | 7 | 3 1/16 |

</TABLE>

B. Holders of Common Stock

As of December 23, 1996, there were 1,692 holders of record of the Company's Common Stock and an additional estimated 7,000 holders who maintain the ownership of their shares in "Street Name".

C. Dividends

The Company has never paid cash dividends on its Common Stock. The Board of Directors currently intends to follow a policy of retaining earnings to finance the growth and development of the Company's business 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.

ITEM 6. SELECTED FINANCIAL DATA

STATEMENT OF OPERATIONS DATA:
(In thousands, except per share data)

<TABLE>
<CAPTION>

| | Fiscal Year Ended September 30, | | | | |
|---|---|---|---|---|---|
| | 1996 | 1995 | 1994 | 1993 | 1992 |
| <S> | <C> | <C> | <C> | <C> | <C> |
| Net revenues | $12,488 | $13,041 | $13,393 | $15,724 | $11,366 |
| Loss from operations | (5,106) | (5,206) | (2,774) | (1,109) | (3,035) |
| Net loss | (4,729) | (5,290) | (2,265) | (561) | (1,961) |
| Net loss per share | (.47) | (.56) | (.25) | (.06) | (.24) |

</TABLE>





BALANCE SHEET DATA:
(In thousands)

<TABLE>
<CAPTION>

| | At September 30, | | | | |
|---|---|---|---|---|---|
| | 1996 | 1995 | 1994 | 1993 | 1992 |
| <S> | <C> | <C> | <C> | <C> | <C> |
| Total assets | $17,739 | $15,040 | $20,498 | $21,554 | $22,405 |
| Total liabilities | 2,302 | 2,941 | 3,304 | 2,949 | 3,665 |
| Working capital | 13,919 | 10,082 | 14,829 | 16,673 | 16,779 |
| Stockholders' equity | 15,270 | 11,957 | 17,081 | 18,517 | 18,649 |

</TABLE>

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

Consolidated Results of Operations
Fiscal years 1996, 1995 and 1994

The following table sets forth certain items in the consolidated statements of operations as a percentage of net revenues for the year ended September 30, 1996 and the prior two fiscal years.

Year Ended September 30,

<TABLE>
<CAPTION>

| | 1996 | 1995 | 1994 |
|---|---|---|---|
| <S> | <C> | <C> | <C> |
| Net revenues | 100.0% | 100.0% | 100.0% |
| Cost of goods sold | 62.3 | 65.8 | 54.1 |
| Research and development | 19.0 | 19.9 | 19.2 |
| Selling, general and administrative | 59.6 | 54.2 | 47.4 |
| Interest income | (3.2) | (2.4) | (2.7) |
| Other (income) expense, net | 0 | 3.0 | (1.1) |
| Net loss | 37.9 | 40.6 | 16.9 |

</TABLE>

Net Revenues

1996 Compared to 1995

Net revenues decreased 4% in fiscal 1996 to $12,488,000 from $13,041,000. Sales in fiscal 1996 decreased from fiscal 1995 principally due to lower sales of plastic fiber optics which declined $298,000 or 9% and sales of urology products which declined $345,000 or 33%. This decline was partially offset by an increase of $177,000 or 2% in orthopedic sales. Total international revenues, which consists of medical device sales, for fiscal 1996 were $2,449,000 compared to $2,055,000 in fiscal 1995 representing 20% of revenues in fiscal 1996 compared to 16% in fiscal 1995. Laser and disposable device sales in orthopedics accounted for approximately 64% of revenues in fiscal 1996 compared to approximately 60% in fiscal 1995.

1995 Compared to 1994

Net revenues decreased 3% in fiscal 1995 to $13,041,000 from $13,393,000 in fiscal 1994. Sales in fiscal 1995 decreased from fiscal 1994 principally due to significantly lower sales of urology products to Bard, which declined $3,724,000 or approximately 78%. This decline was partially offset by a $3,059,000 or 65% increase in orthopedic sales and a 13% increase in Poly-Optical revenues. Total international revenues, which consists of medical device sales, for fiscal 1995 were $2,055,000 compared to $2,035,000 in fiscal 1995, representing 16% and 15% of revenues in fiscal year 1995 and 1994, respectively. Laser and fiber optic device sales in urology and orthopedics accounted for approximately 68% of revenues in fiscal 1995 compared to approximately 70% in fiscal 1994.





Cost of Goods Sold

Cost of goods sold in fiscal 1996 was approximately 62% of net revenue compared to 66% in fiscal 1995 and 54% in fiscal 1994

1996 Compared to 1995

The decrease in cost of goods sold as a percentage of sales was the result of lower material and warranty costs associated with the higher powered Holmium laser, which was first introduced in fiscal 1994, for use in orthopedics offset by additional inventory write-downs of approximately $352,000.

1995 Compared to 1994

The increase in cost of goods sold as percentage of sales was the result of the significant shift in the Company's product mix from urology to orthopedic products, which carry lower profit margins, a write-down of urology inventories, and greater warranty costs associated with the higher powered Holmium laser for use in orthopedics.

Research and Development Expenses (R&D)

R&D expenses were $2,378,000 in fiscal 1996, compared to $2,599,000 in fiscal 1995, and $2,578,000 in fiscal 1994 . R&D spending in fiscal 1997 is expected to be approximately equal to the fiscal 1996 level, as the Company intends to continue to fund development of several new products. R&D as a percentage of net revenues declined slightly to 19% of net revenues in fiscal 1996 vs. 20% and 19% in fiscal years 1995 and 1994, respectively. The decrease in R&D expenses in 1996 was attributed to prior year expenses associated with the development work on the Holmium and Nd:YAG lasers, which has been largely completed.

Selling, General and Administrative Expenses

Selling, general and administrative ("SG&A") expenses increased 5 % to $7,437,000 in fiscal 1996, compared to $7,067,000 in fiscal 1995, which was an 11% increase from the fiscal 1994 total of $6,345,000. This increase was due primarily to the approximately $600,000 increase in legal expenses in fiscal 1996 compared to fiscal 1995 offset in part by lower marketing expenses and commissions paid on decreased sales. Legal expenses associated with current litigation the company is involved in are anticipated to decline in fiscal 1997.

