

Edgar Filing: PARADIGM MEDICAL INDUSTRIES INC - Form 10KSB/A

PARADIGM MEDICAL INDUSTRIES INC
Form 10KSB/A
May 12, 2005

SECURITIES AND EXCHANGE COMMISSION
Washington, D.C. 20549

Form 10-KSB/A

ANNUAL REPORT PURSUANT TO SECTION 13 OR 15(d) OF
THE SECURITIES EXCHANGE ACT OF 1934
For the fiscal year ended December 31, 2004, or

TRANSITION REPORT PURSUANT TO SECTION 13 OR 15(d)
OF THE SECURITIES EXCHANGE ACT OF 1934
For the Transition Period from to
Commission File Number 0-28498

Paradigm Medical Industries, Inc.
(Name of small business issuer in its charter)

DELAWARE	87-0459536
(State or other jurisdiction of incorporation or organization)	(I.R.S. Employer Identification Number)

2355 South 1070 West, Salt Lake City, Utah	84119
(Address of principal executive offices)	(Zip Code)

Registrant's telephone number, including area code: (801) 977-8970

Securities registered pursuant to Section 12(b) of the Act: None

Securities registered pursuant to Section 12(g) of the Act:

Common Stock, par value \$.001 per share
(Title of Class)

Class A Warrant to Purchase One Share of Common Stock
(Title of Class)

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 such filing requirements for the past 90 days. Yes No

Indicate by check mark if disclosure of delinquent filers pursuant to Item 405 of Regulation S-B 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-KSB or any amendment to this Form 10-KSB.

Registrant's revenues for the fiscal year ended December 31, 2004 were \$3,062,000.

The aggregate market value of the voting stock held by non-affiliates of the registrant as of the last business day of registrant's most recently completed first fiscal quarter was \$2,499,000 based on the closing price on that date on the OTC Bulletin Board.

As of March 31, 2005, Registrant had outstanding 27,764,868 shares of common stock, 5,627 shares of Series A preferred stock, 8,986 shares of Series B

Edgar Filing: PARADIGM MEDICAL INDUSTRIES INC - Form 10KSB/A

preferred stock, no shares of Series C preferred stock and 5,000 shares of Series D preferred stock, 1,000 shares of Series E preferred stock, 4,598.75 shares of Series F preferred stock, and 1,726,560 shares of Series G preferred stock.

DOCUMENTS INCORPORATED BY REFERENCE:

Additional documents set forth in Part IV hereof are incorporated by reference.

Transitional Small Business Disclosure Format (check one): Yes [] No [X]

PART I

Item 1. Description of Business

General

The Company develops, manufactures, sources, markets and sells ophthalmic surgical and diagnostic instrumentation and related accessories, including disposable products. The Company's surgical equipment is designed for minimally invasive cataract treatment. The Company markets two cataract surgery systems with related accessories and disposable products. The Company's cataract removal system, the Photon(TM) laser system, is a laser cataract surgery system marketed as the next generation of cataract removal. Because of the "going concern" status of the Company, management has focused efforts on those products and activities that will, in its opinion, achieve the most resource efficient short-term cash flow to the Company. As reflected in the results for the fiscal year ended December 31, 2003, diagnostic products are currently the Company's major focus and the Photon(TM) and other extensive research and development projects have been put on hold pending future evaluation when the financial position of the company improves. Due to the lack of FDA approval and the lack of current evidence to support recoverability, the Company has recorded an inventory reserve to offset the majority of the inventory associated with the Photon(TM). In addition, most inventory associated with the Precisionist Thirty Thousand(TM) has been reserved for due to the estimated lack of recoverability. The Company's focus is not on any specific diagnostic product or products, but rather on its entire group of diagnostic products. The Photon(TM) can be sold in markets outside of the United States. Both the Photon(TM) and the Precisionist ThirtyThousand(TM) are manufactured as an Ocular Surgery Workstation(TM). The Company is considering marketing the Photon(TM) and other lasers for use in eye care.

The Company's diagnostic products include a pachymeter, a P55 pachymetric analyzer, a P37 Ultrasonic A/B Scan, a P40 UBM Ultrasound Biomicroscope, a perimeter, a corneal topographer and the Blood flow Analyzer(TM). The diagnostic ultrasonic products including the P55 pachymetric analyzer, the P37 Ultrasonic A/B Scan and the P40 UBM Ultrasound Biomicroscope were acquired from Humphrey Systems, a division of Carl Zeiss in 1998. The Company developed and offered for sale in the fall of 2000 the P45, which combines the P37 Ultrasonic A/B Scan and the UBM biomicroscope in one machine. The perimeter and the corneal topographer were added when the Company acquired the outstanding shares of the stock of Vismed, Inc. d/b/a/ Dicon(TM) in June 2000. The Company purchased Ocular Blood Flow, Ltd. in June 2000 whose principal product is the Blood Flow Analyzer(TM). This product is designed for the measurement of intraocular pressure and pulsatile ocular blood flow volume for detection and monitoring of glaucoma. The Company is currently developing additional applications for all of its diagnostic products.

A cataract is a condition that largely affects the elderly population, in which the natural lens of the eye hardens and becomes cloudy, thereby

Edgar Filing: PARADIGM MEDICAL INDUSTRIES INC - Form 10KSB/A

reducing visual acuity. Treatment consists of removal of the cloudy lens and replacement with a synthetic lens implant, which restores visual acuity. Cataract surgery is the single largest volume and revenue producing outpatient surgical procedure for ophthalmologists worldwide. The Health Care Finance Administration reports that in the United States approximately two million cataract removal procedures are performed annually, making this the largest outpatient procedure reimbursed by Medicare. Most cataract procedures are performed using a method called phacoemulsification or "phaco", which employs a high frequency (40 kHz to 60 kHz) ultrasonic probe needle device to fragment the cataract while still in the eye and remove it in pieces by suction through a small incision.

In June 1997, the Company received FDA clearance to market the Blood Flow Analyzer(TM) for measurement of intraocular pressure and pulsatile ocular blood flow for the detection of glaucoma and other retina related diseases. Ocular blood flow is critical, the reduction of which may cause nerve fiber bundle death through oxygen deprivation, thus resulting in visual field loss associated with glaucoma. The Company's Blood Flow Analyzer(TM) is a portable automated in-office system that presents an affordable method for ocular blood flow testing for the ophthalmic and optometric practitioner. In June 2000, the Company purchased Ocular Blood Flow, Ltd., the manufacturer of the Blood Flow Analyzer(TM). The terms and conditions of the sale were \$100,000 in cash and 100,000 shares of common stock. In April 2001, the Company received authorization to use a common procedure terminology or CPT code from the American Medical Association for procedures performed with the Blood Flow Analyzer(TM), for reimbursement purposes for doctors using the device. However, certain payers have elected not to reimburse doctors using the Blood Flow Analyzer(TM).

On July 23, 1998, the Company entered into an Agreement for Purchase and Sale of Assets with the Humphrey Systems Division of Carl Zeiss, Inc. to acquire the ownership and manufacturing rights to certain assets of Humphrey Systems that are used in the manufacturing and marketing of an ultrasonic microprocessor-based line of ophthalmic diagnostic instruments, including the Ultrasonic Biometer Model 820, the A/B Scan System Model 837, the Ultrasound Pachymeter Model 855, and the Ultrasound Biomicroscope Model 840, and all accessories, packaging and end-user collateral materials for each of the product lines for the sum of \$500,000, payable in the form of 78,947 shares of common stock which were issued to Humphrey Systems and 26,316 shares of common stock which were issued to business broker Douglas Adams. If the net proceeds received

2

by Humphrey Systems from the sale of the shares issued pursuant to the Agreement was less than \$375,000, after payment of commissions, transfer taxes and other expenses relating to the sale of such shares, the Company would be required to issue additional shares of common stock, or pay additional funds to Humphrey Systems as would be necessary to increase the net proceeds from the sale of the assets to \$375,000. Since Humphrey Systems realized only \$162,818 from the sale of 78,947 shares of its common stock, the Company issued 80,000 additional shares in January 1999 to enable Humphrey Systems to receive its guaranteed amount. The amount of \$21,431 was paid to the Company as excess proceeds from the sale of this additional stock.

The rights to the ophthalmic diagnostic instruments, which have been purchased from Humphrey Systems, complement both the Company's cataract surgical equipment and the Company's ocular Blood Flow Analyzer(TM). The Ultrasonic Biometer calculates the prescription for the intraocular lens to be implanted during cataract surgery. The P55 pachymetric measures corneal thickness for the new refractive surgical applications that eliminate the need for eyeglasses and for optometric applications including contact lens fitting. The P37 Ultrasonic

Edgar Filing: PARADIGM MEDICAL INDUSTRIES INC - Form 10KSB/A

A/B Scan combines the Ultrasonic Biometer and ultrasound imaging for advanced diagnostic testing throughout the eye and is a viable tool for retinal specialists. The P40 UBM Ultrasound Biomicroscope utilizes microscopic digital ultrasound resolution for detection of tumors and improved glaucoma management. The Company introduced the P45 in the fall of 2000, which combines the P37 Ultrasonic A/B Scan, and the Ultrasonic Biometer in one machine.

On October 21, 1999, the Company purchased Mentor's surgical product line, consisting of the Phaco SIsTem(TM), the Odyssey(TM) and the Surg-E-Trol(TM). This acquisition was an attempt to round out the Company's cataract surgery product line by adding entry-level, moderately priced cataract surgery products. The transaction was paid for with \$1.5 million worth of the Company's common stock. Due to the lack of sales volume of these products, they were determined to be obsolete and a reserve was established to offset all inventory associated with these products. During the fourth quarter of 2003, the Company sold all inventory rights associated with the SIsTem(TM) and Odyssey(TM) for \$125,000.

On June 5, 2000, the Company purchased Vismed Inc. d/b/a Dicon(TM) under a pooling of interest accounting treatment. The purchase included the Dicon(TM) perimeter product line consisting of the LD 400, the TKS 5000, the SST(TM), FieldLink(TM), FieldView(TM) and Advanced FieldView and the corneal topographer product line, the CT 200(TM), the CT 50 and an ongoing service and software business. Perimeters are used to determine retinal sensitivity testing the visual pathway. Corneal topographers are used to determine the shape and integrity of the cornea, the anterior surface of the eye. Corneal topographers are used for the refractive surgical applications that eliminate the need for eyeglasses and for optometric applications including contact lens fitting.

In January 2002, the Company purchased the Innovatome(TM) microkeratome of Innovative Optics, Inc. by issuing an aggregate of 1,272,825 shares of its common stock, warrants to purchase 250,000 shares of its common stock at \$5.00 per share, exercisable over a period of three years from the closing date, and \$100,000 in cash. The transaction was accounted for as a purchase in accordance with Statement of Financial Accounting Standards No. 141. The Company acquired from Innovative Optics raw materials, work in process and finished goods inventories. Additionally, the Company acquired the furniture and equipment used in the manufacturing process of the microkeratome console and the inspection and packaging of the disposable blades.

The Company was unsuccessful in supplying the disposable blades. The Company discontinued the marketing and sales efforts of this product during the third quarter of 2002. On April 1, 2002, the Company entered into a consulting agreement with John Charles Casebeer, M.D. to develop and promote the microkeratome. For Dr. Casebeer's services during the period from April 1, 2002 to September 30, 2002, the Company issued him a total of 43,684 shares of its common stock, representing payment of \$100,000 in stock for his services. All assets acquired from Innovative Optics, including remaining inventory with a book value of \$160,000 and equipment and intangible assets with a book value of \$2,082,000, were written off during 2002.

On September 19, 2002, the Company completed a transaction with International Bio-Immune Systems, Inc., a Delaware corporation, in which the Company acquired 2,663,254 shares, or 19.9% of the outstanding shares of its common stock, and warrants to purchase 1,200,000 shares of its common stock at \$2.50 per share for a period of two years, through the exchange and issuance of 736,945 shares of its common stock, the lending of 300,000 shares of its common stock to the company and the payment of certain of its expenses through the issuance of an aggregate of 94,000 shares of its common stock to the company and its counsel. During 2004, the Company sold all 2,663,254 shares of International Bio-Immune Systems stock for net proceeds of \$505,000.

Edgar Filing: PARADIGM MEDICAL INDUSTRIES INC - Form 10KSB/A

International Bio-Immune Systems, Inc. may sell the 300,000 shares of the Company's common stock loaned by the Company and the proceeds therefrom shall be deemed a loan from the Company payable on the earlier of September 19, 2002, or the closing of any private placement or public offering of the securities of International Bio-Immune Systems, any merger involving more than 50% of the outstanding shares of International Bio-Immune Systems, or any sale, dissolution, transfer, or assignment of corporate assets other than in the ordinary course of business. Interest shall accrue on the unpaid principal of the loan at the rate of 10% per annum. If International Bio-Immune Systems does

3

not sell the shares by September 19, 2004, it is required to return the shares, or any amount which has not been sold, to us. International Bio-Immune Systems currently controls the voting decisions regarding these shares. The President and Chief Executive Officer of International Bio-Immune Systems is Leslie F. Stern, who exercises sole voting and investment powers regarding the shares.

On December 3, 2003, the Company executed a purchase agreement with American Optisurgical, Inc. for the sale of the Mentor surgical products line, consisting of the Phaco SlStem(TM) and the Odyssey(TM). The assets sold in the transaction included patents, trademarks, software codes and programs, supplies, work in process, finished goods, and molds related to the equipment. The purchase price paid to the Company by American Optisurgical for the assets was \$125,000. The purchase agreement also contained a noncompete provision in which the Company agreed for a period of three years from the closing date not to own, manage, operate or control any business that competes with cataract removal equipment substantially the same as the proprietary technology of the Phaco SlStem(TM) and the Odyssey(TM).

On September 28, 2004, the Company entered into an Investment Banking Agreement with Alpha Advisory Services, Inc. Under the terms of the agreement, Alpha Advisory Services is to use its best efforts to provide the following services to the Company: (i) review of and make recommendations regarding the Company's business plan and promotional materials; (ii) identify and contact potential investors in the United States and Europe for potential investment in the Company's securities; (iii) organize meetings with potential investors and participate in such meetings; and (iv) assist the Company in future financings, mergers, acquisitions and potential buyouts.

The term of the agreement is for a period of three months, which is to be automatically renewed for successive one-year terms. Following the initial three month period, either party may terminate the agreement upon 15 days written notice to the other party. In consideration for the services to be performed under the agreement, Alpha Advisory Services is to receive a fee of \$3,000 per month, plus reasonable travel and other expenses, and warrants to purchase 25,000 shares of the Company's common stock at \$.15 per share. The warrants are exercisable, on a cashless basis, over a two year period from the date of issuance.

Background

Corporate History: The Company's business originated with Paradigm Medical, Inc., a California corporation formed in October 1989. Paradigm Medical, Inc. developed its present ophthalmic business and was operated by its founders Thomas F. Motter and Robert W. Millar. In May 1993, Paradigm Medical, Inc. merged with Paradigm Medical Industries, Inc. At the time of the merger, the Company was a dormant public shell existing under the name French Bar Industries, Inc. French Bar had operated a mining and tourist business in Montana. Prior to its merger with Paradigm Medical, Inc. in 1993, French Bar had disposed of its mineral and mining assets in a settlement of outstanding debt

Edgar Filing: PARADIGM MEDICAL INDUSTRIES INC - Form 10KSB/A

and had returned to the status of a dormant entity. Pursuant to the merger, the Company caused a 1-for-7.96 reverse stock split of its shares of common stock. The Company then acquired all of the issued and outstanding shares of common stock of Paradigm Medical, Inc. using shares of its own common stock as consideration. As part of the merger, the Company changed its name from French Bar Industries, Inc. to Paradigm Medical Industries, Inc. and the management of Paradigm Medical, Inc. assumed control of the company. In April 1994, the Company caused a 1-for-5 reverse stock split of its shares of common stock. In February 1996, the Company re-domesticated to Delaware pursuant to a reorganization.

Overview

Disorders of the Eye: The human eye is a complex organ which functions much like a camera, with a lens in front and a light-sensitive screen, the retina, in the rear. The intervening space contains a transparent jelly-like substance, the vitreous, which together with the outer layer, the sclera and cornea, helps the eyeball to maintain its shape. Light enters through the cornea, a transparent domed window at the front of the eye. The size of the pupil, an aperture in the center of the iris, controls the amount of light that is then focused by the lens onto the retina as an upside-down image. The lens is the internal optical component of the eye and is responsible for adjusting focus. The lens is enclosed in a capsule. The retina is believed to contain more than 130 million light-receptor cells. These cells convert light into nerve impulses that are transmitted right-side up by the optic nerve to the brain, where they are interpreted. Muscles attached to the eye control its movements.

Birth defects, trauma from accidents, disease and age related deterioration of the components of the eye could all contribute to eye disorders. The most common eye disorders are either pathological or refractive. Many pathological disorders of the eye can be corrected by surgery. These include cataracts (clouded lenses), glaucoma (elevated or low pressure in the eye), loss of nerve fibers resulting in loss of vision, corneal disorders such as scars, defects and irregular surfaces and vitreoretinal disorders such as the attachment of membrane growths to the retina causing blood leakage within the eye. All of these disorders can impair vision. Many refractive disorders can be corrected through the use of eyeglasses and contact lenses. Myopia (nearsightedness), hyperopia (farsightedness) and presbyopia (inability to focus) are three of the most common refractive disorders.

4

Ultrasound Technology: Ultrasound devices have been used in ophthalmology since the late 1960's for diagnostic and surgical applications when treating or correcting eye disorders. In diagnostics, ultrasound instruments are used to measure distances and shapes of various parts of the eye for prescription of eyeglasses and contact lenses and for calculation of lens implant prescriptions for cataract surgery treatment. These devices emit sound waves through a hand-held probe that is placed onto or near the eye with the sound waves emitted being reflected by the targeted tissue. The reflection "echo" is computed into a distance value that is presented as a visual image, or cross-section of the eye, with precise measurements displayed and printed for diagnostic use by the surgeon.

Surgical use of ultrasonics in ophthalmology is limited to treatment of cataract lenses in the eye through a procedure called phacoemulsification or "phaco." A primary objective of cataract surgeries is the removal of the opacified (cataract) lens through an incision that is as small as possible. The opacified lens is then replaced by a new synthetic lens intraocular implant. Phaco technology involves a process by which a cataract is broken into small pieces using ultrasonic shock waves delivered through a hollow, open-ended metal

Edgar Filing: PARADIGM MEDICAL INDUSTRIES INC - Form 10KSB/A

needle attached to a hand-held probe. The fragments of cataracts tissue are then removed through aspiration. Phaco systems were first designed in the late 1960's after various attempts by surgeons to use other techniques to remove opacified lenses, including crushing, cutting, freezing, drilling and applying chemicals to the cataract. By the mid-1970's, ultrasound had proven to be the most effective technology to fragment cataracts. Market Scope's (Manchester, Missouri), The 2001 Report on the Worldwide Cataract Market, January 2001 indicates that phaco cataract treatment was the technology for cataract removal used in over 80% of surgeries in the United States and over 20% of all foreign surgeries.

Laser Technology: The term "laser" is an acronym for Light Amplification by Stimulated Emission of Radiation. Lasers have been commonly used for a variety of medical and ophthalmic procedures since the 1960's. Lasers emit photons into a highly intense beam of energy that typically radiates at a single wavelength or color. Laser energy is generated and intensified in a laser tube or solid-state cavity by charging and exciting photons of energy contained within material called the lasing medium. This stored light energy is then delivered to targeted tissue through focusing lenses by means of optical mirrors or fiber optics. Most laser systems use solid state crystals or gases as their lasing medium. Differing wavelengths of laser light are produced by the selection of the lasing medium. The medium selected determines the laser wavelength emitted, which in turn is absorbed by the targeted tissue in the body. Different tissues absorb different wavelengths or colors of laser light. The degree of absorption by the tissue also varies with the choice of wavelength and is an important variable in treating various tissues. In a surgical laser, light is emitted in either a continuous stream or in a series of short duration "pulses", thus interacting with the tissue through heat and shock waves, respectively. Several factors, including the wavelength of the laser and the frequency and duration of the pulse or exposure, determine the amount of energy that interacts with the targeted tissue and, thus, the amount of surgical effect on the tissue.

Lasers are widely accepted in the ophthalmic community for treatment of certain eye disorders and are popular for surgical applications because of their relatively non-invasive nature. In general, ophthalmic lasers, such as argon, Nd:YAG and excimer (argon-fluoride) are used to coagulate, cut or ablate targeted tissue. The argon laser is used to treat leaking blood vessels on the retina (retinopathy) and retinal detachment. The excimer laser is used in corneal refractive surgery. The Nd:YAG pulsed laser is used to perforate clouded posterior capsules (posterior capsulotomy) and to relieve glaucoma-induced elevated pressure in the eye (iridotomy, trabeculoplasty, transcleral cyclophotocoagulation). Argon, Nd:YAG and excimer lasers are primarily used for one or two clinical applications each. In contrast to these conventional laser systems, the Company's Photon(TM) laser cataract system is designed to be used for multiple ophthalmic applications, including certain new applications that may be made possible with its proprietary technology. Such new applications, however, must be tested in clinical trials and be approved by the FDA.

Products

The Company's principal proprietary surgical products are systems for use by ophthalmologists to perform surgical treatment procedures to remove cataracts. The Company has complete ownership of each product with no technological licensing limitations.

Precisionist ThirtyThousand(TM): The Precisionist ThirtyThousand(TM) is the Company's core phaco surgical technology. The Precisionist(TM) was placed into production and offered for sale in 1997. As a phaco cataract surgery system, the Company believes the Precisionist(TM) with its new fluidics panel is equal or superior to the present competitive systems in the United States. However, due to the lack of recent sales, the majority of the Company's

Edgar Filing: PARADIGM MEDICAL INDUSTRIES INC - Form 10KSB/A

inventory associated with the Precisionist Thirty Thousand(TM) has been estimated to be obsolete and therefore a reserve for such inventory has been recorded. The system features a graphic color display and unique proprietary on-board computer and graphic user interface linked to a soft-key membrane panel for flexible programmable operation. The system provides real-time "on-the-fly" adjustment capabilities for each surgical parameter during the surgical procedure for high-volume applications. In addition, the Precisionist(TM) provides one hundred pre-programmable surgery set-ups, with a second level of sub-programmed custom modes within each major surgical screen (i.e., ultrasound phaco and irrigation/aspiration modes). The Precisionist(TM) features the Company's newly developed proprietary fluidics panel which is completely non-invasive for improved sterility and to provide a surgical environment in the eye that virtually eliminates fluidic surge and solves chamber maintenance problems normally associated with phaco cataract surgery. This new fluidics

5

system provides greater control for the surgeon and allows the safe operation at much higher vacuum settings by sampling changes in aspiration 100 times per second. Greater vacuum in phaco surgery means less use of ultrasound or laser energy to fragment the cataract and less chance for surrounding tissue damage. In addition to the full complement of surgical modalities (e.g., irrigation, aspiration, bipolar coagulation and anterior vitrectomy), system automation includes "dimensional" audio feedback of vacuum levels and voice confirmation for major system functions, providing an intuitive environment in which the advanced phaco surgeon can concentrate on the surgical technique rather than the equipment. Sales of the Precisionist(TM) and related accessories were 0% of total revenues in both the fiscal years 2004 and 2003, respectively.

Ocular Surgery Workstation(TM): The Ocular Surgery Workstation(TM) comprises the base system of the Precisionist ThirtyThousand(TM) and is the first system to the Company's knowledge, which uses the expansive capabilities of today's advanced computer technology to offer seamless open architecture expandability of the system hardware and software modules. The Workstation(TM) utilizes an embedded open architecture computer developed for the Company and controlled by a proprietary software system developed by the Company that interfaces with all components of the system. Ultrasound, fluidics (irrigation), aspiration, venting, coagulation and anterior vitrectomy (pneumatic) are all included in the base model. Each component is controlled as a peripheral module within this fully integrated system. This approach allows for seamless expansion and refinement of the Workstation(TM) with the ability to add other hardware and software features. Expansion such as the Company's Photon(TM) laser system and hardware for additional surgical applications are easily implemented by means of a pre-existing expansion rack, which resides in the base of the Workstation(TM). These expanded capabilities could include, but would not be limited to laser systems, video surgical fiber optic imaging, cutting and electrosurgery equipment. However, there is no guarantee that the Workstation(TM) will be accepted in the marketplace. If the FDA approves the Photon(TM), the Company will refer to the Workstation(TM) as the Photon(TM) Ocular Surgery Workstation(TM). To date, the Company has not commercially developed or offered for sale any other added hardware or software features to its Workstation(TM).

Photon(TM) Laser System: The Photon(TM) laser cataract system, which is still subject to FDA approval, is designed to be installed as a seamless plug-in upgrade or add-on to the Company's Precisionist(TM) Ocular Surgery Workstation(TM). The plug-in platform concept is unique in the ophthalmic surgical market for systems of this magnitude and presents a unique market opportunity for us. The main elements of the laser system are the Nd:YAG laser module, Photon(TM) laser software package and interchangeable disposable hand-held fiber optic laser cataract probe. The Photon(TM) laser utilizes the on-board microprocessor computer of the Workstation(TM) to generate short pulse

Edgar Filing: PARADIGM MEDICAL INDUSTRIES INC - Form 10KSB/A

laser energy developed through the patented LCP(TM) to targeted cataract tissue inside the eye, while simultaneously irrigating the eye and aspirating the diseased cataract tissue from the eye. The probe is smaller in diameter than conventional ultrasound phaco needles and presents no damaging vibration or heat build-up in the eye. The Company's Phase I clinical trials demonstrated that this probe could easily reduce the size of the cataract incision from 3.0 mm to under 2.0 mm thereby reducing surgical trauma and complementing current foldable intraocular implant technology.

The laser probe may also eliminate any possibility for burns around the incision or at the cornea and may therefore be used with cataract surgery techniques that utilize a more delicate clear cornea incision which can eliminate sutures and be conducted with topical anesthesia. However, this system may not effectively remove harder grade cataracts. Harder grade cataracts can be removed using the already existing ultrasound capability of the Precisionist(TM). Because of the "going concern" status of the Company, management has focused efforts on those products and activities that will, in its opinion, achieve the most resource efficient short-term cash flow to the Company. As reflected in the results for the fiscal year ended December 31, 2003, diagnostic products are currently the Company's major focus and the Photon(TM) and other extensive research and development projects have been put on hold pending future evaluation when the Company's financial position improves. Due to the uncertainty surrounding the timetable for obtaining FDA approval and the lack of significant revenue from the other surgical products, the Company has recorded an inventory reserve against the majority of the inventory associated with the Photon(TM) and Precisionist Thirty Thousand (TM). The Company's focus is not on any specific diagnostic product or products, but rather on its entire group of diagnostic products.

At some point in the future, the Company may intend, subject to economic feasibility and the availability of adequate funds, to refine the laser delivery system and laser cataract surgical technique used on soft cataracts through expanded research and clinical studies. Subject to the aforementioned constraints, the Company intends to refine the fluidics management system by improving chamber maintenance during surgical procedures and to develop techniques to optimize time and improve invasive techniques through expanded research and clinical studies. As for as the Company can determine, no integrated single laser photofragmenting probe is presently available on the market that uses laser energy directly, contained in an enclosed probe, to denature cataract tissue at a precise location inside the eye while simultaneously irrigating and aspirating the site.

The Company's laser system is based upon the concept that pulsed laser energy produced with the micro-processor controlled Nd:YAG laser system provides ophthalmic surgeons with a more precise and less traumatic alternative in cataract surgery. Although conventional ultrasonic surgical systems have proven

6

effective and reliable in clinical use for many years, their use of high frequency shock waves and vibration to fragment the cataract can make the procedure difficult and can present risk of complication both during and after surgery. In contrast, the Company's laser system, which utilizes short centralized energy bursts, should permit the delivery of the laser beam with less trauma to adjacent tissue. Therefore, unlike ultrasonic systems, whose vibrations and shock waves affect (and can damage) non-cataracts tissues within the eye, the Company's Photon(TM) laser cataract system should only affect tissues with which it comes into direct contact.

In October of 2000, the Company received FDA approval for the Photon(TM) Workstation(TM) to be used with a 532nm green laser which is

Edgar Filing: PARADIGM MEDICAL INDUSTRIES INC - Form 10KSB/A

effective for medical procedures other than cataract removal, such as photocoagulation of retinal and venous anomalies within or outside the eye, pigmented lesions around the orbital socket, posterior or anterior procedures associated with glaucoma or diabetes and general photocoagulation for various dermatological venous anomalies including telangiectasia (surface veins), or commonly referred to as "spider veins". The goal is to be able to integrate multiple laser wavelengths into one system or workstation that can be used for multiple medical specialties. This approval represents only one of the potential applications that could represent substantial growth opportunities including additional sales of equipment, instruments, accessories and disposables.

The Photon(TM) Ocular Surgery Workstation(TM) has not been commercially developed with any other added hardware or software features. There is no guarantee that the ophthalmic surgery market will accept the laser in this capacity or that the FDA will grant approval. Regulatory approval would require completion of pending Photon(TM) clinical trials and resubmission of a 510(k) predicate device application to the FDR. Because of the "going concern" status of the Company, management has focused efforts on those products and activities that will, in its opinion, achieve the most resource efficient short-term cash flow to the Company. As reflected in the results for the fiscal year ended December 31, 2003, diagnostic products consisting mainly of the P40 UBM Ultrasound Biomicroscope, perimeter, CT 50 Corneal Topographer, and Blood Flow Analyzer(TM) are currently the Company's major focus and the Photon(TM) and other extensive research and development projects have been put on hold pending future evaluation when the financial position of the company improves. The Company's focus is not on any specific diagnostic product or products, but rather on the entire group of diagnostic products.

The SIStem(TM) and the Odyssey(TM): The SIStem(TM) and the Odyssey(TM) have been the Company's entry-level phacoemulsification systems. The SIStem(TM) and the Odyssey(TM) were designed to be a full-featured, cost-effective, reliable phaco machines; however, due to the lack of sales in 2002, the products were determined to be obsolete. Sales of the SIStem(TM), the Odyssey(TM) and related accessories represented approximately 4% and 0% of the total revenues for fiscal years 2004 and 2003, respectively. On December 3, 2003, the Company completed the sale of the SIStem(TM) and the Odyssey(TM), including patents, trademarks, software codes and programs, supplies, work in process, finished goods and molds, to American Optisurgical, Inc.

Surgical Instruments and Disposables: In addition to the cataract surgery equipment, the Company's surgical systems utilize or will utilize accessory instruments and disposables, some of which are proprietary to us. These include replacement ultrasound tips, sleeves, tubing sets and fluidics packs, instrument drapes and laser cataract probes. The Company intend to expand its disposable accessories as it further penetrates the cataract surgery market and expands the treatment applications for its Workstation(TM). These products contributed approximately 0% of total revenues for both 2004 and 2003, respectively.

Diagnostic Eye Care Products: Glaucoma is a second leading cause of adult blindness in the world. Glaucoma is described as a partial or total loss of visual field resulting from certain progressive disease or degeneration of the retina, macula or nerve fiber bundle. The cause and mechanism of the glaucoma pathology is not completely understood. Present detection methods focus on the measurement of intraocular pressure in the eye, visual field and observation of the optic nerve head to determine the possibility of pressure being exerted upon the retina, and optic nerve fiber bundle, which can diminish visual field. Recently, retinal blood circulation has been indicated as a key component in the presence of glaucoma. Some companies produce color Doppler equipment in the \$80,000 price range intended to provide measurement of ocular blood flow activity in order to diagnose and treat glaucoma at an earlier stage.

Edgar Filing: PARADIGM MEDICAL INDUSTRIES INC - Form 10KSB/A

Blood Flow Analyzer(TM): In June 1997, the Company received FDA clearance to market the Blood Flow Analyzer(TM) for early detection and treatment management of glaucoma and other retina related diseases. The device measures not only intraocular pressure but also pulsatile ocular blood flow, the reduction of which may cause nerve fiber bundle death through oxygen deprivation thus resulting in visual field loss associated with glaucoma. The Company's Blood Flow Analyzer(TM) is a portable automated in-office system that presents an affordable method for ocular blood flow testing for the ophthalmic and optometric practitioner. This was its first diagnostic eye care device. The device is a portable desktop system that utilizes a proprietary and patented pneumatic Air Membrane Applanation Probe(TM) or AMAP(TM), which can be attached to any model of standard examination slit lamp, which is then placed on the cornea of the patient's eye to measure the intraocular pressure within the eye. The device is unique in that it reads a series of intraocular pressure pulses over a short period of time (approximately five to ten seconds) and generates a waveform profile, which can be correlated to blood flow volume within the eye. A proprietary software algorithm developed by David M. Silver, Ph.D., at Johns Hopkins University, calculates the blood flow volume. The device presents a

7

numerical intraocular pressure reading and blood flow analysis rating in a concise printout, which is affixed to the patient history file. In addition, the data generated by the device can be downloaded to a personal computer system for advanced database development and management.