SG&A expenses increased as a percentage of net revenues in fiscal 1996 over fiscal 1995 and 1994 (60%, 54%,and 47%, respectively), due to a higher level of legal expenses incurred as noted above, in connection with litigation.

Interest Income, Taxes and Net Loss

Interest income in fiscal 1996 was $395,000, compared to $309,000 in fiscal 1995 and $359,000 in fiscal 1994. The levels of cash and equivalents available for investment in interest bearing securities were $8,100,000, $4,415,000, and $8,661,000 as of September 30, 1996, 1995 and 1994, respectively. In 1996, the Company generated higher income on its investments than in 1995 due to the higher overall level of cash available for investment during the current fiscal year.

The fiscal 1996 net loss was $4,729,000 compared to a net loss of $5,290,000 in fiscal 1995 and $2,265,000 in fiscal 1994.

Due to the net losses incurred, the Company did not pay income taxes for fiscal 1996, 1995 and 1994.

Liquidity and Capital Resources

As of September 30, 1996, the Company had working capital of $13,919,000, compared to $10,082,000 at the end of fiscal 1995. Cash, cash

equivalents and marketable securities increased by $3,685,000 in fiscal 1996 to $8,100,000 at September 30, 1996 from $4,415,000 at September 30, 1995. The increase in working capital and cash,




cash equivalents and marketable securities was due to the following fiscal 1996 events: (i) the Company completed an offering of equity securities, which included the sale of 855,000 shares of common stock along with warrants to purchase 338,750 shares of common stock, resulting in net proceeds of $4.5 million and (ii) the exercise of stock options by employees, repayment of option exercise loans and the exercise of outstanding warrants resulting in the receipt of approximately $3.5 million in cash proceeds. These factors were partially offset by cash used for operating activities totaling approximately $4 million and capital and patent expenditures of $354,000.

The Company believes its current cash and cash equivalents and other resources will be sufficient to meet its anticipated operating and capital requirements for at least the next two years.

ITEM 8. FINANCIAL STATEMENTS AND SUPPLEMENTARY DATA

The financial statements and financial statement schedules required by Item 8 of this report are set forth in the index on page F-1.

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

None.

## PART III

ITEM 10. IDENTIFICATION OF DIRECTORS AND EXECUTIVE OFFICERS

Information with respect to this item is incorporated by reference from the Company's definitive Proxy Statement to be filed with the Commission within 120 days after the close of Registrant's fiscal year.

ITEM 11. EXECUTIVE COMPENSATION

Information with respect to this item is incorporated by reference from the Company's definitive Proxy Statement to be filed with the Commission within 120 days after the close of Registrant's fiscal year.

ITEM 12. SECURITY OWNERSHIP OF CERTAIN BENEFICIAL OWNERS AND MANAGEMENT

Information with respect to this item is incorporated by reference from the Company's definitive Proxy Statement to be filed with the Commission within 120 days after the close of Registrant's fiscal year.

ITEM 13. CERTAIN RELATIONSHIPS AND RELATED TRANSACTIONS

Information with respect to this item is incorporated by reference from the Company's definitive Proxy Statement to be filed with the Commission within 120 days after the close of Registrant's fiscal year.





## PART IV

ITEM 14. EXHIBITS, FINANCIAL STATEMENT SCHEDULES, AND REPORTS ON FORM 8-K

(a) The following documents are filed as a part of this report:

1. Financial Statements.

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

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

3. Exhibits pursuant to No. 10 of Item 601 of S-K.

FILED PREVIOUSLY

10(a) Agreement with James Capel Incorporated dated August 1, 1991.

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(e) Poly-Optical lease with Elpal Electronics Inc. dated August 13, 1993.

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

10(g) Patent assignment agreement with Robert Ginsburg, M.D. dated July 1, 1993

10(h) License agreement with Christodoulos Stafanadis, M.D. and Pavlos Toutouzas, M.D. dated April 1, 1993

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

10(j)* Settlement Agreement and Mutual Release among Royice B. Everett, M.D., Trimedyne, Inc., and C.R. Bard dated June 9, 1994.

10(k)* Settlement Agreement and Mutual Release among Myriadlase, Inc., Trimedyne, Inc., and C.R. Bard dated June 9, 1994.

10(l)* Amended and Restated Licensing Agreement with Royice B. Everett M.D. dated June 9, 1994.

10(m)* License Agreement with Coherent dated December 9, 1994.

FILED HEREWITH

23.1 Consent of Independent Accountants

27 Financial Data Schedule

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



(b) No reports on Form 8-K were filed during the fourth quarter of the fiscal year ended September 30, 1996.

## 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: December 24, 1996

/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.

<TABLE>
<CAPTION>

| Signature | Title | Date |
|---|---|---|
| <S> | <C> | <C> |
| /s/ Marvin P. Loeb<br>---<br>Marvin P. Loeb | Chairman of the Board of Directors<br>Chief Executive Officer | Dec. 24, 1996 |
| /s/ Peter T. Hyde<br>--- | President and Chief Operating | Dec. 24, 1996 |

| | | |
|---|---|---|
| Peter T. Hyde | Officer | |
| /s/ Donald Baker<br>Donald Baker | Director | Dec. 24, 1996 |
| /s/ Bruce N. Barron<br>Bruce N. Barron | Director | Dec. 24, 1996 |
| /s/ Richard F. Horowitz<br>Richard F. Horowitz | Director | Dec. 24, 1996 |
| /s/ James L. Kelly<br>James L. Kelly | Vice President-<br>Finance and<br>Chief Financial<br>and Accounting Officer | Dec. 24, 1996 |

</TABLE>





TRIMEDYNE, INC.

INDEX TO CONSOLIDATED FINANCIAL STATEMENTS

The following consolidated financial statements of Trimedyne, Inc. and its subsidiary are included in Item 8:


| | Page |
|---|---|
| Consolidated Financial Statements: | |
| Report of Independent Accountants | F-2 |
| Consolidated Balance Sheets at September 30, 1996 and 1995 | F-3 |
| Consolidated Statements of Operations for the three years ended September 30, 1996 | F-4 |
| Consolidated Statements of Changes in Stockholders' Equity for the three years ended September 30, 1996 | F-5 |
| Consolidated Statements of Cash Flows for the three years ended September 30, 1996 | F-6 |
| Notes to Consolidated Financial Statements | F-7 |


The following consolidated financial statement schedule of Trimedyne, Inc. and its subsidiary are included in Item 14(d):


| | | Page |
|---|---|---|
| II. | Valuation and qualifying accounts | F-15 |


All other schedules for which provision is made in the applicable accounting regulation of the Securities and Exchange Commission are not required under the related instructions or are inapplicable and, therefore, have been omitted.