The Company markets the Blood Flow Analyzer(TM) as a stand-alone model packaged with a custom built computer system. The Blood Flow Analyzer(TM) utilizes a single-use disposable cover for the Air Membrane Applanation Probe(TM), a corneal probe which is shipped in sterile packages. The probe tip cover provides accurate readings and acts as a prophylactic barrier for the patient. The device has been issued a patent in the European Economic Community and the United States and has a patent pending in Japan. The FDA cleared the Blood Flow Analyzer(TM) for marketing in June 1997 and the Company commenced selling the system in September 1997. In addition to the Humphrey products, this diagnostic product allowed the Company to expand its market to approximately 35,000 optometry practitioners in the United States in addition to the approximately 18,000 ophthalmic practitioners who currently perform eye surgeries and are candidates for the Company's surgical systems.

In April 2001, the Company received written authorization from the CPT Editorial Research and Development Department of the American Medical Association to use common procedure terminology or CPT code number 92120 for its Blood Flow Analyzer(TM), for reimbursement purposes for doctors using the device. However, certain payers have elected not to reimburse doctors using the Blood Flow Analyzer(TM). The Company is continuing its aggressive campaign to educate the payers about the Blood Flow Analyzer(TM), its purposes and the significance of its performance in patient care in order to achieve reimbursements to the doctors. Currently, there is reimbursement by insurance payors to doctors using the Blood Flow Analyzer(TM) in 22 states and partial reimbursement in four other states. The amount of reimbursement to doctors using the Blood Flow Analyzer(TM) generally ranges from \$56.00 to \$76.00 per patient, depending upon the insurance payor. Insurance payors providing reimbursement for the Blood Flow Analyzer(TM) have the discretion to increase or reduce the amount of reimbursement. The Company is endeavoring to obtain reimbursement by insurance payors in other states where there is currently no reimbursement being made.

The manufacturing activities for the Blood Flow Analyzer(TM) have been moved to the Salt Lake City facility from the outsourced plant located in England. On October 21, 2002, the Company received FDA approval on its 510(k)

Edgar Filing: PARADIGM MEDICAL INDUSTRIES INC - Form 10KSB/A

application for additional indications of use for the Blood Flow Analyzer(TM). The additional indications include pulsatile ocular blood flow and pulsatile ocular blood volume. These are diagnostic measurements that assess the hemodynamic and vascular health of the eye. Also, the Company is continuing its aggressive campaign to educate the insurance payers about the Blood Flow Analyzer(TM), its purposes and the significance of its performance in patient care in order to achieve reimbursements to the doctors using its Blood Flow Analyzer(TM). Sales of the Blood Flow Analyzer(TM) and related accessories accounted for approximately 19% and 16% of total sales for the fiscal years ended December 31, 2004 and 2003, respectively.

Dicon(TM) Perimeters: Dicon(TM) perimeters consist of the LD 400, the TKS 5000, the SST(TM), FieldLink(TM), FieldView(TM) and Advanced FieldView. Perimeters are used to determine retinal sensitivity testing the visual pathway. Perimeters have become a standard of care in the detection and monitoring of glaucoma worldwide. Perimetry is reimbursable worldwide. The Dicon(TM) perimeters feature patented kinetic fixation and voice synthesis now in 27 different languages. Software programs are sold to assist in the analysis of the test results. Sales of the perimeters and related accessories generated approximately 27% of the total revenues for both 2004 and 2003, respectively.

Dicon(TM) Corneal Topographers: Dicon(TM) corneal topographers include the CT 200(TM) and the CT 50. Corneal topographers are used to determine the shape and integrity of the cornea, the anterior surface of the eye. Clinical applications for corneal topographers include refractive surgery that eliminates the need for eyeglasses and optometric applications including contact lens fitting. Revenues from the topographer and related accessories were 6% and 9% of the total revenues for 2004 and 2003, respectively. An enhanced version of the CT 200(TM), the CT 2000(TM), is scheduled to be introduced during the fourth quarter of 2003. The Company is completing the development of upgrades to the CT 200(TM) and the CT 50 Corneal Topographer, which will be operating upon completion of the upgrades with Windows XP software rather than the former Windows 95 operating systems. The Company is also revising its upgrade to offer the CT 200(TM) with Windows 2000 software rather than the Windows XP software that the Company announced in August 2003.

P55 Pachymetric Analyzer: The ultrasonic pachymeter is used for measurement of corneal thickness. The Model P55 is positioned as a standard office pachymeter. This device is targeted to the refractive surgery market and contributed approximately 3% of the total revenues for both 2004 and 2003, respectively.

P20 A-Scan Biometric Ultrasonic Analyzer: The A-Scan has been removed from the Company's line of diagnostic products. The A-Scan is a prerequisite procedure reimbursed by Medicare and is performed before every cataract surgery. Over 5,000 A-Scan systems have been installed in the worldwide market, representing a substantial market opportunity for software upgrades and extended warranty contract sales. A-Scan sales were approximately ___% and 2% of the total revenues for 2004 and 2003, respectively.

8

P37 A/B Scan Ocular Ultrasound Diagnostic: The A/B Scan is used by retinal sub-specialists to identify foreign bodies in the posterior chamber of the eye and to evaluate the structural integrity of the retina. The A/B Scan is attractive to the general ophthalmic community at large because of its lower price point. Sales from this product were approximately 8% and 4% of the total revenues for 2004 and 2003, respectively.

P40 and P45 UBM Ultrasound Biomicroscopes: Humphrey Systems developed the P40 UBM Ultrasound Biomicroscope in conjunction with the New York Eye and

Edgar Filing: PARADIGM MEDICAL INDUSTRIES INC - Form 10KSB/A

Ear Infirmary in Manhattan and the University of Toronto. The P40 biomicroscope and its intellectual property were included in the purchase from Humphrey Systems and gives the Company the proprietary rights to this device. The P40 biomicroscope creates a high-resolution computer image of the unseen parts of the eye that is a "map" for the glaucoma surgeon. The P40 biomicroscope is an "enabling technology" for the ophthalmologist, one that the Company has repositioned for broader market sales penetration. Formerly sold only to glaucoma sub-specialty practitioners, the Company reintroduced the P40 biomicroscope at a price-point targeted for the average practitioners seeking to add glaucoma filtering surgical procedures and income to their cataract surgical practice.

The P40 biomicroscope related surgical filtering procedures are fully reimbursable by Medicare and insurance providers. This untapped new market positions the Company with its proprietary P40 biomicroscope and, to its knowledge, the only commercially viable product of this type on the market, as a leader in the rapidly expanding glaucoma imaging and treatment segment. In the fall of 2000, the Company introduced the P45 UBM Ultrasonic Biomicroscope, which combines the P40 biomicroscope and the P37 A/B Scan Ocular Ultrasound Diagnostic in one instrument. The Company believes that by combining functions, the P45 will appeal to a broader market. The P40 biomicroscope and related accessories sales were approximately 12% and 7% of the total revenues for 2004 and 2003, respectively. The P45 biomicroscope and related accessories sales contributed approximately 16% and 13% of the total revenues for 2004 and 2003, respectively.

On October 25, 2004, the Company entered into a Manufacturing and Distribution Agreement with E-Technologies, Inc., a Iowa based developer of software and related technology for technical applications. Under the terms of the agreement, E-Technologies granted to the Company the exclusive right to manufacture, market, sell and distribute an ultrasound biomicroscope. Upon execution of the agreement, the Company paid \$30,000 to E-Technologies for engineering costs associated with the development of the biomicroscope. Once the bioimicroscope receives FDA approval, the Company agrees to pay E-Technologies an additional fee of \$45,000.

In consideration for the exclusive right to manufacture and distribute the biomicroscope, the Company agrees to pay E-Technologies the sum of \$5,000 for each of the first 25 biomicroscopes sold by the Company. Thereafter, the Company agrees to pay E-Technologies the sum of \$4,000 for each biomicroscope sold. As an additional condition, the Company agrees to sell 25 biomicroscopes during the first 12 months after the biomicroscope receives FDA approval. The agreement is effective for a term of two years. After the expiration of the two year period, the agreement is to automatically renew for additional one year periods, unless either party elects to terminate the agreement upon at least 30 days prior written notice to the other party before the end of any term of the agreement.

In July of 2000, the Company received ISO 9001 and EN 46001 certification using TUV Essen as the notified body. Under ISO 9001 certification, its products are now CE marked. The CE mark allows the Company to ship product for revenue into the European Community. The Company successfully retained its certification in 2002.

Parts and Services: The parts and service revenue from the repair and service of equipment sold accounted for approximately 8% of total revenues in both 2004 and 2003, respectively.

Sales of other products represented approximately 1% of total revenues in both 2004 and 2003, respectively.

The following table identifies each product class, status of commercial development, the percentage of sales contributed by that class, reimbursement

Edgar Filing: PARADIGM MEDICAL INDUSTRIES INC - Form 10KSB/A

status, and status of applicable United States and foreign regulatory approvals:

9

Product (1)	Product Class	Commercial Development	Reimbursement Status	% 2003 Sales	%2003 Sales
P55 Pachymetric Analyzer	System, Imaging, Pulsed Echo Diagnostic	Complete	Yes	3%	3%
P20 A-Scan Biometric Ultrasound Analyzer	System, Imaging, Pulsed Echo Diagnostic	Discontinued	Yes	2%	0%
P37 A/B Scan Ocular Ultrasound Diagnostic	Transducer, Ultrasound Diagnostic	Complete	Yes	4%	8%
P40 UBM Ultrasound BioMicroscope	System, Imaging, Pulsed Echo Ultrasound Diagnostic	Complete	Yes	7%	12%
P45 UBM Ultrasound Biomicroscope, Workstation Plus	System, Imaging, Pulsed Echo Ultrasound Diagnostic	Complete	Yes	13%	16%
BFA Ocular Blood Flow Analyzer(TM) and Disposables	Tonometer, Manual Diagnostic	Complete	Yes****	16%	19%
CT 200 Corneal Topography System	Topographer Corneal AC-Powered Diagnostic	Complete	Yes	9%	6%
LD 400 Autoperimetry System	Perimeter, Automatic AC-Powered Diagnostic	Complete	Yes	24%	24%
TKS 5000 Autoperimetry System	Perimeter, Automatic AC-Powered, Diagnostic	Complete	Yes	3%	3%
Precisionist Thirty Thousand(TM), Ocular Surgery Workstation with Surgical Equipment and Disposables	Phacofragmentation	Complete	Yes	0%	0%
SIStem(TM) and Odyssey(TM) (2)	Phacofragmentation	Sold	Yes	11%	0%
Photon(TM) Laser, Ocular Surgery Workstation with Surgical Equipment and	Phacoemulsification BFA tips	In-Process (4)	No	0%	0%

Edgar Filing: PARADIGM MEDICAL INDUSTRIES INC - Form 10KSB/A

Disposables(3)

Parts and Services	Perimeter, BFA, Tonometer, Topographer, Ultrasound Workstations, Systems, Imaging	Complete	Yes	8%	9
--------------------	---	----------	-----	----	---

10

- (1) Except for the Photon(TM) Ocular Surgery Workstation, which can only be sold in countries outside the United States, these products can be sold in the United States and in foreign countries including but not limited to Argentina, Australia, Bangladesh, Borneo, Brazil, Canada, China, Czechoslovakia, Egypt, France, Germany, Greece, Hong Kong, India, Israel, Italy, Japan, Jordan, Korea, Malaysia, Mexico, New Zealand, Pakistan, Peru, Poland, Puerto Rico, Russia, Saudi Arabia, Spain, Sri Lanka, Taiwan, Thailand, Turkey, United Kingdom, and United Arab Emirates
- (2) Due to the lack of recent sales volume, the inventory associated with the Precisionist Thirty Thousand (TM), the SISTem(TM) and the Odyssey(TM) has been deemed obsolete and a reserve has been recorded to offset such inventory.
- (3) Due to the lack of recent evidence to support the recoverability of inventory associated with the Photon(TM), the Company has recorded a reserve to offset the majority of such inventory on hand.
- (4) The Photon(TM) is in-process and not complete because the Company has not completed the clinical trials in order to obtain FDA regulatory approval.
- * FDA 510(K) K844299 represents domestic approval by U.S. Food and Drug Administration
- ** ISO 9001: 1994, EN ISO 9001 represents international approval
- *** IDE G940151 represents approval for international distribution only
- **** Represents full reimbursement in 22 states and partial reimbursement in four other states.

As detailed in the table above, except for the Photon(TM) Laser Ocular Surgery Workstation, which requires additional development and regulatory approvals, the Company's current products are developed and available for sale in the footnote (1) of the table. The Company's possible future efforts to finalize development of the Photon(TM) and obtain the necessary regulatory approvals would depend on its economic evaluations and adequate funding. If these efforts were undertaken but proved to be unsuccessful, the impact would include the costs associated with these efforts and the anticipated future revenues which the Company would not receive as expected. The Company anticipates that a majority of the estimated costs for Research and Development will be used for the enhancement and upgrading of its current products approved for sale. The Company is unable to provide an estimate of the details of possible liquidity needs and expected source of funds for possible future efforts to finalize development of the Photon(TM) and obtain the necessary regulatory approvals since this estimate would depend on a possible comprehensive economic evaluation.

Any possible future efforts to complete development of the Photon(TM) and obtain the necessary regulatory approvals would depend on the Company's economic evaluations and adequate funding. If these efforts were undertaken but proved to be unsuccessful, the impact would include the costs associated with these efforts and the anticipated future revenues that the Company would not receive as expected. The Company anticipates that a majority of the estimated

Edgar Filing: PARADIGM MEDICAL INDUSTRIES INC - Form 10KSB/A

costs for research and development will be used for the enhancement and upgrading of its current products being offered for sale. The Company is unable to provide a detailed estimate of possible liquidity needs and expected sources of funds for possible future efforts to complete development of the Photon(TM) and obtain the necessary regulatory approvals since this estimate would depend on a comprehensive economic evaluation.

The Company currently purchases components and parts used in its products from a limited number of key suppliers. The Company's reliance on its principal suppliers could result in delays associated with redesigning a product due to an inability to obtain an adequate supply of required components and parts, and reduced control over pricing, quality and timely delivery. The loss of any of these principal suppliers or the inability of a supplier to meet performance and quality specifications, requested quantities or delivery schedules could cause the Company's revenues to decline. In addition, any interruption or discontinuance in the supply of components or parts could have an adverse effect on the Company's business, results of operation and financial condition. The Company's principal suppliers include Capistrano Labs, US Ultrasound and Anello.

Marketing and Sales

Ophthalmologists are mainly office-based and perform their surgeries in local hospitals or surgical centers that provide the necessary surgical equipment and supplies. Ophthalmologists are generally involved in decisions relating to the purchase of equipment and accessories for their independent ambulatory surgical centers and for the hospitals with which they are affiliated. This provides the opportunity for direct, targeted, personal selling, responsive high quality customer service and short buying cycles to achieve a product sale in the office or hospital. Hospitals also comprise a significant market, as recent demand for ultrasonic surgery technology has put pressure on the ophthalmologist, who in turn persuades the hospital to install the latest technology system so that he can offer this procedure to his patients and the community.

Industry analysts report that the United States ophthalmic surgical device market has been characterized by slower growth in recent years. This has apparently been caused by the potential reforms associated with the health care industry. Further, hospitals have been inclined to keep their older phaco machines longer than expected as they have been forced to mind budgets more carefully and have become less willing to invest in capital equipment until more information on health care reform becomes available. However, analysts predict that the ophthalmic surgical device market will see renewed growth in the coming years as the health care environment stabilizes and as the growing elderly population produces an increased number of cataract surgeries. As a consequence of these factors, the market should see a greater rate of replacement of older machines that hospitals and surgeons have been postponing for longer than usual.

11

Current Market Acceptance and Potential: The principal purchasers of the Company's products have been ophthalmologists, optometrists and clinics in many countries throughout the world. The Company believes that the market for its products is being driven by: (i) the aging of the population, which is evidenced by the domestic and international cataract surgery volume growth trend over the past ten years, (The National Eye Institute reported in March 2002 that the number of blind or visually impaired Americans is likely to double over the next 30 years.) (ii) the entry by emerging countries (including China, Russia, and other countries in Asia, Eastern Europe and Africa) into advanced technology medical care for their populations, (iii) increased awareness worldwide of the benefits of the minimally invasive phaco cataract procedure and (iv) the

Edgar Filing: PARADIGM MEDICAL INDUSTRIES INC - Form 10KSB/A

introduction of technology improvements such as the Company's laser system.

Marketing Organization: The Company markets its products internationally through a network of dealers and domestically through direct sales representatives, independent sales representatives, and ophthalmic product distributors. As of December 31, 2003, the Company had five direct domestic sales representatives in the United States and 65 foreign dealers. These sales representatives are assigned exclusive territories and have entered into contracts with the Company that contain performance quotas. Domestic sales channels have been expanded to include independent sales representatives and distributors who began training on its products in August 2003. The Company also plans to continue to market its products by identifying customers through internal market research, trade shows and direct marketing programs. The Company also utilizes a Clinical Advisory Board comprised of leading ophthalmic surgeons in the United States and Europe who speak at conventions, train ophthalmologists and visit foreign doctors and dealers to promote its products.