REPORT OF INDEPENDENT ACCOUNTANTS

To the Board of Directors and Stockholders of Trimedyne, Inc.

In our opinion, the consolidated financial statements listed in the index appearing under Item 14. (a)(1) and (2) on page F-1 present fairly, in all material aspects, the financial position of Trimedyne, Inc. and its subsidiary at September 30, 1996 and 1995, and the results of their operations and their cash flows for each of the three years in the period ended September 30, 1996, in conformity with generally accepted accounting principles. These financial

statements are the responsibility of the Company's management; our responsibility is to express an opinion on these financial statements based on our audits. We conducted our audits of these statements in accordance with generally accepted auditing standards which require that we plan and perform the audit to obtain reasonable assurance about whether the financial statements are free of material misstatement. An audit requires examining, on a test basis, evidence supporting the amounts and disclosures in the financial statements, assessing the accounting principles used and significant estimates made by management, and evaluating the overall financial statement presentation. We believe that our audits provide a reasonable basis for the opinion expressed above.

PRICE WATERHOUSE LLP
Costa Mesa, California
December 24, 1996



TRIMEDYNE, INC.
CONSOLIDATED BALANCE SHEETS
ASSETS

<TABLE>
<CAPTION>

| | SEPTEMBER 30, 1996 | SEPTEMBER 30, 1995 |
|---|---|---|
| <S> | <C> | <C> |
| Current assets: | | |
| Cash and cash equivalents | $ 5,575,000 | $ 1,367,000 |
| Marketable securities (Note 2) | 2,525,000 | 3,048,000 |
| Trade accounts receivable, net of allowance for doubtful accounts of $337,000 and $315,000 | 2,512,000 | 2,098,000 |
| Inventories (Note 3) | 5,214,000 | 5,798,000 |
| Other | 395,000 | 712,000 |
| Total current assets | 16,221,000 | 13,023,000 |
| Net properties (Note 3) | 1,224,000 | 1,368,000 |
| Prepaid royalties (Note 10) | | 355,000 |
| Intangible assets, net of accumulated amortization of $373,000 and $315,000 | 294,000 | 294,000 |
| | $ 17,739,000 | $ 15,040,000 |
| LIABILITIES AND STOCKHOLDERS' EQUITY | | |
| Current liabilities: | | |
| Accounts payable | $ 683,000 | $ 1,021,000 |
| Accrued expenses (Note 3) | 1,433,000 | 1,833,000 |
| Deferred income (Note 2) | 186,000 | 87,000 |
| Total current liabilities | 2,302,000 | 2,941,000 |
| Commitments and contingencies (Notes 9 and 10) | | |
| Minority interest (Note 2) | 167,000 | 142,000 |
| Stockholders' equity (Note 6): | | |
| Common stock - .01 par value; 15,000,000 shares authorized, 10,991,956 and 9,573,910 shares issued | 110,000 | 96,000 |
| Capital in excess of par value | 42,081,000 | 35,007,000 |
| Accumulated deficit | (26,175,000) | (21,446,000) |
| Notes receivable under stock option plans (Notes 2 and 8) | | (982,000) |
| Unrealized gain on securities available for sale | (33,000) | (5,000) |
| | 15,983,000 | 12,670,000 |
| Less shares of common stock in treasury, 101,609 and 101,609 shares | (713,000) | (713,000) |
| Total stockholders' equity | 15,270,000 | 11,957,000 |
| | $ 17,739,000 | $ 15,040,000 |

</TABLE>

See Notes to Consolidated Financial Statements

22

TRIMEDYNE, INC.
CONSOLIDATED STATEMENTS OF OPERATIONS

<TABLE>
<CAPTION>

| | FOR THE YEAR ENDED SEPTEMBER 30, | | |
|---|---|---|---|
| | 1996 | 1995 | 1994 |
| <S> | <C> | <C> | <C> |
| Net revenues | $12,488,000 | $13,041,000 | $13,393,000 |
| Costs of goods sold | 7,779,000 | 8,581,000 | 7,244,000 |
| Gross Profit | 4,709,000 | 4,460,000 | 6,149,000 |
| Selling, general and administrative expenses | 7,437,000 | 7,067,000 | 6,345,000 |
| Research and development expenses | 2,378,000 | 2,599,000 | 2,578,000 |
| Loss from operations | (5,106,000) | (5,206,000) | (2,774,000) |
| Other income (expense): | | | |
| Interest income | 395,000 | 309,000 | 359,000 |
| Minority interest in earnings of consolidated subsidiary company | (25,000) | (29,000) | (25,000) |
| Other | 7,000 | (364,000) | 175,000 |
| Loss before income taxes | (4,729,000) | (5,290,000) | (2,265,000) |
| Income tax provision (Note 5) | | | |
| Net loss | $(4,729,000) | $(5,290,000) | $(2,265,000) |
| Net loss per share (Note 2) | $ (.047) | $ (0.56) | $ (0.25) |