Product advertising is intended to be focused in the major industry trade newspapers. Most of the ophthalmologists or optometrists in the United States receive one or more of these magazines through professional subscription programs. The media has shown strong interest in the Company's technology and products, as evidenced by several recent front-page articles in these publications.

Manufacturing and Raw Materials: Currently, the Company maintains a 23,238 square foot facility in Salt Lake City. The Company transferred the manufacturing activities for the Blood Flow Analyzer(TM) to San Diego from Occular Blood Flow, Ltd. in England during 2001. During the second quarter of 2002, the Company consolidated and closed the San Diego operations into the Salt Lake City facility. The facility accommodates its manufacturing, marketing and engineering capabilities. The Company manufactures under systems of quality control and testing, which complies with the Quality System Requirements established by the FDA, as well as similar guidelines established by foreign governments, including the CE Mark and ISO-9001.

The Company subcontracts the manufacturing of some of its ancillary instruments, accessories and disposables through specified vendors in the United States. These products are contracted in quantities and at costs consistent with its financial purchasing capabilities and pricing needs. The Company manufactures certain accessories and fluidics surgical tubing sets at its facility in Salt Lake City.

Product Service and Support: Service for the Company's products is overseen from its Salt Lake City location and is augmented by its international dealer network who provide technical service and repair. Installation, on-site training and a limited product warranty are included as the standard terms of sale. The Company provides distributors with replacement parts at no charge during the warranty period. International distributors are responsible for installation, repair and other customer service to installed systems in their territory. All systems parts are modular sub-components that are easily removed and replaced. The Company maintains adequate parts inventory and provides overnight replacement parts shipments to its dealers.

On July 11, 2002, the Company entered into a Major Account Facilitator Contract with Peter Kristensen and F. Briton McConkie. Under the terms of the contract, Messrs. Kristensen and McConkie agreed to serve as intermediators between the Company and an international agent or customer that would result in an order for 150 Photon(TM) laser systems in Asia. The contract provides that upon execution, the Company is to issue 100,000 shares of its common stock to Messrs. Kristensen and McConkie to cover all expenses associated with the pursuit of the transaction, and upon presentation of a verified order to us, the Company has agreed to issue an additional 100,000 shares of common stock to

Edgar Filing: PARADIGM MEDICAL INDUSTRIES INC - Form 10KSB/A

Messrs. Kristensen and McConkie. Upon completion, and delivery and receipt of payment in full from the international agent or customer for the 150 Photon(TM) laser systems, Messrs. Kristensen and McConkie would be issued an additional 480,000 shares of common stock for serving as transaction facilitator. The Company has issued a total of 100,000 shares of its common stock to Messrs. Kristensen and McConkie pursuant to the terms of the contract.

Messrs. Kristensen and McConkie have retained Ralph Thompson of Novus Technologies, a Utah based firm, to assist in the marketing and sales of the Company's Photon(TM) laser system in Asia. Mr. Thompson, who lived in China for over 10 years, represents U.S. businesses doing business in China. He currently makes trips to China on a regular basis on behalf of the businesses he represents. Although Mr. Thompson continues to represent the Company in the sale of its Photon(TM) laser system in Asia, he has not been successful to date in selling its Photon(TM) laser system to any customers in China or other Asian countries.

12

Research and Development

The Company's primary market for its surgical products is the cataract surgery market. However, the Company believes that its laser systems may potentially have broader ophthalmic applications. Consequently, the Company believes that a strong research and development capability is important for its future. In addition to its expanded in-house research and development capabilities, the Company has enlisted several recognized and respected consultants and other technical personnel to act in technical and medical advisory capacities.

The Company believes its research and development capabilities provide it with the ability to respond to regulatory developments, including new products, new product features devised from its users and new applications for its products on a timely and proprietary basis. The Company intends to continue investing in research and development and to strengthen its ability to enhance existing products and develop new products.

Research, development and service expenses (which includes production and manufacturing support and the service department expenses) decreased by \$264,000, or 26%, to \$768,000 for the twelve months ended December 31, 2004, from \$1,033,000 for the same period in 2003. None of the costs of research and development activities during 2004 and 2003 was borne directly by customers.

From December 1, 2000 to November 30, 2002, the Company entered into a series of consulting agreements with Michael B. Limberg, M.D., in which he agreed to evaluate new technologies and instruments for us. For his services during that period, the Company issued Dr. Limberg a total of 48,000 shares of its common stock and warrants to purchase 300,000 shares of common stock at exercise prices ranging from \$4.00 to \$6.75 per share.

During the period in which Thomas F. Motter served as the Company's Chairman and Chief Executive Officer, he formed a clinical advisory board and met from time to time with the board. Jeffrey F. Poore, who served as the Company's President and Chief Executive Officer from March 2003 to March 2004, decided not to utilize the clinical advisory board. Instead, he consulted with former members of the advisory board on an informal basis. The Company currently has no agreements with any former members of the clinical advisory board and none of these former members hold or own any rights to its products or technologies.

Competition

Edgar Filing: PARADIGM MEDICAL INDUSTRIES INC - Form 10KSB/A

General. The Company is subject to competition in the cataract surgery and the glaucoma diagnostic markets from two principal sources: (i) manufacturers of competing ultrasound systems used when performing cataract treatments and (ii) developers of technologies for ophthalmic diagnostic and surgical instruments used for treatment. A few large companies that are well established in the marketplace, have experienced management, are well financed and have well recognized trade names and product lines dominate the surgical equipment industry. The Company believes that the combined sales of five entities account for over 90% of the cataract surgery market. The remaining market is fragmented among emerging smaller companies, some of which are foreign. The ophthalmic diagnostic market has a similar composition.

Most major competitors either entered or expanded into the cataract or glaucoma markets through the acquisition of smaller, entrepreneurial high-technology manufacturing companies. Therefore, because existing competitors or other entities desiring to enter the market could conceivably acquire current entrepreneurial enterprises with small market activity, any and all competitors must be considered to be formidable.

The Cataract Surgical System Industry. The major manufacturers utilizing ultrasonic technology offer products currently in use. Those systems rely on accessories including single-use cassette packs and other ancillary surgical disposables such as saline solution, sutures and intraocular lenses for their profits. The cassette packs are required for fluid and tissue collection during the surgical procedure. The cassette packs are generally unique and proprietary to their respective systems and represent a barrier to entry for third-party, lower-cost after-market suppliers. While there is growing market resistance in the United States and internationally to single-use cassettes, anticipates that manufacturers of ultrasound equipment will continue to develop and enhance their present ultrasound products in order to protect their investments in system and cassette technology and to protect their profits from sales of these cassettes and accessories. The Company's Precisionist Thirty Thousand(TM) ultrasonic phaco system has the ability to use either reusable or single-use disposable components. The Photon(TM) laser cataract system will utilize probes and cassette packs designed for single-use and semi-disposable instruments priced at a level consistent with the demands of health care cost containment. This will allow the health care providers a substantial measure of cost containment, while providing the Company with the quality control and income capability of cassette sales.

The international market, with significantly lower medical budgets, has not been able to justify the expense of using disposable components. Budgetary constraints have limited current manufacturers from gaining a significant share of the international ultrasound equipment market, and have provided a niche for the emerging smaller companies discussed above.

13

Ultrasound Equipment Manufacturers. As a relatively recent entrant into the cataract surgical equipment market with a newer equipment line, the Company is establishing itself and, as yet, does not hold a significant share of the market. The Company currently recognize Bausch & Lomb, Alcon Laboratories, and Allergan Medical Optics as its primary competitors in the ultrasound phaco cataract equipment market.

Laser Equipment Manufacturers. There are several other companies attempting to develop laser equipment for cataract surgery. These companies can be differentiated by the laser wavelength employed for the cataract surgery. Based on the information currently available to us; Er:YAG laser wavelength appears to offer a less viable means of removing cataracts than the Nd:YAG

Edgar Filing: PARADIGM MEDICAL INDUSTRIES INC - Form 10KSB/A

wavelength used by the Photon(TM). One competitor uses a Nd:YAG wavelength, however the laser is used only to vibrate an ultrasonic needle. Thus the device remains an ultrasonic system subject to same risk factors of phaco, thereby eliminating the benefits of using a laser to remove the cataract. The Company also believes that its product is sufficiently distinctive and, if properly marketed, can capture a significant share of the cataract surgical device market. However, there are substantial risks in undertaking a new venture in an established and already highly competitive industry. In the short-term, the Company is seeking to exploit these opportunities. Depending upon further developments, the Company may ultimately exploit those opportunities through a merger with a stronger entity already established or one that desires to enter the medical industry.

The Company believes that its ability to compete successfully will depend on its capability to create and maintain advanced technology, develop proprietary products, attract and retain scientific personnel, obtain patent or other proprietary protection for its products and technologies, obtain required regulatory approvals and manufacture, assemble and successfully market products either alone or through third parties.

The Retinal Diagnostic Market. The Glaucoma Research Foundation suggests that with the aging of the so-called baby boom generation, there will be an increase of macular degeneration and glaucoma in the United States, the leading causes of adult blindness worldwide. The National Eye Institute stated in 2002 that the number of visually impaired Americans is likely to double over the next three decades. Their report estimated that 2.4 million people suffer some vision impairment in this country. The damage caused by these diseases is irreversible. The preconditions for the onset of macular degeneration or glaucoma are low ocular blood flow and/or high intraocular pressure. Diagnostic screening is important for individuals susceptible to these diseases. People in high risk categories include: African Americans over 40 years of age, all persons over 60 years of age, persons with a family history of glaucoma or diabetes, and the very nearsighted. The glaucoma Research Foundation recommends that these high risk individuals be tested regularly for glaucoma. According to the U.S. Census Bureau, in 1995 there were over 30 million adults 65 years of age and older and 8 million African Americans 45 years of age and older. The Glaucoma Research Foundation reports that glaucoma currently accounts for more than 7 million visits to physicians annually.

The Company is subject to intense competition in the ophthalmic diagnostic market from well-financed, established companies with recognizable trade names and product lines and new and developing technologies. The industry is dominated by several large entities which the Company believes accounts for the majority of diagnostic equipment sales. The Company continues to derive revenues from the sale of its ultrasound diagnostic equipment and blood flow analyzer. The blood flow analyzer is designed to detect glaucoma in an earlier stage than is presently possible. In addition, the device performs tonometry and blood flow analysis. Other ophthalmic diagnostic devices that do not detect glaucoma in the early stages of the disease as does the Company's analyzer retail at comparable prices. Thus, the Company believes that it can compete in the diagnostic market place based upon the lower price and improved diagnostic functions of the analyzer.

Intellectual Property Protection

The Company's cataract surgical products are proprietary in design, engineering and performance. Its surgical ultrasonic products have not been patented to date because the primary technology for ultrasonic tissue fragmentation, as available to all competitors in the market, is mainly in the public domain.

The Company acquired proprietary intellectual property in the

Edgar Filing: PARADIGM MEDICAL INDUSTRIES INC - Form 10KSB/A

transaction with Humphrey Systems when the Company purchased the diagnostic ultrasonic product line in 1999. This technology uses ultrasound to create a high-resolution computer image of the unseen parts of the eye that is a "map" for the practitioner. The P40 UBM Ultrasound Biomicroscope, one of the ultrasonic products the Company purchased, is subject to a license agreement dated September 27, 1990, with Sunnybrook Health Science Center. Under the terms of the license agreement, the Company has the exclusive worldwide rights to manufacture and sell the UBM biomicroscope, for which the Company is required to pay a royalty of \$150 for each licensed product sold. The license agreement was automatically terminated by its terms on September 27, 2002, at which time the Company has a royalty free world-wide license to use and sell the P40 UBM Ultrasound Biomicroscope. However, the Company has a continuing obligation after such termination to continue to use and sell the biomicroscope only in the field of ophthalmology.

14

The Photon(TM) laser cataract probe is protected under a United States patent issued to Daniel M. Eichenbaum, M.D. in 1987 and subsequently assigned to PhotoMed International, Inc. and a Japanese patent issued to the Company in 1997 for the utility and methods of laser ablation, aspiration and irrigation of tissue through a hand-held probe of a unique design. The United States patent is due to expire in September 2004.

The Company secured the exclusive worldwide rights to this patent shortly after its issue, and to the international patents pending, from PhotoMed by means of a license agreement dated July 7, 1993. The license agreement provides the Company with the rights to manufacture, distribute and sell a laser system using the Photon(TM) laser cataract probe and related components to customers on a world wide basis, for which PhotoMed is to receive a 1% royalty on all net sales of such systems and related components sold worldwide.

Under the license agreement PhotoMed is entitled to all royalty payments from net sales at the time of billing to the purchaser or within 30 days of the date of shipment, whichever occurs first. The Company is required each quarter to prepare a summary of sales and the royalties to which PhotoMed is entitled to be paid. The sales summary must list the number of surgical systems and disposable units sold in each country, the dollar value of gross and net sales, the amount of the royalty to which PhotoMed is entitled, and any other information requested by PhotoMed from time to time. Under the terms of the agreement, the Company has agreed to be actively engaged in either research and development of a saleable product utilizing the patent or in marketing and selling such a product.

The license agreement was amended on December 5, 1997 to allow PhotoMed the right to conduct research, development and marketing utilizing the patent in certain medical subspecialties other than ophthalmology for which the Company would receive royalty payments equal to 1% of the proceeds from the net sales of products utilizing the patent. The license agreement expires when the United States patent rights expire in September 2004, but the license agreement shall be automatically extended or renewed for any term of extension or renewal awarded for the patent rights. In addition, the Company has the right to terminate the license agreement at any time after July 7, 2003 upon 90 days prior written notice to PhotoMed.

PhotoMed and Dr. Eichenbaum brought legal action against the Company on September 11, 2000 involving an amount of royalties that are allegedly due and owing to them from the sale of equipment by us. The Company has paid \$14,736 to bring all royalty payments up to date through June 30, 2001. The Company has been working with PhotoMed and Dr. Eichenbaum to ensure that the royalty calculations have been correctly made. It is anticipated that once the parties

Edgar Filing: PARADIGM MEDICAL INDUSTRIES INC - Form 10KSB/A

agree on the correct royalty calculations, the legal action will be dismissed. However, if the parties are unable to agree on a method for calculating royalties, there is a risk that PhotoMed and Dr. Eichenbaum might amend the complaint to request termination of the license agreement and, if successful, the Company would lose its rights to manufacture or sell the Photon(TM) laser system.

The Photon(TM) laser cataract probe is also protected under a United States patent issued to the Company in 2002 for a laser surgical device for the removal of intraocular tissue including a handpiece and a trap. The patent is due to expire in August 2019. There are also two pending United States patents relating to the Photon(TM) laser cataract probe.

The Blood Flow Analyzer(TM) has been granted a patent in the United Kingdom in 1998 and in the United States in 1999, and has a patent pending in Japan. These patents relate to pneumatic pressure probes for use in measuring change in intra-ocular pressure and in measuring pulsatile ocular blood flow. The United States patent rights expire in January 2019 and the United Kingdom patent rights expire in November 2015.

The Dicon(TM) Perimeter and the Dicon(TM) Corneal Topographer each have a U.S. patent with a wide scope of claims. The United States patent for the Dicon(TM) Perimeter was issued in 1991 and the patent rights expire in March 2010. The United States patent for the Dicon(TM) Corneal Perimeter was issued in 2002 and the patent rights expire in January 2018.

The Company's trademarks are important to its business. It is its policy to pursue trademark registrations for its trademarks associated with its products as appropriate. Also, the Company relies on common law trademark rights to protect its unregistered trademarks, although common law trademark rights do not provide the Company with the same level of protection as would U.S. federal registered trademarks. Common law trademark rights only extend to the geographical area in which the trademark is actually used while U.S. federal registration prohibits the use of the trademark by any party anywhere in the United States.

The Company also relies on trade secret law to protect some aspects of its intellectual property. All of its key employees, consultants and advisors are required to enter into a confidentiality agreement with us. Most of its third-party manufacturers and formulators are also bound by confidentiality agreements with us.

Regulation

The FDA under the Food, Drug and Cosmetics Act regulates the Company's surgical and diagnostic systems as medical devices. As such, these devices require premarket clearance or approval by the FDA prior to their marketing and sale. Such clearance or approval is premised on the production of evidence

sufficient for the Company to show reasonable assurance of safety and effectiveness regarding its products. Pursuant to the Food, Drug and Cosmetics Act, the FDA regulates the manufacture, distribution and production of medical devices in the United States and the export of medical devices from the United States. Noncompliance with applicable requirements can result in fines, injunctions, civil penalties, recall or seizure of products, total or partial suspension of production, denial of premarket clearance or approval for devices. Recommendations by the FDA that the Company not be allowed to enter into government contracts and criminal prosecution may also be made.