</TABLE>

See Notes to Consolidated Financial Statements



23

TRIMEDYNE, INC.
CONSOLIDATED STATEMENTS OF CHANGES IN STOCKHOLDERS' EQUITY

<TABLE>
<CAPTION>

| | COMMON STOCK $.01 PAR VALUE | | CAPITAL IN EXCESS OF | ACCUMULATED | TREASURY | NOTE RECEIVABLE UNDER STOCK |
|---|---|---|---|---|---|---|
| | SHARES | AMOUNT | PAR VALUE | DEFICIT | STOCK | OPTION PLANS |
| <S> | <C> | <C> | <C> | <C> | <C> | <C> |
| Balance at September 30, 1993 | 9,074,490 | $ 91,000 | $33,030,000 | $(13,891,000) | $(713,000) | |
| Exercise of stock options | 419,820 | 5,000 | 1,376,000 | | | |
| Exercise of stock warrants | 44,000 | | 460,000 | | | |
| Stock issued to Company's 401(k) plan | 10,000 | | 66,000 | | | |
| Notes receivable from officer | | | | | | $(982,000) |
| Net loss for the year | | | | (2,265,000) | | |
| Balance at September 30, 1994 | 9,548,310 | 96,000 | 34,932,000 | (16,156,000) | (713,000) | (982,000) |
| Exercise of stock options | 25,600 | | 75,000 | | | |
| Net loss for the year | | | | (5,290,000) | | |
| Balance at September 30, 1995 | 9,573,910 | 96,000 | 35,007,000 | (21,446,000) | (713,000) | (982,000) |
| Net proceeds from securities offering | 855,000 | 9,000 | 4,576,000 | | | |
| Exercise of stock warrants | 30,000 | | 309,000 | | | |
| Exercise of stock options | 513,046 | 5,000 | 2,129,000 | | | |
| Stock issued to Company's 401K plan | 20,000 | | 60,000 | | | |
| Payments received from officer | | | | | | 982,000 |
| Net loss for the year | | | | (4,729,000) | | |
| Balance at September 30, 1996 | 10,991,956 | $110,000 | $42,081,000 | $(26,175,000) | $(713,000) | $ 0 |

</TABLE>

</TABLE>

See Notes to Consolidated Financial Statements



TRIMEDYNE, INC.
CONSOLIDATED STATEMENTS OF CASH FLOWS

<TABLE>
<CAPTION>

| | FOR THE YEAR ENDED SEPTEMBER 30, | | |
|---|---|---|---|
| | 1996 | 1995 | 1994 |
| <S> | <C> | <C> | <C> |
| Cash flows from operating activities: | | | |
| Net loss | $(4,729,000) | $(5,290,000) | $(2,265,000) |
| Adjustments to reconcile net loss to net cash used for operating activities: | | | |
| Depreciation and amortization | 499,000 | 567,000 | 548,000 |
| Provision for excess and obsolete inventory | 352,000 | 122,000 | 319,000 |
| Write-off of prepaid royalties | 355,000 | | |
| Loss on disposal of assets | (2,000) | 21,000 | 45,000 |
| Minority interest in earnings of subsidiary | 25,000 | 29,000 | 25,000 |
| Changes in operating assets and liabilities: | | | |
| (Increase) decrease in trade accounts receivable, net | (414,000) | 510,000 | 531,000 |
| Decrease (increase) in inventories | 232,000 | (190,000) | (1,517,000) |
| Decrease in other current assets | 317,000 | 422,000 | 8,000 |
| Decrease (increase) in prepaid royalties | | 84,000 | (439,000) |
| (Decrease) increase in accounts payable | (338,000) | (276,000) | 610,000 |
| (Decrease) increase in accrued expenses | (400,000) | 8,000 | (275,000) |
| Increase (decrease) in deferred income | 100,000 | (95,000) | 20,000 |
| Net cash used for operating activities | (4,003,000) | (4,088,000) | (2,390,000) |
| Cash flows from investing activities: | | | |
| Capital expenditures | (296,000) | (259,000) | (608,000) |
| Patent expenditures | (58,000) | (65,000) | (42,000) |
| Payments received on note receivable from sale of subsidiary | | | 63,000 |
| Sale of (investment in) marketable securities | 495,000 | 2,521,000 | (1,915,000) |
| Net cash provided by (used for) investing activities | 141,000 | 2,197,000 | (2,502,000) |
| Cash flows from financing activities: | | | |
| Proceeds from exercise of stock options | 2,134,000 | 75,000 | 399,000 |
| Proceeds from stock issued under 401(k) program | 60,000 | | 66,000 |
| Net proceeds from exercise of warrants | 309,000 | | 460,000 |
| Net proceeds from securities offering | 4,585,000 | | |
| Payments received on notes receivable under stock option plan | 982,000 | | |
| Net cash provided by financing activities | 8,070,000 | 75,000 | 925,000 |
| Net increase (decrease) in cash and cash equivalents | 4,208,000 | (1,816,000) | (3,967,000) |
| Cash and cash equivalents at beginning of period | 1,367,000 | 3,183,000 | 7,150,000 |
| Cash and cash equivalents at end of period | $ 5,575,000 | $ 1,367,000 | $ 3,183,000 |

</TABLE>

See Notes to Consolidated Financial Statements



TRIMEDYNE, INC.
NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

NOTE 1. THE COMPANY:

Trimedyne, Inc. ("the Company") is engaged primarily in the research and development, manufacture and sale of lasers and disposable laser devices in the medical field. The Company is also engaged in the development, manufacture

and sale of plastic fiber-optic illumination devices through its subsidiary, Poly-Optical Products, Inc. ("Poly-Optical").

NOTE 2. SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES:

Basis of Presentation

The consolidated financial statements include the accounts of the Company and its 90% owned subsidiary, Poly-Optical Products, Inc. All significant intercompany accounts and transactions have been eliminated in consolidation.

Inventories

Inventories are recorded at the lower of cost or market, cost being determined on a first-in, first-out (FIFO) basis.

Use of estimates by management

The preparation of financial statements in conformity with generally accepted accounting principles 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 those made surrounding inventory valuation. The Company's inventory largely relates to technologies which have yet to gain wide spread market acceptance. Management believes no loss will be incurred on the disposition of its inventory. If wide spread market acceptance of the Company's products is not achieved, the carrying amount of inventory could be materially reduced.

Depreciation and amortization

Depreciation of furniture and equipment is calculated on a straight-line basis over the estimated useful lives of the assets ranging from three to seven years. Leasehold improvements are amortized on a straight-line basis over the lesser of the useful lives or the term of the lease. Intangible assets, which consist primarily of patents, are amortized on a straight-line basis over the life of the patent.

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 accounts for income taxes in accordance with Statement of Financial Accounting Standards No. 109 (SFAS 109), Accounting for Income Taxes. SFAS 109 requires the liability method for accounting for income taxes.



The liability method 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.