Edgar Filing: PARADIGM MEDICAL INDUSTRIES INC - Form 10KSB/A

Following the enactment of the Medical Device Amendments to the Food, Drug and Cosmetics Act in May 1976, the FDA began classifying medical devices in commercial distribution into one of three classes: Class I, II or III. This classification is based on the controls that are perceived to be necessary to reasonably ensure the safety and effectiveness of medical devices. Class I devices are those devices, the safety and effectiveness of which can reasonably be ensured through general controls, such as adequate labeling, advertising, pre-marketing notification and adherence to the FDA's Quality System Requirements regulations. Some Class I devices are exempt from some of the general controls. Class II devices are those devices the safety and effectiveness of which can reasonably be assured through the use of special controls, such as performance standards, postmarket surveillance, patient registries and FDA guidelines. Class III devices are devices that must receive pre-marketing approval by the FDA to ensure their safety and effectiveness. Generally, Class III devices are limited to life-sustaining, life-supporting or implantable devices, or to new devices that have been found not to be substantially equivalent to legally marketed devices.

There are two principal methods by which FDA approval may be obtained. One method is to seek FDA approval through a pre-marketing notification filing under Section 510(k) of the Food, Drug and Cosmetics Act. If a manufacturer or distributor of a medical device can establish that a proposed device is "substantially equivalent" to a legally marketed Class I or Class II medical device or to a pre-1976 Class III medical device for which the FDA has not called for a pre-marketing approval, the manufacturer or distributor may seek FDA Section 510(k) pre-marketing clearance for the device by filing a Section 510(k) pre-marketing notification. The Section 510(k) notification and the claim of substantial equivalence will likely have to be supported by various types of data and materials, possibly including clinical testing results, obtained under an Investigational Device Exemption granted by the FDA. The manufacturer or distributor may not place the device into interstate commerce until an order is issued by the FDA granting pre-marketing clearance for the device. There can be no assurance that the Company will obtain Section 510(k) pre-marketing clearance for any of the future devices for which the Company seeks such clearance including the Photon(TM) laser system.

The FDA may determine that the device is "substantially equivalent" to another legally marketed Class I, Class II or pre-1976 Class III device for which the FDA has not called for a pre-marketing approval, and allow the proposed device to be marketed in the United States. The FDA may determine, however, that the proposed device is not substantially equivalent, or may require further information, such as additional test data, before the FDA is able to make a determination regarding substantial equivalence. A "not substantially equivalent" determination or a request for additional information could delay the Company's market introduction of its products and could have a material adverse effect on its business, operating results and financial condition.

The alternate method to seek approval is to obtain pre-marketing approval from the FDA. If a manufacturer or distributor of a medical device cannot establish that a proposed device is substantially equivalent to another legally marketed device, whether or not the FDA has made a determination in response to a Section 510(k) notification, the manufacturer or distributor will have to seek pre-marketing approval for the proposed device. A pre-marketing approval application would have to be submitted and be supported by extensive data, including preclinical and clinical trial data to prove the safety and efficacy of the device. If human clinical trials of a proposed device are required and the device presents a significant risk, the manufacturer or the distributor of the device will have to file an Investigational Device Exemption application with the FDA prior to commencing human clinical trials. The Investigational Device Exemption application must be supported by data,

Edgar Filing: PARADIGM MEDICAL INDUSTRIES INC - Form 10KSB/A

typically including the results of animal and mechanical testing. If the Investigational Device Exemption application is approved, human clinical trials may begin at a specific number of investigational sites, and the approval letter could include the number of patients approved by the FDA.

An Investigational Device Exemption clinical trial can be divided into several parts or phases. Sometimes, a company will conduct a feasibility study (Phase I) to confirm that a device functions according to its design and operating parameters. This is a usual clinical trial site. If the Phase I results are promising, the applicant may, with the FDA's permission, expand the number of clinical trial sites and the number of patients to be treated to assure reasonable stability of clinical results. Phase II studies are performed to confirm predictability of results and the absence of adverse reactions. The applicant may, upon receipt of the FDA's authorization, subsequently expand the study to a third phase with a larger number of clinical trial sites and a greater number of patients. This involves longer patient follow-up times and the collection of more patient data. Product claims, labeling and core data for the pre-marketing approval are derived primarily from this portion of the clinical trial. The applicant may also, upon receipt of the FDA's permission, consolidate one or more of such portions of the study. Sponsors of clinical trials are permitted to sell those devices distributed in the course of the study, provided such compensation does not exceed recovery of the costs of manufacture, research, development and handling. Although both approval methods may require clinical testing of the device in question under an approved Investigational Device Exemption, the pre-marketing approval procedure is more complex and time consuming.

16

Upon receipt of the pre-marketing approval application, the FDA makes a threshold determination whether the application is sufficiently complete to permit a substantive review. If the FDA determines that the pre-marketing approval is sufficiently complete to permit a substantive review, the FDA will "file" the application. Once the submission is filed, the FDA has by regulation 90 days to review it; however, the review time is often extended significantly by the FDA asking for more information or clarification of information already provided in the submission. During the review period, an advisory committee may also evaluate the application and provide recommendations to the FDA as to whether the device should be approved. In addition, the FDA will inspect the manufacturing facility to ensure compliance with the FDA's Quality System Requirements prior to approval of a pre-marketing application. While the FDA has responded to pre-marketing approval applications within the allotted time period, pre-marketing approval reviews generally take approximately 12 to 18 months or more from the date of filing to approval. The pre-marketing approval process is lengthy and expensive, and there can be no assurance that such approval will be obtained for any of the Company's products determined to be subject to such requirements. A number of devices for which other companies have sought pre-marketing approval have never been approved for marketing.

Any products manufactured or distributed by the Company pursuant to a premarket clearance notification or pre-marketing approval are or will be subject to pervasive and continuing regulation by the FDA. The Food, Drug and Cosmetics Act also requires that the Company's products be manufactured in registered establishments and in accordance with Quality System Requirements regulations. Labeling, advertising and promotional activities are subject to scrutiny by the FDA and, in certain instances, by the Federal Trade Commission. The export of medical devices is also subject to regulation in certain instances. In addition, the use of the Company's products may be regulated by various state agencies. All lasers manufactured for the Company are subject to the Radiation Control for Health and Safety Act administered by the Center for Devices and Radiological Health of the FDA. The law requires laser manufacturers

Edgar Filing: PARADIGM MEDICAL INDUSTRIES INC - Form 10KSB/A

to file new product and annual reports and to maintain quality control, product testing and sales records, to incorporate certain design and operating features in lasers sold to end users pursuant to specific performance standards, and to comply with labeling and certification requirements. Various warning labels must be affixed to the laser, depending on the class of the product, as established by the performance standards.

Although the Company believes that it currently complies and will continue to comply with all applicable regulations regarding the manufacture and sale of medical devices, such regulations are always subject to change and depend heavily on administrative interpretations. There can be no assurance that future changes in review guidelines, regulations or administrative interpretations by the FDA or other regulatory bodies, with possible retroactive effect, will not materially adversely affect us. In addition to the foregoing, the Company is subject to numerous federal, state and local laws relating to such matters as safe working conditions, manufacturing practices, environmental protection, fire hazard control and disposal of potentially hazardous substances. There can be no assurance that the Company will not be required to incur significant costs to comply with such laws and regulations and that such compliance will not have a material adverse effect upon the Company's ability to conduct business.

The Company and the manufacturers of its products may be inspected on a routine basis by both the FDA and individual states for compliance with current Quality System Requirements regulations and other requirements.

Congress has considered several comprehensive federal health care programs designed to broaden coverage and reduce the costs of existing government and private insurance programs. These programs have been the subject of criticism within Congress and the health care industry, and many alternative programs and features of programs have been proposed and discussed. Therefore, the Company cannot predict the content of any federal health care program, if any is passed by Congress, or its effect on the Company and its business. Some measures that have been suggested as possible elements of a new program, such as government price ceilings on non-reimbursable procedures and spending limitations on hospitals and other healthcare providers for new equipment, could have an adverse effect on its business, operating results or financial condition. Uncertainty concerning the features of any health care program considered by the Congress, its adoption by the Congress and the effect of the program on the Company's business could result in volatility of the market price of its common stock.

Furthermore, the introduction of the Company's products in foreign countries may require it to obtain foreign regulatory clearances. The Company believes that only a limited number of foreign countries have extensive regulatory requirements, including France, Germany, Korea, China and Japan. The time involved for regulatory approval in foreign countries varies and can take a number of years. A number of European and other economically advanced countries, including Italy, Norway, Spain and Sweden, have not developed regulatory agencies for intensive supervision of such devices. Instead, they generally have been willing to accept the approval of the FDA. Therefore, a pre-marketing approval, Section 510(k) or approved Investigational Device Exemption from the FDA is tantamount to approval in those countries. These countries and most developing countries have simply deferred direct discretion to licensed practicing surgeons to determine the nature of devices that they will use in medical procedures. The Company's two ultrasound systems, the Photon(TM) laser cataract system it is developing and the ocular blood flow analyzer are all

devices, which require FDA approval. Therefore, a significant aspect of the

Edgar Filing: PARADIGM MEDICAL INDUSTRIES INC - Form 10KSB/A

acceptance of the devices in the market is the Company's effectiveness in obtaining the necessary approvals. Having an approved Investigational Device Exemption allows the Company to export a product to qualified investigational sites.

Regulatory Status of Products

All of the Company's products, with the exception of the Photon(TM), are approved for sale in the U.S. by the FDA under a 510(k). All of its products have been accepted for import into CE countries and various non-CE countries.

The Company acquired permission from the FDA to export the Photon(TM) Laser Cataract System outside the United States under an open Investigational Device Exemption granted by the FDA in September 1994. Although the Photon(TM) laser cataract system is uniquely configured in an original and proprietary manner, the laser system, a Nd:YAG laser, is not proprietary to the device or the Company and is widely used in the medical industry and other industries as well. Of particular significance is the fact that this particular component has received previous market clearance from the FDA for other ophthalmic and medical applications. Also of significance is the Company's belief that the surgical treatment method used with the Photon(TM) laser is similar to the current ultrasound cataract treatment employed by ophthalmologists.

The Company submitted a Premarket Notification 510(k) application to the FDA for the Photon(TM) laser cataract system in September 1993. The FDA requested clinical support data for claims made in the 510(k), and in October 1994 the Company submitted an Investigational Device Exemption application to provide for a "modest clinical study" in order to collect the data required by the FDA for clearance of the Photon(TM) laser cataract system. The FDA granted this Investigational Device Exemption in May 1995 for a Phase I Feasibility Study. The Company began human clinical trials in April 1996 and completed the Phase I study in November 1997. The Company started Phase II trials in September 1998 and completed numerous cases of treatment group and control group patients, which were included in its submission to the FDA.

The Company received a warning letter dated August 30, 2000, from the Office of Compliance, Center for Devices and Radiological Health of the Food and Drug Administration relating to certain deficiencies in the human clinical trials for its Photon(TM) Laser Cataract System. The warning letter concerns the conditions found by the FDA during several audits at its clinical sites. The FDA's comments were isolated to the administrative procedures of compiling data from the clinical sites. The Company responded to the warning letter in a submission dated September 27, 2000. In the submission the Company took corrective action that included submitting a revised clinical protocol and case report forms and procedures for the collection and control of data. In a subsequent letter dated November 2, 2000 to us, the FDA granted conditional approval provided that the Company correct certain deficiencies. After providing several additional submissions to the FDA, the Company received a letter dated February 13, 2001 from the FDA stating that the deficiencies had been corrected and the clinical trials could continue.

Subsequent to the warning letter, the Company received approval to continue its clinical trials, the results of which were included in its supplemental submission to the FDA in October 2001 for the existing (510)(k) predicate device application for the Photon(TM) laser system. In December 2001, the Company received a preliminary review from the FDA regarding the supplemental submission. As a result of that preliminary review, the Company submitted additional clinical information to the FDA on February 6, 2002. The application is receiving ongoing review by the FDA. On May 7, 2002, the Company received a letter from the FDA requesting further clinical information. The Company has generated additional clinical information in response to the letter and are uncertain if the Company will make a submission to the FDA with the

Edgar Filing: PARADIGM MEDICAL INDUSTRIES INC - Form 10KSB/A

additional clinical information. Because of the "going concern" status of the Company, management has focused efforts on those products and activities that will, in its opinion, achieve the most resource efficient short-term cash flow to the Company. Its diagnostic products are currently its major focus and the Photon(TM) and other extensive research and development prospects have been put on hold pending future evaluation when the Company's financial position improves. Its focus is not on any specific diagnostic product or products, but rather on its entire group of diagnostic products.

Employees

As of March 31, 2005, the Company had 27 full-time employees. This number does not include its manufacturer's representatives who are independent contractors rather than its employees. The Company also utilizes several consultants and advisors. There can be no assurance that the Company will be successful in recruiting or retaining key personnel. None of its employees are a member of a labor union and the Company has never experienced any business interruption as a result of any labor disputes.

In December 2001, the Company initiated the first phase of a corporate downsizing program to reduce its operating expenses. The Company implemented the second phase of its downsizing program in the second quarter of 2002, by closing and transferring its manufacturing from its site in San Diego, California to Salt Lake City, resulting in further reductions in operating expenses. As a

18

result of the downsizing program and some resignations, the number of its employees has been reduced by 72% from 112 to 31 employees. The estimated cost savings from the downsizing program will be in excess of \$2,000,000 annually. The costs of downsizing have included one-time expenses of approximately \$43,000 for moving and travel. In addition, the Company incurred additional one-time expenses of approximately \$18,000 for housing accommodations for key employees working in Salt Lake City. The Company realized a net cost savings from downsizing of approximately \$2,394,000 during the twelve months ended December 31, 2002.

Item 2. Description of Property

The Company's executive offices are currently located at 2355 South 1070 West, Salt Lake City, Utah. This facility consists of approximately 23,238 square feet of leased office space under a three-year lease that was to expire on March 1, 2003 with an additional three-year renewal option. These facilities are leased from Eden Roc, a California partnership, at a base monthly rate of \$21,163 plus a \$3,342 monthly common area maintenance fee. In January 2003, the Company renegotiated a three-year lease with Eden Roc at a monthly rate of \$9,295 plus a \$1,859 common area maintenance fee for the year 2003, with rate increases to \$9,574 for 2004 and to \$9,861 for 2005. Pursuant to the lease, the Company pays all real estate and personal property taxes and the insurance costs on the premises.

The Company believes that these facilities are adequate and satisfy its needs for the foreseeable future.

Item 3. Legal Proceedings

An action was brought against the Company in March 2000 by George Wiseman, a former employee, in the Third District Court of Salt Lake County, State of Utah. The complaint alleges that the Company owes Mr. Wiseman 6,370 shares of its common stock plus costs, attorney's fees and a wage penalty (equal to 1,960 additional shares of its common stock) pursuant to Utah law. The action

Edgar Filing: PARADIGM MEDICAL INDUSTRIES INC - Form 10KSB/A

is based upon an extension of a written employment agreement. The Company disputes the amount allegedly owed and intends to vigorously defend against the action.

An action was brought against the Company on September 11, 2000 by PhotoMed International, Inc. and Daniel M. Eichenbaum, M.D. in the Third District Court of Salt Lake County, State of Utah. The action involves an amount of royalties that are allegedly due and owing to PhotoMed International, Inc. and Dr. Eichenbaum under a license agreement dated July 7, 1993, with respect to the sale of certain equipment, plus costs and attorneys' fees. Certain discovery has taken place and the Company has paid royalties of \$15,717, which the Company believes brings all payments current as of the date of last payment on January 7, 2005. The Company has been working with PhotoMed and Dr. Eichenbaum to ensure that the calculations have been correctly made on the royalties paid as well as the proper method of calculation for the future.

It is anticipated that once the parties can agree on the correct calculations on the royalties, the legal action will be dismissed. An issue in dispute concerning the method of calculating royalties is whether royalties should be paid on returned equipment. Since July 1, 2001, only one Photon(TM) laser system has been sold and no systems returned. However, if the parties are unable to agree on a method for calculating royalties, there is a risk that PhotoMed and Dr. Eichenbaum might amend their complaint to request termination of the license agreement and, if successful, the Company would lose its right to manufacture and sell the Photon(TM) laser system.

On May 14, 2003, a complaint was filed in the United States District Court, District of Utah, captioned Richard Meyer, individually and on behalf of all others similarly suited v. Paradigm Medical Industries, Inc., Thomas Motter, Mark Miehle and John Hemmer, Case No. 2:03 CV00448TC. The complaint also indicates that it is a "Class Action Complaint for Violations of Federal Securities Law and Plaintiffs Demand a Trial by Jury." The Company has retained legal counsel to review the complaint, which appears to be focused on alleged false and misleading statements pertaining to the Blood Flow Analyzer(TM) and concerning a purchase order from Valdespino Associates Enterprises and Westland Financial Corporation.

More specifically, the complaint alleges that the Company falsely stated in its Securities and Exchange Commission filings and press releases that it had received authorization to use an insurance reimbursement CPT code from the CPT Code Research and Development Division of the American Medical Association for reimbursement to doctors in connection with the Blood Flow Analyzer(TM), adding that the CPT code provides for a reimbursement to doctors of \$57.00 per patient for use of the Blood Flow Analyzer(TM). According to the complaint, the CPT code was critical. Without a reimbursement code, physicians would not purchase the Blood Flow Analyzer(TM) because they could not receive compensation for performance of medical procedures using the medical device. The complaint further contends that the Company never received the CPT code from the American Medical Association at any time. Nevertheless, it is alleged that the Company continued to misrepresent in its SEC filings and press releases that it had received the CPT code. It is also alleged that the Company have never made a full, corrective disclosure with respect to this alleged misstatement.

The complaint also alleges that on July 11, 2002, the Company issued a press release falsely announcing that it had received a purchase order from Valdespino Associates Enterprises and Westland Financial Corporation for 200 sets of its entire portfolio of products, with \$70 million in systems to be delivered over a two-year period, then another \$35 million of orders to be completed in the third year. The complaint further alleges that the Company had

Edgar Filing: PARADIGM MEDICAL INDUSTRIES INC - Form 10KSB/A

never received a true purchase order for its products. As a result of these alleged misstatements, the complaint contends that the price of the Company's shares of common stock was artificially inflated during the period from April 25, 2001 through May 14, 2003, and the persons who purchased or retained the Company's common shares during that period suffered substantial damages. The complaint requests judgment for unspecified damages, together with interest and attorney's fees.

The Company disputes having issued false and misleading statements concerning the Blood Flow Analyzer(TM) and a purchase order from Westland Financial Corporation and Valdespino Associates Enterprises. On April 25, 2001, the Company issued a press release that stated it had received authorization to use common procedure terminology or CPT code number 92120 for the Blood Flow Analyzer(TM). This press release was based on a letter the Company received from the CPT Editorial Research and Development Department of the American Medical Association stating that CPT code number 92120 was the appropriate common procedure terminology or CPT code number for doctors to use when reporting certain procedures performed with the Blood Flow Analyzer(TM).

Currently, there is reimbursement by insurance payors to doctors using the Blood Flow Analyzer(TM) in 22 states and partial reimbursement in four other states. The amount of reimbursement to doctors using the Blood Flow Analyzer(TM) generally ranges from \$56.00 to \$76.00 per patient, depending upon the insurance payor. Insurance payors providing reimbursement for the Blood Flow Analyzer(TM) have the discretion to increase or reduce the amount of reimbursement. The Company is endeavoring to obtain reimbursement by insurance payors in other states where there is currently no reimbursement being made. The Company believes it has continued to correctly represent in its Securities and Exchange Commission filings that the CPT Editorial Research and Development Department of the American Medical Association has informed the Company that CPT code number 92120 is the appropriate code for doctors to use when reporting certain procedures performed with the Blood Flow Analyzer(TM).

On July 11, 2002, the Company issued a press release that stated it received a purchase order from Valdespino Associates Enterprises and Westland Financial Corporation for 200 complete sets of the Company's entire product portfolio of diagnostic and surgical equipment for Mexican ophthalmic practitioners, to be followed by a second order of 100 sets of equipment. The press release was based on a purchase order dated July 10, 2002 that the Company entered into with Westland Financial Corporation for the sale of 200 complete sets of the Company's surgical and diagnostic equipment to Mexican ophthalmic practitioners. The press release also stated that the initial order was for \$70 million of the Company's equipment to be filled over a two-year period followed by the second order of \$35 million in equipment to be completed in the third year. The press release further stated that delivery would be made in tranches of 25 complete sets of the Company's equipment, beginning in 30 days from the date of the purchase order.

On September 13, 2002, the board of directors issued a press release updating the status of its product sales to the Mexican ophthalmic practitioners. In that press release the board stated that the Company had been in discussions for the prior nine months with Westland Financial Corporation, aimed at supplying its medical device products to the Mexican market. In the past, the Company has had a business relationship with Westland Financial. Upon investigation, the board of directors had determined that the purchase order referenced in the July 11, 2002 press release was not of such a nature as to be enforceable for the purpose of sales or revenue recognition. In addition, the Company had not sent any shipment of medical products to Mexican ophthalmic practitioners nor received payment for those products pursuant to those discussions. The September 13, 2002 press release also stated that discussions were continuing with Westland Financial Corporation regarding sales and marketing activities for the Company's medical device products in Mexico, but

Edgar Filing: PARADIGM MEDICAL INDUSTRIES INC - Form 10KSB/A

the Company could not, at the time, predict or provide any assurance that any transactions would result.

On June 2, 2003, a complaint was filed in the United States District Court, captioned Michael Marrone v. Paradigm Medical Industries, Inc., Thomas Motter, Mark Miehle and John Hemmer, Case No. 2:03 CV00513 PGC. On July 11, 2003, a complaint was filed in the same United States District Court, captioned Lidia Milian v. Paradigm Medical Industries, Inc., Thomas Motter, Mark Miehle and John Hemmer, Case No. 2:03 CV00617PGC. Both complaints seek class action status. These cases are substantially similar in nature to the Meyer case, including the contention that as a result of allegedly false statements regarding the Blood Flow Analyzer(TM) and the purchase order from Westland Financial Corporation and Valdespino Associates Enterprises, the price of the Company's common stock was artificially inflated and the persons who purchased the Company's common shares during the class period suffered substantial damages. In a press release dated July 11, 2003, captioned "Milberg Weiss announces the filing of a class action suit against Paradigm Medical Industries, Inc. on behalf of investors," the law firm of Milberg Weiss Bershad Hynen & Levach LLP, which represents purchasers of the Company's securities in the class action suit filed on July 11, 2003, stated that the Company alleged misrepresentations caused the market price of the stock to be artificially inflated during the class period. As a result, it is alleged that investors suffered millions of dollars in damages from the Company's alleged misstatements.

20

The cases request judgment for unspecified damages, together with interest and attorney's fees. These cases have now been consolidated with the Meyer case into a single action, captioned In re: Paradigm Medical Industries Securities Litigation, Case No. 03-CV-448TC. The law firm of Milberg Weiss Bershad & Schulman LLP is representing purchasers of the Company's securities in the consolidated class action. On June 28, 2004, a consolidated amended class action complaint was filed on behalf of purchasers of the Company's securities. The consolidated complaint is similar to the three class action complaints and alleges that the Company made false representations regarding the CPT code for the Blood Flow Analyzer(TM), but it includes additional allegations that the Company failed to disclose in a timely manner that doctors were being denied reimbursement for procedures performed with the Blood Flow Analyzer(TM). The consolidated complaint also alleges that the Company made false statements regarding the purchase order from Westland Financial Corporation and Valdespino Associates Enterprises. The Company believes the consolidated complaint is without merit and intends to vigorously defend and protect its interests in the case.

The Company was issued a Directors and Officers Liability and Company Reimbursement Policy by United States Fire Insurance Company for the period from July 10, 2002 to July 10, 2003 that contains a \$5,000,000 limit of liability, which is excess of a \$250,000 retention. The officers and directors named in the consolidated cases have requested coverage under the policy. U.S. Fire is currently investigating whether it may have a right to deny coverage for the consolidated cases based upon policy terms, conditions and exclusions or to rescind the policy based upon misrepresentations contained in its application for insurance.

The Company has paid \$30,000 to U.S. Fire toward satisfaction of the \$250,000 retention that is applicable to the consolidated cases. The Company has advised U.S. Fire that it cannot pay the \$250,000 retention due to its current financial circumstances. As a consequence, on January 8, 2004, the Company entered into a non-waiver agreement with U.S. Fire in which U.S. Fire agreed to fund and advance the Company's retention obligation in consideration for which

Edgar Filing: PARADIGM MEDICAL INDUSTRIES INC - Form 10KSB/A

the Company has agreed to reimburse U.S. Fire the sum of \$5,000 a month, for a period of six months, with the first of such payments due on February 15, 2004. Thereafter, commencing on August 15, 2004, the Company is currently required to reimburse U.S. Fire the sum of \$10,000 per month until the entire amount of \$250,000 has been reimbursed to U.S. Fire. The Company has made payments to U.S. Fire in the aggregate amount of \$30,000 of which its last payment of \$10,000 was made on October 11, 2004. These payments were for the \$5,000 monthly payments due during the six month period from February 15 to July 15, 2004, leaving a remaining retention obligation to U.S. Fire of \$220,000.

In the event U.S. Fire determines that the Company or the former officers and directors named in the consolidated cases are not entitled to coverage under the policy, or that it is entitled to rescind the policy, or should the Company be declared in default under the non-waiver agreement on account of its failure to make the monthly payments owed to U.S. Fire for funding the Company's retention obligation, then the Company agrees to pay U.S. Fire, on demand, the full amount of all costs advanced by U.S. Fire, except for those amounts that the Company may have reimbursed to U.S. Fire pursuant to the monthly payments due under the non-waiver agreement. Moreover, if U.S. Fire denies coverage for the consolidated cases under the policy, the Company would owe its litigation counsel in the class action lawsuits, for any legal fees not paid by U.S. Fire. However, U.S. Fire has currently agreed to pay the legal fees relating to the class action lawsuits.

The Company will be in default under the non-waiver agreement if it fails to make any payment due to U.S. Fire thereunder when such payment is due, or institute proceedings to be adjudicated as bankrupt or insolvent. U.S. Fire's obligation to advance defense costs under the agreement will terminate in the event that the \$5,000,000 policy limit of liability is exhausted. If U.S. Fire denies coverage for the consolidated cases under the policy and the Company is not successful in defending and protecting its interests in the cases, resulting in a judgment against the Company for substantial damages, the Company would not be able to pay such liability and, as a result, would be forced to seek bankruptcy protection.

On July 10, 2003, an action was filed in the United States District Court, District of Utah, by Innovative Optics, Inc. and Barton Dietrich Investments, L.P. Defendants include us, Thomas Motter, Mark Miehle and John Hemmer, former officers of the company. The complaint claims that Innovative and Barton entered into an asset purchase agreement with the Company on January 31, 2002, in which the Company agreed to purchase all the assets of Innovative in consideration for the issuance of 1,310,000 shares of the Company's common stock to Innovative. The complaint claims the Company breached the asset purchase agreement. The complaint also claims that the Company allegedly made false and misleading statements pertaining to the Blood Flow Analyzer(TM) and concerning a purchase order from Valdespino Associates Enterprises and Westland Financial Corporation. The purpose of these statements, according to the complaint, was to

21

induce Innovative to sell its assets and purchase the shares of the Company's common stock at artificially inflated prices while simultaneously deceiving Innovative and Barton into believing that the Company's shares were worth more than they actually were. The complaint contends that had Innovative and Barton known the truth they would not have sold Innovative to us, would not have purchased the Company's stock for the assets of Innovative, or would not have purchased the stock at the inflated prices that were paid. The complaint further contends that as a result of the allegedly false statements, Innovative and Barton suffered substantial damages in an amount to be proven at trial.

The complaint also claims that 491,250 of the shares to be issued to

Edgar Filing: PARADIGM MEDICAL INDUSTRIES INC - Form 10KSB/A

Innovative in the asset purchase transaction were not issued on a timely basis and the Company also did not file a registration statement with the Securities and Exchange Commission within five months of the closing date of the asset purchase transaction. As a result, the complaint alleges that the value of the shares of the Company's common stock issued to Innovative in the transaction declined, and Innovative and Barton suffered damages in an amount to be proven at trial. The Company filed an answer to the complaint and also filed counterclaims against Innovative and Barton for breach of contract. The Company believes the complaint is without merit and intends to vigorously defend and protect its interests in the action. If the Company is not successful in defending and protecting its interests in this action, resulting in a judgment against the Company for substantial damages, and U.S. Fire denies coverage in the litigation under the Directors and Officers Liability and Company Reimbursement Policy, the Company would not be able to pay such liability and, as a result, would be forced to seek bankruptcy protection.

On October 14, 2003, an action was filed in the Third Judicial District Court, Salt Lake County, State of Utah, captioned Albert Kinzinger, Jr., individually and on behalf of all others similarly situated vs. Paradigm Medical Industries, Inc., Thomas Motter, Mark Miehle, Randall A. Mackey, and John Hemmer, Case No. 030922608. The complaint also indicates that it is a "Class Action Complaint for Violations of Utah Securities Laws and Plaintiffs Demand a Trial by Jury." The Company has retained legal counsel to review the complaint, which appears to be focused on alleged false or misleading statements pertaining to the Blood Flow Analyzer(TM). More specifically, the complaint alleges that the Company falsely stated in Securities and Exchange Commission filings and press releases that it had received authorization to use an insurance reimbursement CPT code from the CPT Code Research and Development Division of the American Medical Association in connection with the Blood Flow Analyzer(TM), adding that the CPT code provides for a reimbursement to doctors of \$57.00 per patient for the Blood Flow Analyzer(TM).

The purpose of these statements, according to the complaint, was to induce investors to purchase shares of the Company's Series E preferred stock in a private placement transaction at artificially inflated prices. The complaint contends that as a result of these statements, the investors that purchased shares of its Series E preferred stock in the private offering suffered substantial damages to be proven at trial. The complaint also alleges that the Company sold Series E preferred shares without registering the sale of such shares or obtaining an exemption from registration. The complaint requests rescission, compensatory damages and treble damages, including interest and attorneys' fees. The Company filed an answer to the complaint. The Company believes the complaint is without merit and intends to vigorously defend its interests in the action. If the Company is not successful in defending and protecting its interests in the action, resulting in a judgment against it for substantial damages, and U.S. Fire denies coverage in the litigation under the Directors and Officers Liability and Company Reimbursement Policy, the Company would not be able to pay such liability and, as a result, would be forced to seek bankruptcy protection.

On January 26, 2005, the Company completed a written settlement agreement to settle the lawsuit that Innovative Optics, Inc. and Barton Dietrich Investments, L.P. brought against the Company and its former executive officers. Under the terms of the settlement, U.S. Fire agreed to pay Innovative Optics, Inc. and Barton Dietrich Investments, L.P. the sum of \$367,500 in cash. Payment of this amount is contingent, however, upon the courts in the federal and state class action lawsuits granting final approval of the settlements reached in those respective actions, and such orders becoming final and non-appealable.

On February 23, 2005, the Company executed written settlement agreements to settle the federal and state court class action lawsuits that were filed against the Company and its former executive officers. Under the terms of

Edgar Filing: PARADIGM MEDICAL INDUSTRIES INC - Form 10KSB/A

settlement of the federal court class action lawsuit, U.S. Fire agreed to pay the sum of \$1,507,500 in cash to the class members that purchased the Company's securities during the period between April 17, 2002 and November 4, 2002. Under the terms of settlement of the state court class action lawsuit, U.S. Fire agreed to pay the sum of \$625,000 in cash to the class members that purchased shares of Series E Convertible preferred stock on or about July 11, 2001.

As a condition to the settlement agreements to settle the federal and state court class action lawsuits, the courts in such lawsuits must have entered orders granting final approval of the settlements reached in those respective actions, and such orders must have become final and non-appealable. On March 3, 2005, the federal court entered an order granting preliminary approval of the settlement in the federal court class action lawsuit and providing for notice to be sent to potential class members. On April 18, 2005, a hearing was held in the state court and the court entered a minute entry granting preliminary approval of the settlement in the state court class action lawsuit.

As a further condition to the settlement agreements to settle the federal and state court class action lawsuits, both settlement agreements provide that U.S. Fire must not have exercised its option to terminate the settlement agreements. U.S. Fire has the option to terminate the settlement agreements if the cumulative dollar value of the claims held by individuals or entities that "opt out" of the federal and state class action lawsuits exceeds \$250,000. If such "opt outs" exceed \$250,000, however, plaintiffs in the federal and state court class action lawsuits will have five days to cure by reducing the amount of "opt outs" to less than \$250,000.

22

If U.S. Fire exercises its option to terminate the settlement agreements, then all parties to the settlement agreements will be restored to their respective positions in the various actions as of the date of the settlement agreements. In addition, the terms and provisions of the settlement agreements will have no further force and effect on the various parties and will be deemed null and void in their entirety.