Accounting for stock-based compensation

The Financial Accounting Standards Board has issued Statement of Financial Accounting Standards No. 123, "Accounting for Stock-Based Compensation" ("SFAS 123"), effective for years beginning after December 15, 1995, which establishes a fair value-based method of accounting for stock-based compensation plans. The statement allows companies to continue to use the intrinsic value-based approach, supplemented by footnote disclosure of the pro forma net income and earnings per share of the fair value-based approach. The Company intends to follow this method allowed by SFAS 123.

Loss per share

Loss per share is based on the weighted average number of common shares outstanding. Common stock equivalents are not included in the calculation because their inclusion would be antidilutive. Common stock equivalents include dilutive stock options and warrants, if any, using the treasury stock method. The weighted average number of shares used in the calculation of earnings per share for the three years ended September 30 are 10,082,844, 9,449,468, and 9,052,089 for 1996, 1995 and 1994, respectively.

Extended warranty/service contracts and deferred income

Deferred income consists of the unamortized portion of payments received from customers for extended warranty contracts. Revenue earned under these service contracts is recognized ratably over the life of the related contract (typically one year).

Cash and cash equivalents

Cash in excess of requirements is principally invested in short-term corporate and government obligations, money market funds and certificates of deposit with an average maturity of three months or less. Such investments are deemed to be cash equivalents for purposes of the Statements of Cash Flows.

Marketable Securities

The amortized cost and fair market values of all marketable securities at September 30, 1996 are as follows:

<TABLE>
<CAPTION>

| Securities available for sale (mature within three years) | Amortized Cost Basis (plus interest) | Fair Value (plus accrued interest) | Gross Unrealized Gain |
|---|---|---|---|
| <S> | <C> | <C> | <C> |
| U.S. government and government agencies | $2,492,000 | $2,525,000 | $33,000 |

</TABLE>

The specific identification method has been used to determine cost for each security. The net unrealized holding gain on securities available for sale which is included in stockholders' equity for fiscal 1996 was $33,000. These securities are interest-earning securities.

Consolidated Statements of Cash Flows

During fiscal 1994, an officer-director exercised a 340,000 share stock option and borrowed $982,000 under the Employee Stock Option Loan Program. In March 1996 the loan was repaid in full with accrued interest of $112,643.

The Company made no cash payments for interest or income taxes in 1996, 1995, or 1994.



NOTE 3. COMPOSITION OF CERTAIN BALANCE SHEET CAPTIONS:

Inventories consist of the following at September 30, 1996 and 1995:

<TABLE>
<CAPTION>

| | 1996 | 1995 |
|---|---|---|
| <S> | <C> | <C> |
| Raw materials | $3,280,000 | $3,362,000 |
| Work-in-process | 1,584,000 | 633,000 |
| Finished goods | 3,445,000 | 4,546,000 |
| | 8,309,000 | 8,541,000 |
| Reserve for excess and obsolete inventory | (3,095,000) | (2,743,000) |
| Net inventory | $5,214,000 | $5,798,000 |

</TABLE>

Net properties consist of the following at September 30, 1996 and 1995:

<TABLE>
<CAPTION>

| | 1996 | 1995 |
|---|---|---|
| <S> | <C> | <C> |
| Furniture and equipment | $4,321,000 | $ 4,593,000 |
| Leasehold improvements | 278,000 | 278,000 |
| Other | 637,000 | 72,000 |
| | 5,236,000 | 4,943,000 |
| Accumulated depreciation and amortization | (4,012,000) | (3,575,000) |
| Net properties | $1,224,000 | $ 1,368,000 |

</TABLE>

</TABLE>

Accrued expenses consist of the following at September 30, 1996 and 1995:

<TABLE>
<CAPTION>

| | 1996 | 1995 |
|---|---|---|
| <S> | <C> | <C> |
| Professional fees | $ 72,000 | $ 198,000 |
| Commissions | 292,000 | 401,000 |
| Salaries, wages and benefits | 459,000 | 549,000 |
| Sales tax | 201,000 | 268,000 |
| Printing | 84,000 | 89,000 |
| Product warranty | 177,000 | 186,000 |
| Other | 148,000 | 142,000 |
| | $1,433,000 | $1,833,000 |

</TABLE>

NOTE 4. DEVELOPMENT SUPPLY AND LICENSE AGREEMENT

In June 1991, the Company entered into an agreement (the "Agreement") granting worldwide rights to market the Company's side-firing laser devices in the medical specialty fields of urology, gynecology and gastroenterology to C.R. Bard, Inc. ("Bard").

Pursuant to the terms of the Agreement, (i) the Company received a royalty amount (subject to certain specified volume adjustments) from the unit sales price for the Company's products charged by Bard to its customers, (ii) an



additional 4% of the unit sales price was appropriated to an escrow fund for reimbursing the Company for the future development of other urological products or improvements to existing urological products, (iii) the Company also received a monthly research and development allowance of $33,333 for the first twelve months of the agreement, and (iv) the cost of certain future patent preparation and filing cost was borne by Bard. In addition, Bard agreed to pay a portion of royalty and patent litigation costs relating to the Company's lateral lasing device (see Note 10). During fiscal 1995, in management's opinion, Bard discontinued fulfilling its obligations under the agreement. Accordingly, the Company initiated litigation against Bard (see Note 10).

Under the Agreement, net revenues and royalties earned from Bard accounted for 0%, 3%, and 23% of the Company's net revenues for the fiscal years ended September 30, 1996, 1995 and 1994, respectively. In addition, during the year ended September 30, 1996, 1995 and 1994, the Company incurred $0, $0 and $184,500, respectively, of reimbursable development costs related to urological applications. At September 30, 1996, 1995 and 1994, the Company included $382,000, $382,000 and 403,000 respectively, in other assets. Such amounts represent monies receivable from Bard for royalties earned, reimbursable legal costs incurred and reimbursable R&D expenses incurred. The Company recorded a reserve equal to the amount included in other assets, $382,000, as of September 30, 1996

NOTE 5. INCOME TAXES:

Due to the net operating losses incurred by the Company in the fiscal years ended September 30, 1996, 1995 and 1994, no provision for income taxes has been made. The deferred tax balances are comprised as follows:

<TABLE>
<CAPTION>

| | September 30, 1996 | September 30, 1995 |
|---|---|---|
| <S> | <C> | <C> |
| Deferred tax assets: | | |
| Net operating loss carryforwards | $ 8,593,000 | $ 6,574,000 |
| Research & development credits | 1,739,000 | 1,546,000 |
| Inventory obsolescence reserves | 1,238,000 | 1,056,000 |
| Accrued expenses | 332,000 | 360,000 |
| Account receivable reserves | 135,000 | 103,000 |
| Valuation allowance | (11,833,000) | (9,531,000) |
| | 204,000 | 108,000 |
| Deferred tax liabilities: | | |
| Fixed asset basis | (204,000) | (108,000) |
| | $ 0 | $ 0 |

</TABLE>

The net change in the valuation allowance for deferred tax assets was an increase of approximately $2,302,000 from the balance at September 30, 1995 The change primarily relates to additional net operating loss carryforwards generated in fiscal 1996, which were fully reserved for at September 30, 1996.

At September 30, 1996, the Company had net operating loss carryforwards for federal and state income tax purposes totaling approximately $22,863,000 and $13,664,000, respectively, which begin to expire in 2006. The Tax Reform Act of 1986 includes provisions which may limit the net operating loss carryforwards available for use in any given year if certain events occur, including significant changes in stock ownership.



NOTE 6 STOCKHOLDERS' EQUITY:

Securities Offering:

In March, 1996, the Company completed an offering of 855,000 shares of its common stock, which were sold with warrants to purchase 338,750 shares of common stock, resulting in net proceeds to the Company totaling $4,585,000. This offering was completed pursuant to Regulation S of the Securities and Exchange Commission.

Stock Options:

The Company has adopted stock option plans that authorize the granting of options to key employees, directors, and/or 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 within five years from the date of grant, and expire in ten years.

Activity during the years ended September 30, 1996, 1995 and 1994 under the plans was as follows:

Stock Options Outstanding

<TABLE>
<CAPTION>

| | Options | Option Exercise Price Per Share | Aggregate Exercise Price |
|---|---|---|---|
| <S> | <C> | <C> | <C> |
| September 30, 1993 | 1,326,050 | 1/100 - 9 3/4 | 7,683,741 |
| Granted | 287,000 | 3 5/8 - 14 5/8 | 2,515,750 |
| Exercised | (419,820) | 2 3/8 - 8 1/4 | (1,377,190) |
| Canceled | (65,400) | 2 3/8 - 11 1/4 | (429,075) |
| Exchanged | (956,080) | 5 7/8 - 14 5/8 | (7,741,733) |
| Reissued | 956,080 | 5 1/2 | 5,249,538 |
| September 30, 1994 | 1,127,830 | 1/100 - 5 1/2 | 5,901,031 |
| Granted | 302,500 | 2 3/4 - 3 3/8 | 1,034,562 |
| Exercised | (25,600) | 1/100 - 5 1/2 | (61,463) |
| Canceled | (25,400) | 3 3/8 - 5 1/2 | (105,411) |
| Exchanged | (697,080) | 3 5/8 - 5 1/2 | (3,766,838) |
| Reissued | 697,080 | 3 1/2 | 2,439,780 |
| September 30, 1995 | 1,379,330 | 1/100 - 5 1/2 | $5,441,661 |
| Granted | 489,000 | 2 3/4 - 6 7/8 | 3,205,220 |
| Exercised | (493,046) | 2 3/4 - 6 3/4 | (2,090,580) |
| Canceled | (139,150) | 2 3/8 - 6 5/8 | (520,209) |
| September 30, 1996 | 1,236,134 | 1/100 - 6 7/8 | 6,036,092 |

</TABLE>

As of September 30, 1996, the Company had granted all available options reserved for granting of options authorized under the above option plans. Of the shares previously granted and outstanding at September 30, 1996, 261,076 shares were vested and exercisable at prices ranging from $.01 to $5.50 per share.

As options are generally granted at an exercise price equal to the fair market value of the underlying stock at the date of grant, there are generally no charges to income in connection with the issuance of options. Upon exercise, proceeds from the sale of shares under the stock options plans are credited to common stock and additional paid-in capital.

On August 18, 1994 the Board of Directors approved the exchange of all outstanding Incentive Stock Options and Non-Qualified Stock Options held by directors, consultants, officers and employees of the Company that were in

excess of $5.50 per share for new options exercisable at $5.50 per share with the same vesting periods. The closing price of the common stock on such date was $3.25 as reported by the NASDAQ National Market System. On



September 11, 1995 the Board of Directors approved the exchange of all outstanding Incentive Stock Options and NonQualified Stock Options held by consultants, officers (excluding the President and the Chairman of the Company) and employees of the Company that were in excess of $3.50 per share for new options exercisable at $3.50 per share with the same vesting periods. The closing price of the common stock on such date was $3.375 as reported by the NASDAQ National Market System.

Warrants:

During fiscal 1994, 44,000 warrants issued in connection with a prior securities offering were exercised and total proceeds of $460,000 were received. During fiscal 1996, 30,000 warrants were exercised, resulting in proceeds of $309,000. As of September 30, 1996, 326,000 warrants were outstanding at an exercise price of $10.31, and 130,000 warrants at a price of $11.86 were outstanding.

In addition to the above warrants, in connection with the Company's sale of equity securities, the Company issued warrants with an exercise price ranging from $6.53 to $8.125, to purchase 338,750 shares of common stock. These warrants expire in May and June, 1998 and contain certain redemption features that, if the warrants are unexercised and the Company's shares are trading in excess of certain per share prices, allow the Company to redeem the warrants for $.01 each.

NOTE 7. EMPLOYEE BENEFIT PLAN:

Effective February 1, 1989, the Company adopted 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 2% of eligible employee compensation. Employees become vested in the Company's contribution at 20% per year over five years. The Company's contributions to the Retirement Plan totaled $72,000, $76,000, and $69,000, for 1996, 1995, and 1994, respectively.

NOTE 8. RELATED PARTY TRANSACTIONS:

The Company has made payments of $54,000, $30,000 and $43,000, in the fiscal years ending 1996, 1995 and 1994, respectively, to two law firms. A director of the Company is a member of one of the law firms. Another director was a member of the other law firm until his retirement from that law firm in 1994.