Under the terms of the settlement agreements regarding the federal and state court class action lawsuits and the lawsuit that Innovative Optics, Inc. and Barton Dietrich Investors, L.P. brought against the Company and its former executive officers, U.S. Fire has agreed to pay a total of \$2,500,000 in cash to the classes in the class action lawsuits and to Innovative Optics, Inc. and Barton Dietrich Investments, L.P. in settlement of these lawsuits. Under the terms of settlement, Paradigm Medical is to pay U.S. Fire the sum of \$220,000 representing the remaining amount owing under the \$250,000 retention obligation in the insurance policy, and to execute a policy release in favor of U.S. Fire as to coverage under the insurance policy.

An action was filed on June 20, 2003, in the Third Judicial District Court, Salt Lake County, State of Utah (Civil No. 030914195) by CitiCorp Vendor Finance, Inc., formerly known as Copelco Capital, Inc. The complaint claims that \$49,626 plus interest is due for the leasing of three copy machines that were delivered to the Company's Salt Lake City facilities on or about April of 2000. The action also seeks an award of attorney's fees and costs incurred in the collection. The Company disputes the amounts allegedly owed, asserting that two of the machines were returned to the leasing company because they did not work properly. A responsive pleading has been filed. The Company was engaged in settlement discussions with CitiCorp until counsel for CitiCorp withdrew from the case. New counsel for CitiCorp has been appointed and it is anticipated that settlement discussions will resume.

An action was filed in June, 2003 in the Third Judicial District Court,

Edgar Filing: PARADIGM MEDICAL INDUSTRIES INC - Form 10KSB/A

Salt Lake County, State of Utah (Civil No. 030914719) by Franklin Funding, Inc. in which it alleges that the Company had entered into a lease agreement for the lease of certain equipment for which payment is due. It is claimed that there is due and owing approximately \$89,988 after accruing late fees, interest, repossession costs, collection costs and attorneys' fees. On August 28, 2003, the Company agreed to a settlement of the case with Franklin Funding by agreeing to make 24 monthly payments of \$2,300 to Franklin Funding, with the first monthly payment due on August 29, 2003. As of March 31, 2005, the Company has made 19 monthly payments of \$2,300 each to Franklin Funding.

The Company received demand letters dated July 18, 2003, September 26, 2003 and November 10, 2003 from counsel for Douglas A. MacLeod, M.D., a shareholder of the company. In the July 18, 2003 letter, Dr. MacLeod demands that he and certain entities with which he is involved or controls, namely the Douglas A. MacLeod, M.D. Profit Sharing Trust, St. Marks' Eye Institute and Milan Holdings, Ltd., be issued a total of 2,296,667 shares of the Company's common stock and warrants to purchase 1,192,500 shares of its common stock at an exercise price of \$.25 per share. Dr. MacLeod claims that these common shares and warrants are owing to him and the related entities under the terms of a mutual release dated January 16, 2003, which he and the related entities entered into with us. Dr. MacLeod renewed his request for these additional common shares and warrants in the September 26, 2003 and November 10, 2003 demand letters. The Company believes that Dr. MacLeod's claims and assertions are without merit and that neither he nor the related entities are entitled to any additional shares of its common stock or any additional warrants under the terms of the mutual release. The Company intends to vigorously defend against any legal action that Dr. MacLeod may bring.

On August 3, 2003, a complaint was filed against the Company by Corinne Powell, a former employee, in the Third Judicial District Court, Salt Lake County, State of Utah (Civil No. 030918364). Defendants consist of the Company and Randall A. Mackey, Dr. David M. Silver and Keith D. Ignatz, directors of the Company. The complaint alleges that at the time the Company laid off Ms. Powell on March 25, 2003, she was owed \$2,030 for business expenses, \$11,063 for accrued vacation days, \$12,818 for unpaid commissions, the fair market value of 50,000 stock options exercisable at \$5.00 per share that she claims she was prevented from exercising, attorney's fees and a continuing wage penalty under Utah law. On March 29, 2005, the Company agreed to a settlement with Ms. Powell of her claims for unpaid business expenses, accrued vacation days, and unpaid commissions by agreeing to pay her \$13,000. The Company has not yet made payment to Ms. Powell for the agreed upon settlement amount.

On September 10, 2003, an action was filed against the Company by Larry Hicks in the Third Judicial District Court, Salt Lake County, State of Utah, (Civil No. 030922220), for payments due under a consulting agreement with us. The complaint claims that monthly payments of \$3,083 are due for the months of October 2002 to October 2003 under a consulting agreement and, if the agreement is terminated, for the sum of \$110,000 minus whatever the Company has paid Mr. Hicks prior to such termination, plus costs, attorney's fees and a wage penalty pursuant to Utah law. The Company has filed an answer in which it denies any liability to Mr. Hicks. Formal discovery in the matter has commenced. The Company disputes the amount allegedly owed and intends to vigorously defend against such action.

On November 7, 2003, a complaint was filed against the Company by Todd Smith, a former employee, in the Third Judicial District Court, Salt Lake County, State of Utah (Civil No. 030924951 CN). Defendants consist of the Company and Randall Mackey, a director of the Company. The complaint alleges that while an employee of the Company, Mr. Smith was granted stock options to

Edgar Filing: PARADIGM MEDICAL INDUSTRIES INC - Form 10KSB/A

purchase 16,800 shares of common stock exercisable at \$5.00 per share. Mr. Smith claims unpaid wages in the amount of the fair market value of the stock options he claims he was prevented from exercising, attorney's fees, and a continuing wage penalty under Utah law. The Company believes the claims are without merit and intends to vigorously defend against such action.

On May 25, 2004, an action was brought against the Company by Jeffrey F. Poore, former President and Chief Executive Officer of the Company, in the Third Judicial District Court of Salt Lake County, State of Utah (Civil No. 040910875). The complaint alleges that the Company unlawfully terminated the written employment agreement between Mr. Poore and the Company. As a result, Mr. Poore demands judgment against the Company for \$350,000, representing his annual salary for the two remaining years under the employment agreement, for money judgment based on the value of his benefits for the two remaining years under the employment agreement, including profit sharing plans, 401(k) and cafeteria plans, health, hospitalization, dental, disability and other insurance plans canceled by the Company, and for money judgment equal to the value of the stock options granted to him under the employment agreement. The Company disputes the amounts allegedly owed in the complaint and believes that there was a sufficient basis to terminate Mr. Poore's employment for cause under the terms of the employment agreement. Accordingly, the Company intends to vigorously defend against the action.

On August 9, 2004, a third party complaint was brought against the Company by Wakefield Eye Center and Dr. Kenneth C. Westfield (collectively "Westfield"). The original action was brought by American Express Business Finance Corporation against Westfield on May 27, 2004 in the District Court, Clark County, State of Nevada (Civil No. A486307, Dept. No. XXI) concerning the financing of the purchase of a Blood Flow Analyzer(TM) involving Westfield Eye Center. The transaction took place during the latter half of 2001. Westfield takes the position that if there is liability of Westfield to American Express this liability is ultimately ours and the other third-party defendants. The amount being sought against Westfield by American Express in the original action includes the sum of \$29,765.83, together with interest and attorney's fees. Westfield's alleged claims against the Company include fraud, breach of contract, promissory estoppel, declaratory relief, negligence, negligent supervision, damages for injuries resulting from actions of employee/contractor, wilful and wanton misconduct, conspiracy, and breach of fiduciary duty as well as costs and attorney's fees. Westfield also seeks punitive damages. The Company has filed an answer to the third party complaint in which the Company denies liability. Formal discovery in the matter involving us has commenced. The case has been referred to arbitration. The Company intends to vigorously defend the action.

On March 31, 2005, an action was filed against the Company by Joseph W. Spadafora in the United States District Court, District of Utah (Civil No. 2:05CV00278 TS). The complaint alleges that Dr. Spadafora was a clinical investigator in the study for the FDA involving the Company's Photon(TM) laser system where he performed numerous surgeries using the Photon(TM). Dr. Spadafora contends that in meetings with Company personnel he suggested ways in which the handpiece on the Photon(TM) could be improved. Dr. Spadafora further contends that on August 5, 1999, the Company filed a patent application for an improved handpiece with the United States Patent and Trademark Office but he was not named as one of the inventors or a co-inventor on the patent application.

On September 24, 2004, the Company was issued a patent entitled, "Laser Surgival Handpiece with Photon Trap." Because the Company did not list Dr. Spadafora as one of the inventors or a co-inventor on the patent, Dr. Spadafora is requesting in his complaint that a court order be entered declaring that he is the inventor or co-inventor of the patent and, as a result, is entitled to all or part of the royalties and profits that the Company earned or will earn from the sale of any product incorporating or using the improved handpiece, plus

Edgar Filing: PARADIGM MEDICAL INDUSTRIES INC - Form 10KSB/A

interest and attorney's fees. The Company disputes the claims made by Dr. Spadafora and intends to vigorously defend against such action.

The Company is not a party to any other material legal proceedings outside the ordinary course of its business or to any other legal proceedings, which, if adversely determined, would have a material adverse effect on its financial condition or results of operations.

Item 4. Submission of Matters to a Vote of Security Holders

No matters were submitted to a vote of the Company's shareholders during the quarter ended December 31, 2004.

PART II

Item 5. Market for Common Equity and Related Stockholder Matters

The Company's authorized capital stock consists of 80,000,000 shares of common stock, \$.001 par value per share, and 5,000,000 shares of preferred stock, \$.001 par value per share. The Company has created seven classes of preferred stock, designated as Series A preferred stock, Series B preferred stock, Series C preferred stock, Series D preferred stock, Series E preferred stock, Series F preferred stock and Series G preferred stock.

24

The Company's common stock and Class A warrants trade on the OTC Bulletin Board under the respective symbols of "PMED.OB" and "PMEDW.OB." Prior to July 22, 1996, there was no public market for the common stock. From July 22, 1996 to June 25, 2003, its common stock and Class A warrants were listed on the Nasdaq SmallCap Market. Since June 25, 2003, its common stock and Class A warrants have traded on the OTC Bulletin Board. As of April 26, 2005, the closing sale prices of the common stock and Class A warrants were \$.07 per share and \$.01 per warrant, respectively. The following are the high and low sale prices for the common stock and Class A warrants by quarter as reported by Nasdaq from January 1, 2000 to June 25, 2003 and by the OTC Bulletin Board since June 25, 2003.

Period (Calendar Year)	Common Stock Price Range		Class A Warrants Price Range	
	High	Low	High	Low
2000				
First Quarter.....	14.50	6.88	6.50	2.63
Second Quarter.....	10.50	4.19	3.63	1.19
Third Quarter.....	6.19	3.38	2.00	.50
Fourth Quarter.....	4.94	1.31	1.25	.50
2001				
First Quarter.....	4.13	1.50	1.00	.19
Second Quarter.....	3.50	1.61	.74	.19
Third Quarter.....	2.75	1.86	.45	.16
Fourth Quarter.....	3.08	1.94	.39	.17
2002				
First Quarter.....	3.31	2.21	.38	.19
Second Quarter.....				.05
Third Quarter.....	1.91	.60	.32	.08
Fourth Quarter.....	1.50	.16	.20	.01

Edgar Filing: PARADIGM MEDICAL INDUSTRIES INC - Form 10KSB/A

Fourth Quarter.....	.30	.13	.10	
2003				
First Quarter.....	.42	.14	.12	.01
Second Quarter.....	.74	.14	.44	.01
Third Quarter.....	.42	.18	.18	.01
Fourth Quarter24	.15	.10	.02
2004				
First Quarter21	.15	.05	.02
Second Quarter.....	.16	.07	.05	.03
Third Quarter.....	.12	.09	.03	.02
Fourth Quarter.....	.12	.08	.02	.02
2005				
First Quarter10	.08	.02	.01
Second Quarter (through April 26, 2005)...	.09	.07	.01	.01

The Company's Series A preferred stock, Series B preferred stock, Series C preferred stock, Series D preferred stock, Series E preferred stock, Series F preferred stock and Series G preferred stock are not publicly traded. As of March 31, 2004, there were 717 record holders of common stock, six record holders of Series A preferred stock, four record holders of Series B preferred stock, no record holders of Series C preferred stock, one record holder of Series D preferred stock, 14 record holders of Series E preferred stock, 52 record holders of Series F preferred stock, and two record holders of Series G preferred stock.

The Company has never paid any cash dividends on its common stock and does not anticipate paying any cash dividends on its common stock in the foreseeable future. The Company must pay cash dividends to holders of its Series A preferred, Series B preferred, Series C preferred, Series D preferred stock, Series E preferred, Series F preferred stock and Series G preferred stock before it can pay any cash dividend to holders of its common stock. Dividends paid in cash pursuant to outstanding shares of its Series A, Series B, Series C, Series D, Series E, Series F and Series G preferred stock are only payable from its surplus earnings, and are non-cumulative and therefore, no deficiencies in dividend payments from one year will be carried forward to the next.

25

The Company currently intends to retain future earnings, if any, to fund the development and growth of its proposed business and operations. Any payment of cash dividends in the future on the common stock will be dependent upon its financial condition, results of operations, current and anticipated cash requirements, plans for expansion, restrictions, if any, under any debt obligations, as well as other factors that its board of directors deems relevant. The Company issued 6,764 shares of its Series A preferred and 6,017 shares of its Series B preferred on January 8, 1996 as a stock dividend to Series A and Series B preferred shareholders of record as of December 31, 1994.

Item 6. Management's Discussion and Analysis or Plan of Operation

This report contains forward-looking statements and information relating to the Company that is based on beliefs of management as well as assumptions made by, and information currently available to management. These statements reflect its current view respecting future events and are subject to risks, uncertainties and assumptions, including the risks and uncertainties noted throughout the document. Although the Company has attempted to identify important factors that could cause the actual results to differ materially, there may be other factors that cause the forward-looking statements not to come

Edgar Filing: PARADIGM MEDICAL INDUSTRIES INC - Form 10KSB/A

true as anticipated, believed, projected, expected or intended. Should one or more of these risks or uncertainties materialize, or should underlying assumptions prove incorrect, actual results may differ materially from those described herein as anticipated, believed, projected, estimated, expected or intended.

Critical Accounting Policies

Revenue Recognition. The Company recognizes revenue in compliance with Staff Accounting Bulletin 101, Revenue Recognition in Financial Statements (SAB 101), as revised by Staff Accounting Bulletin No. 104, Revenue Recognition (SAB 104). SAB 101 and SAB 104 detail four criteria that must exist before revenue is recognized:

1. Persuasive evidence of an arrangement exists. Prior to shipment of product, the Company required a signed purchase order and, depending upon the customer, a down payment toward the final invoiced price or full payment in advance with certain international product distributors.

2. Delivery and performance have occurred. Unless the purchase order requires specific installation or customer acceptance, the Company recognizes revenue when the product ships. If the purchase order requires specific installation or customer acceptance, the Company recognizes revenue when such installation or acceptance has occurred. Title to the product passes to its customer upon shipment. This revenue recognition policy does not differ among its various different product lines. The Company guarantees the functionality of its product. If its product does not function as marketed when received by the customer, the Company either makes the necessary repairs on site or has the product shipped to the Company for the repair work. Once the product has been repaired and retested for functionality, it is re-shipped to the customer. The Company provides warranties that generally extend for one year from the date of sale. Such warranties cover the necessary parts and labor to repair the product as well as any shipping costs that may be required. The Company maintains a reserve for estimated warranty costs based on its historical experience and management's current expectations.

3. The sales price is fixed or determinable. The purchase order received from the customer includes the agreed-upon sales price. The Company does not accept customer orders, and therefore does not recognize revenue, until the sales price is fixed.

4. Collectibility is reasonably assured. With limited exceptions, the Company requires down payments on product prior to shipment. In some cases the Company requires payment in full prior to shipment. The Company also performs credit checks on new customers and ongoing credit checks on existing customers. The Company maintains an allowance for doubtful accounts receivable based on historical experience and management's current expectations.

Recoverability of Inventory. Since its inception, the Company has purchased several complete lines of inventory. In some circumstances the Company has been able to utilize certain items acquired and others remain unused. On a quarterly basis, the Company attempts to identify inventory items that have shown relatively no movement or very slow movement. Generally, if an item has shown little or no movement for over a year, it is determined not to be recoverable and a reserve is established for that item. In addition, if the Company identifies products that have become obsolete due to product upgrades or enhancements, a reserve is established for such products. The Company intends to make efforts to sell these items at significantly discounted prices. If items are sold, the cash received would be recorded as revenue, but there would be no

Edgar Filing: PARADIGM MEDICAL INDUSTRIES INC - Form 10KSB/A

cost of sales on such items due to the reserve that has been recorded. At the time of sale, the inventory would be reduced for the item sold and the corresponding inventory reserve would also be reduced.