On August 18, 1994, the Compensation Committee of the Board of Directors approved a loan to an officer director for the purchase of 340,000 shares of Common Stock of the Company for an aggregate of $982,000 as a result of the exercise of Options. The principal amount and interest due was loaned without recourse to the officer-director, and the sole collateral for the note was the 340,000 shares of common stock held in the officer-director's name. In March 1996, the loan was repaid in full with accrued interest of $112,643.

NOTE 9. COMMITMENTS:

The Company is obligated under certain facility lease agreements to make minimum rental payments, excluding taxes and common area maintenance costs, for the years ending September 30 as follows:

<TABLE>
<S>

| | <C> |
|---|---|
| 1997 | $310,889 |
| 1998 | 324,929 |
| 1999 | 65,077 |
| TOTAL | $700,895 |

</TABLE>

The lease on the Company's headquarters facility expires in December, 1998. The Company has an option to renew the lease for one period of thirty months. The Company's Poly-Optical Products, Inc. facility lease expires October 31, 1998 and contains renewal options totaling two and one-half years.



Rent expense for the years ended September 30, 1996, 1995 and 1994 was

approximately $294,000, 315,000, and $280,000, respectively.

NOTE 10. LITIGATION:

In connection with the June 9, 1994 settlement of litigation with the co-inventor of the Urolase(R) fiber, the Company amended and restated its licensing agreement with the co-inventor. The Company paid $90,000 of the settlement amount for royalties owed on past Urolase(R) fiber sales and $585,000 of the settlement amount as a non-refundable prepayment of future royalties which otherwise would be owed to the co-inventor on future sales of the Urolase(R) fiber. In addition, the Company is required to pay a royalty on sales of Urolase(R) fibers over the term of the agreement. At the end of fiscal 1996, the Company had a balance of $355,000 in prepaid royalties. On September 30, 1996, the Company established a reserve for the remaining prepaid royalty balance due to the uncertainty of future urology revenues.

In early 1995, the Company filed a lawsuit against Surgical Laser Technologies, Inc. (SLT) charging infringement of the Company's U.S. Patents No. 4,646,737 and 5,380,317, which are owned by the Company, and U.S. Patent No. 5,380,317, which is owned jointly by the Company and a co-inventor. The Court granted SLT's motion for summary judgment that all three U.S. Patents are not infringed by SLT's laser devices. The Company believes that the Court's granting SLT's motions for summary judgment is incorrect, and the Company has decided, upon advice of its counsel, to appeal the Court's decision on the latter two of the above patents.

As described above, on October 6, 1995, the Company filed a lawsuit against Bard claiming damages of at least $72 million for Bard's failure to perform its obligations as Trimedyne's exclusive distributor under the Agreement and pay certain amounts due under the agreement.

The Company has been named as a defendant in one product liability lawsuit which is being handled by the Company's insurance carrier. The Company believes this lawsuit will not have a material effect upon its finances and is expected to be either settled or dismissed in 1997. The Company is currently involved in various disputes and other lawsuits and others may arise from time to time arising from its normal operations. The litigation process is inherently uncertain and it is possible that the resolution of the Company's existing litigation may adversely affect the Company. However, it is the opinion of management that the outcome of such matters will not have a material adverse impact on the Company's financial position, results of operations or cash flows.

NOTE 11. CONCENTRATION OF CREDIT RISK AND MAJOR CUSTOMER

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. No single customer represented more than 10% of sales in either fiscal 1996 or fiscal 1995. One customer accounted for approximately 23% of net revenues in fiscal 1994.

Sales in foreign countries accounted for approximately 20% of the Company's total sales. The breakdown by geographic region is as follows:

<TABLE>
<S>
<C>

| | |
|---|---|
| Asia | $ 636,000 |
| Latin America | 353,000 |
| Middle East | 33,000 |
| Europe | 1,129,000 |
| Other (Australia, New Zealand, South Africa) | 298,000 |
| Total | $2,449,000 |

</TABLE>

The Company performs ongoing credit evaluations of its customers and generally does not require collateral. The Company maintains reserves for potential credit losses and such losses have been within management's expectations.



NOTE 12. INDUSTRY SEGMENT FINANCIAL DATA:

During the three fiscal years ended 1996, 1995, and 1994, the Company operated in two industry segments: medical lasers and disposable devices and plastic optical fibers. Operations in the medical laser and disposable device industry consist primarily of the sale of Nd:YAG and Holmium medical laser systems and the manufacture and sale of related disposable devices. The Company's operations in the fiber optics industry relate principally to the manufacture and sale of plastic optical fibers and fiber-optic illumination products through its subsidiary, Poly-Optical.

Industry segment information for the years ended September 30, 1996, 1995 and 1994 is as follows:

<TABLE>
<CAPTION>

| | 1996 | | 1995 | | 1994 | |
|---|---|---|---|---|---|---|
| | Amount | % | Amount | % | Amount | % |
| <S> | <C> | <C> | <C> | <C> | <C> | <C> |
| Net revenues: | | | | | | |
| Fiber Optics Industry | $ 3,105,000 | 25 % | $ 3,403,000 | 26 % | $ 2,990,000 | 22 % |
| Medical Products | 9,383,000 | 75 % | 9,638,000 | 74 % | 10,403,000 | 78 % |
| Total | $12,488,000 | 100 % | $13,041,000 | 100 % | $13,393,000 | 100 % |
| Income (loss) from operations: | | | | | | |
| Fiber Optics Industry | $ 252,000 | 5 % | $ 373,000 | 7 % | $ 235,000 | 8 % |
| Medical Products | (5,358,000) | (105)% | (5,579,000) | (107)% | (3,009,000) | (108)% |
| Total | $(5,106,000) | (100)% | $(5,206,000) | (100)% | $(2,774,000) | (100)% |
| Assets: | | | | | | |
| Fiber Optics Industry | $ 1,771,000 | 10 % | $ 1,945,000 | 13 % | $ 1,771,000 | 9 % |
| Medical Products | 15,968,000 | 90 % | 13,095,000 | 87 % | 18,727,000 | 91 % |
| Total | $17,739,000 | 100 % | $15,040,000 | 100 % | $20,498,000 | 100 % |
| Depreciation and amortization: | | | | | | |
| Fiber Optics Industry | $ 134,000 | 27 % | $ 137,000 | 24 % | $ 126,000 | 23 % |
| Medical Products | 365,000 | 73 % | 430,000 | 76 % | 422,000 | 77 % |
| Total | $ 499,000 | 100 % | $ 567,000 | 100 % | $ 548,000 | 100 % |
| Capital expenditures: | | | | | | |
| Fiber Optics Industry | $ 68,000 | 23 % | $ 104,000 | 40 % | $ 189,000 | 31 % |
| Medical Products | 228,000 | 77 % | 155,000 | 60 % | 419,000 | 69 % |
| Total | $ 296,000 | 100 % | $ 259,000 | 100 % | $ 608,000 | 100 % |

</TABLE>

NOTE 13. SUBSEQUENT EVENTS

The Company has entered into an agreement, subject to, among other significant conditions, the availability of financing, for the sale of Poly-Optical. In the event that the proposed sale of Poly-Optical is not consummated, the Company plans to continue operating Poly-Optical as a subsidiary. For the year ended September 30, 1996, Poly-Optical had sales of $3,105,000 and income from operations of $252,000 compared to sales of $3,403,000 and income from operations of $373,000 in the prior year.

In October, 1996, the Company created Cardiodyne, Inc., a wholly owned subsidiary that will specialize in developing laser and laser related products for use in the cardiovascular field.



SCHEDULE VIII

TRIMEDYNE, INC. AND SUBSIDIARY
VALUATION AND QUALIFYING ACCOUNTS

<TABLE>
<CAPTION>

| DESCRIPTION | BALANCE AT BEGINNING OF PERIOD | CHARGE TO EXPENSE | WRITE OFF TO RESERVE | BALANCE AT END OF PERIOD |
|---|---|---|---|---|
| <S> | <C> | <C> | <C> | <C> |
| FOR THE YEAR ENDED SEPTEMBER 30, 1996 | | | | |
| Allowance for bad debt | $ 315,000 | $48,000 | $ 70,000 | $ 337,000 |
| Inventory reserve | 2,743,000 | | 352,000 | 3,095,000 |

| | | | | |
|---|---|---|---|---|
| Tax reserve | 9,531,000 | 2,302,000 | | 11,833,000 |

</TABLE>

<TABLE>
<CAPTION>

| DESCRIPTION | BALANCE AT BEGINNING OF PERIOD | CHARGE TO EXPENSE | WRITE OFF TO RESERVE | BALANCE AT END OF PERIOD |
|---|---|---|---|---|
| <S> | <C> | <C> | <C> | <C> |
| FOR THE YEAR ENDED SEPTEMBER 30, 1995 | | | | |
| Allowance for bad debt | $ 335,000 | $ 62,000 | $ (82,000) | $ 315,000 |
| Inventory reserve | 2,621,000 | 685,000 | (563,000) | 2,743,000 |
| Tax reserve | 7,428,000 | 2,103,000 | | 9,531,000 |

</TABLE>

<TABLE>
<CAPTION>

| DESCRIPTION | BALANCE AT BEGINNING OF PERIOD | CHARGE TO EXPENSE | WRITE OFF TO RESERVE | BALANCE AT END OF PERIOD |
|---|---|---|---|---|
| <S> | <C> | <C> | <C> | <C> |
| FOR THE YEAR ENDED SEPTEMBER 30, 1994 | | | | |
| Allowance for bad debt | $ 302,000 | $ 53,000 | $ (20,000) | $ 335,000 |
| Inventory reserve | 2,302,000 | 319,000 | | 2,621,000 |
| Tax reserve | 6,231,000 | 1,197,000 | | 7,428,000 |

</TABLE>

EXHIBIT 23.1

# CONSENT OF INDEPENDENT ACCOUNTANTS

We hereby consent to the incorporation by reference in the Prospectus constituting part of the Registration Statement on Form S-8 of Trimedyne, Inc. of our report dated December 24, 1996 appearing on page F-2 of this Form 10-K. We also consent to the reference to us under the heading "Experts" in such Prospectus.

PRICE WATERHOUSE LLP
Costa Mesa, California
December 27, 1996

<TABLE> <S> <C>

<ARTICLE> 5
<MULTIPLIER> 1000
<CURRENCY> U.S. DOLLARS

| <S> | <C> |
|---|---|
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| <FISCAL-YEAR-END> | SEP-30-1996 |
| <PERIOD-START> | OCT-01-1995 |
| <PERIOD-END> | SEP-30-1996 |
| <EXCHANGE-RATE> | 1 |
| <CASH> | 5,575 |
| <SECURITIES> | 2,525 |
| <RECEIVABLES> | 2,849 |
| <ALLOWANCES> | 337 |
| <INVENTORY> | 5,214 |
| <CURRENT-ASSETS> | 16,221 |
| <PP&E> | 5,236 |
| <DEPRECIATION> | 4,012 |
| <TOTAL-ASSETS> | 17,739 |
| <CURRENT-LIABILITIES> | 2,302 |
| <BONDS> | 0 |
| <PREFERRED-MANDATORY> | 110 |
| <PREFERRED> | 0 |
| <COMMON> | 0 |
| <OTHER-SE> | 15,160 |
| <TOTAL-LIABILITY-AND-EQUITY> | 17,739 |
| <SALES> | 12,488 |
| <TOTAL-REVENUES> | 12,883 |
| <CGS> | 7,779 |
| <TOTAL-COSTS> | 17,594 |
| <OTHER-EXPENSES> | (18) |
| <LOSS-PROVISION> | 0 |
| <INTEREST-EXPENSE> | 0 |
| <INCOME-PRETAX> | (4,729) |
| <INCOME-TAX> | 0 |
| <INCOME-CONTINUING> | 0 |
| <DISCONTINUED> | 0 |
| <EXTRAORDINARY> | 0 |
| <CHANGES> | 0 |
| <NET-INCOME> | (4,729) |
| <EPS-PRIMARY> | (.47) |
| <EPS-DILUTED> | (.47) |

</TABLE>