Recoverability of Goodwill and Other Intangible Assets. The Company's intangible assets consist of goodwill, product and technology rights, engineering and design costs, and patent costs. Intangibles with a determined life are amortized on a straight-line basis over their determined useful life and are also evaluated for potential impairment if events or circumstances indicate that the carrying amount may not be recoverable. Intangibles with an indefinite life, such as goodwill, are not amortized but are tested for impairment on an annual basis or when events and circumstances indicate that the asset may be impaired. Impairment tests include comparing the fair value of a reporting unit with its carrying net book value, including goodwill. To date, the Company's determination of the fair value of the reporting unit has been based on the estimated future cash flows of that reporting unit.

Allowance for Doubtful Accounts. The Company records an allowance for doubtful accounts to offset estimated uncollectible accounts receivable. Bad debt expense associated with the increases in the allowance for doubtful accounts is recorded as part of general and administrative expense. The Company's accounting policy generally is to record an allowance for receivables over 90 days past due unless there is significant evidence to support that the receivable is collectible.

General

The following Management's Discussion and Analysis of Financial Condition and Results of Operations, contains forward-looking statements, which involve risks and uncertainty. The Company's actual results could differ materially from those anticipated in these forward-looking statements as a result of certain factors discussed in this section. The Company's fiscal year is from January 1 through December 31.

The Company is engaged in the design, development, manufacture and sale of high technology diagnostic and surgical eye care products. Given the "going concern" status of the Company, management has focused efforts on those products and activities that will, in its opinion, achieve the most resource efficient short-term cash flow. As seen in the results for the twelve months ended December 31, 2004, diagnostic products have been the major focus and the Photon(TM) and other extensive research and development projects have been put on hold pending future evaluation when the Company's financial position improves. The Company does not focus on a specific diagnostic product or products but, instead, on this entire diagnostic product group.

During the year ended December 31, 2004, the Company recorded a reduction in the warranty accrual of approximately \$308,000. This reduction was a result of a comprehensive analysis by management regarding historical warranty costs. Historically, the Company has recorded a monthly warranty expense and related increase to the warranty accrual. However, in recent periods the usage of the warranty accrual has continued to decline. After reviewing the recent historical data, management determined that the warranty accrual should be reduced by approximately \$308,000. Management will continue to closely monitor the warranty accrual usage to ensure that the proper amount has been accrued.

During the twelve months ended December 31, 2003, management made certain adjustments to the financial statements, including an increase in the reserve for obsolete or estimated non-recoverable inventory of \$484,000, consisting of an increase in the reserve of \$403,000, offset by a decrease of \$887,000 due to the sale of the SIStem(TM) and the Odyssey(TM) product lines, which were fully reserved. The Company also recorded a net increase in the allowance for doubtful accounts receivable of \$123,000, impairment of

Edgar Filing: PARADIGM MEDICAL INDUSTRIES INC - Form 10KSB/A

intangibles of \$150,000, and increases in accruals to settle outstanding disputes in the amount of \$443,000.

27

The Company's ultrasound diagnostic products include a P55 pachymetric analyzer, a P37 Ultrasound A/B Scan, a P40 Ultrasound BioMicroscope and a P45 Plus UBM Ultrasound BioMicroscope, the technology for which was acquired from Humphrey Systems in 1998. The Company introduced the P45 Plus in the fall of 2000, which combines the A/B Scan, and the biomicroscope into one instrument. In addition, the Company markets its Blood Flow Analyzer(TM) acquired in the purchase of Ocular Blood Flow Ltd. in June 2000. Other diagnostic products are the Dicon(TM) LD400 Auto Perimeter and the Dicon (TM) CT200e Corneal Topographer, which were acquired in the acquisition of Vismed d/b/a Dicon in June 2000. The Company purchased the inventory, design and production rights of the SIStem(TM) , the Odyssey and the Surgetrol from Mentor Corporation in October 1999, which was designed to perform minimally invasive cataract surgery. In November 1999, the Company entered into a Mutual Release and Settlement Agreement with the manufacturer of the Precisionist ThirtyThousand(TM), in which the Company purchased the raw materials and finished goods inventory to bring the manufacturing of this product in-house. During the fourth quarter of 2003, the Company sold all inventory and rights associated with the SIStem(TM) and Odyssey(TM) for \$125,000. This transaction resulted in sales of \$125,000 with no cost of sales because a reserve for obsolete inventory had been recorded on all SIStem(TM) and Odyssey(TM) inventory.

Because of the "going concern" status of the Company, management has focused efforts on those products and activities that will, in its opinion, achieve the most resource efficient short-term cash flow to the Company. As reflected in the results for the fiscal year ended December 31, 2004, diagnostic products are currently the Company's major focus and the Photon(TM) and other extensive research and development projects have been put on hold pending future evaluation when the financial position of the Company improves. Due to the lack of current evidence to support recoverability, the Company has recorded an inventory reserve to offset the inventory associated with the Precisionist Thirty Thousand(TM) and the Photon(TM) as well as certain other inventory items that are estimated to be non-recoverable due to the lack of significant turnover of such items in recent periods. The Company does not focus on a specific diagnostic product or products but, instead, on this entire product group.

The Company has shown improvement in its manufacturing efficiencies, as well as the timeliness and the quality of the Company's services to its customers. For example, a great deal of the improvement is attributable to reforms in operations, which enabled dramatically improved availability of product and decreased lead times. Additional reorganization of services enabled substantially reduced wait times and reserve requirements. Specifically, during 2004, the Company was able to record an increase in income of approximately \$300,000 from a reduction in warranty reserves. This reduction was a result of a comprehensive analysis by management regarding historical warranty costs. Historically, the Company has recorded a monthly warranty expense and related increase to the warranty accrual; however, in recent periods the usage of the warranty accrual has continued to decline. After reviewing the recent historical data, the Company determined that the warranty accrual should be reduced by approximately \$300,000. The Company will continue to closely monitor the warranty accrual usage to ensure that the proper amount has been accrued.

Activities for the twelve months ended December 31, 2004 and 2003 included sales of the Company's products and related accessories and disposable products. In March 2003, the Company named a new president and chief executive officer, Jeffrey F. Poore. Mr. Poore was subsequently replaced by John Y. Yoon as President and Chief Executive Officer on March 18, 2004. The Company named a

Edgar Filing: PARADIGM MEDICAL INDUSTRIES INC - Form 10KSB/A

new vice president of sales and marketing, Ray Cannefax, during the first quarter of 2003, and a new vice president of finance and chief financial officer, Gregory C. Hill, during the second quarter of 2003. Mr. Hill resigned as vice president of finance and chief financial officer on December 5, 2003.

On March 18, 2004, the Company named a new President and Chief Executive Officer, John Y. Yoon. On March 23, 2004, the Company named as new Vice President of Operations and Chief Operating Officer, Aziz A. Mohabbat.

On May 7, 2002, the Company received a letter from the FDA requesting further clinical information regarding the Photon(TM). The Company is in the process of generating the additional clinical information in response to the letter. The Company cannot market or sell the Photon(TM) in the United States until FDA approval is granted. On November 4, 2002, the Company received FDA approval for expanded indications of use of the Blood Flow Analyzer(TM) for

28

pulsatile ocular blood flow, volume and pulsatility equivalence index. Also, the Company is continuing its efforts to educate the payors of Medicare claims throughout the country about the Blood Flow Analyzer(TM), its purposes and the significance of its performance in patient care in order to achieve reimbursements to the providers. These efforts should lead to a more positive effect on sales.

In April 2001, the Company received written authorization from the CPT Editorial Research and Development Department of the American Medical Association to use a common procedure terminology or CPT code number 92120 for its Blood Flow Analyzer(TM), for reimbursement purposes for doctors using the device. However, certain insurance payors have elected not to reimburse doctors using the Blood Flow Analyzer(TM). The Company believes the reasons why insurance payors initially elected not to reimburse doctors using the CPT code were the relatively high volume of claims that began to be submitted under CPT code number 92120 compared to the limited volume of claims previously submitted under this code, and the time consumed by the Blood Flow Analyzer(TM) test, which some payors may have believed was less than what is allowed under CPT code number 92120. This trend began shortly after insurance payors were presented with reimbursement requests under this code, and the Company believes these reasons were the basis for the initiation of non-payment.

The impact of this nonpayment by certain payors on the Company's future operations is a lower volume of sales, particularly in those states where reimbursement is not yet approved or is delayed. Currently, there is reimbursement by insurance payors in 22 states and partial reimbursement in four other states. As insurance payors have the prerogative whether to provide reimbursement to doctors using the Blood Flow Analyzer(TM), the Company is continuing to work with insurance payors in states where there is no reimbursement to doctors using the CPT code to demonstrate the value of the instrument. However, some insurance payors are currently not providing reimbursement to doctors where a regional or state administrator of Medicare has elected not to provide Medicare coverage for the Blood Flow Analyzer(TM). The Company is continuing to work with the regional and state administrators of Medicare who have denied Medicare coverage for the Blood Flow Analyzer(TM) to demonstrate the value of the instrument.

There were a number of factors that contributed to the decrease in sales of the Blood Flow Analyzer (TM) and other products. September 11, 2001, the ensuing Afghanistan conflict, and the Iraq war had a significant impact on the Company's international sales. The U.S. recessionary economic trend has impacted its domestic sales. Additionally, the Company restructured its sales organization and sales channels by decreasing its direct sales force who are

Edgar Filing: PARADIGM MEDICAL INDUSTRIES INC - Form 10KSB/A

full-time employees from 10 direct sales employees on January 1, 2003, to five direct sales employees on December 31, 2004. The dependent sales force was reduced because the Company does not have sufficient revenues to justify the larger direct sales force. One of the challenges for fiscal 2005 will be the judicious reconstruction of the sales force in anticipation of increased sales.

The Company intends to increase its efforts to sell its diagnostic products through independent sales representatives and ophthalmic equipment distributors, which are paid commissions only for their sales. As of December 31, 2004, the Company had two independent sales representatives and two ophthalmic equipment distributors in the United States and 26 ophthalmic and medical product distributors outside the United States. The Company hopes to benefit from these recently hired sales representatives and distributors in the United States as they gain familiarity, through training, of the Company's diagnostic products. Due to concerns over the budget and the effectiveness of trade shows, the Company exhibited at only two trade shows during 2004. The Company monitors trade show attendance to determine the extent to which it will exhibit at future trade shows.

On September 19, 2002, the Company completed a transaction with International Bio-Immune Systems, Inc., a privately held biotechnology based, cancer diagnostic and immunotherapy company, in which the Company acquired 2,663,254 of its shares, or 19.9% of its outstanding shares, and warrants to purchase 1,200,000 shares of common stock of International Bio-Immune Systems at \$2.50 per share for a period of two years, through the exchange and issuance of 736,945 shares of the Company's common stock, the lending of 300,000 shares of the Company's common stock to the company, and the payment of certain of its expenses through the issuance of an aggregate of 94,000 shares of common stock to International Bio-Immune Systems and its counsel. On August 3, 2004, the Company sold its investment in International Bio-Immune Systems for net proceeds of \$505,000 pursuant to a stock purchase and sale agreement with William Ungar, a current director and shareholder of International Bio-Immune Systems. The securities sold to Mr. Ungar consisted of 2,663,254 common shares of International Bio-Immune Systems and warrants to purchase 1,200,000 common shares of International Bio-Immune Systems at \$2.50 per share. Because, for book purposes, the Company's investment in International Bio-Immune Systems had been reduced to \$0, the full amount of the \$505,000 received from the sale of the International Bio-Immune Systems common shares and warrants was reported as a gain in 2004.

29

Results of Operations

Fiscal Year Ended December 31, 2004 Compared to Fiscal Year Ended December 31, 2003

Net sales increased by \$3,000, or 0.1%, to \$3,062,000 for the twelve months ended December 31, 2004, from \$3,059,000 for the comparable period in 2003. Sales of the Company's diagnostic products and related accessories increased by \$296,000, or 19%, to \$2,780,000, or 91% of revenues, during the twelve months ended December 31, 2004 compared with \$2,484,000, or 81% of total revenues, for the comparable period of 2003.

In 2004, sales of the Company's P40 and P45 UBM Ultrasound Biomicroscopes and related accessories were \$855,000, or 28% of total revenues, compared to \$615,000, or 20% of total revenues, in the same period of 2003. Sales from the Blood Flow Analyzer(TM) and related accessories increased by \$175,000 to \$674,000, or 22% of total revenues, during the year ended December 31, 2004 compared with \$499,000, or 13% of total revenues, in the same period of 2003.

Edgar Filing: PARADIGM MEDICAL INDUSTRIES INC - Form 10KSB/A

During 2004, sales from P37 A/B Scan Ocular Ultrasound Diagnostic increased to \$257,000, or 8% of total revenue, slightly up from the \$133,000, or 4% of total revenues, in the same period last year. Sales of the LD 400 and TKS 5000 Autoperimeters and the CT 200 Corneal Topographer and related accessories were slightly lower, with total revenue of \$1,022,000, or 33% of total revenues, in 2004 compared with \$1,100,000, or 36% of total revenues, during the same period of 2003.

Sales of surgical products are at a standstill pending FDA approval of the Photon(TM) laser system. In the twelve month period ended December 31 2004, the Company realized a loss of \$3,000 in the surgical line consisting of the Precisionist Thirty Thousand (TM) and the Photon(TM) laser system. This compared to \$94,000 in sales for the comparable period of 2003, which was mainly from the sale of the SIStem(TM) and Odyssey(TM) product lines.

There were a number of material reasons that contributed to flat sales during the twelve months ended December 31, 2004, compared to the period of 2003. Along with generally weak economic conditions in the United States, the Company initiated aggressive cost-cutting efforts and was able to successfully reduce operating expenses. One of the negative consequences of such aggressive cost cutting was a slow down in the upgrade programs for the Company's product lines. The Company's objective is to focus its sales efforts on the products with the highest potential for sales and strong margins.

During 2004, the Company hired three sales representatives and replaced one bringing the total to four domestic and one international sales representative and one independent representative. International sales were impacted by weakness in the economies of the large industrial countries and by the residual impact of the situation in the Middle East, which had a negative impact on sales to the Middle East, Pakistan, India and other countries in that region.

Gross profit for the twelve months ended December 31, 2004 increased to 60% of total revenues, compared to 32% of total revenues for the same period in 2003. The increase was mainly due to an increase in the inventory reserve of \$403,000 in the twelve months ending December 31, 2003. The \$403,000 increase in inventory reserve in 2003 resulted in an increase to cost of sales. There was no increase or decrease to cost of sales as a result of a change to the reserve for obsolete inventory in 2004. The other major contributing factor to the improved margins was greater operational efficiencies and more timely production planning and scheduling.

On a quarterly basis, we attempt to identify inventory items that have shown relatively no movement or very slow movement. Generally, if an item has shown little or no movement for over a year, it is determined not to be recoverable and a reserve is established for that item. In addition, if we identify products that have become obsolete due to product upgrades or enhancements, a reserve is established for such products. Such analysis resulted in a material increase in the reserve for obsolete or estimated non-recoverable

30

inventory in 2003. There can be no assurance that we will not identify further obsolete inventory due to significant declines in sales of certain products or technological advances of products in the future. We intend to make efforts to sell many of these items at significantly discounted prices. If items are sold, the cash received would be recorded as revenue, but there would be no cost of sales on such items due to the reserve that has been recorded. At the time of sale, the inventory would be reduced for the item sold and the corresponding inventory reserve would also be reduced. We do not expect the sales of these

Edgar Filing: PARADIGM MEDICAL INDUSTRIES INC - Form 10KSB/A

items to be significant in the future. During 2003, we sold all inventory, rights, and technology related to the SIStem and Odyssey product lines for \$125,000. All of the inventory sold in this transaction had previously been fully reserved. Therefore, upon the sale, we reduced inventory by \$887,000 for the original book value of the inventory, reduced the reserve for \$887,000, and recorded revenue for the cash received of \$125,000.

Marketing and selling expenses decreased by \$119,000, or 13%, to \$801,000 for the twelve months ended December 31, 2004, from \$920,000 for the comparable period in 2003. This reduction was due primarily to more effective use of marketing programs. During this period three additional full-time salespersons were added, a print advertising campaign initiated, and plans were made to support a major trade show in the fourth quarter of 2004. At the same time, the use of consultant services declined considerably enabling an overall savings.

General and administrative expenses decreased by \$1,572,000, or 64%, to \$874,000 for the twelve months ended December 31, 2004, from \$2,446,000 for the same period in 2003. The favorable reduction in general and administrative expense in 2004 also reflected the ongoing results of the Company's new budget management and cost reduction programs. In addition, during the period ended December 31, 2004, the Company recorded a reduction in the warranty accrual of approximately \$308,000. This reduction was a result of a comprehensive analysis by management regarding historical warranty costs. Historically, the Company has recorded a monthly warranty expense and related increase to the warranty accrual. However, in recent periods the usage of the warranty accrual has continued to decline. After reviewing the recent historical data, management determined that the warranty accrual should be reduced by approximately \$308,000. Management will continue to closely monitor the warranty accrual usage to ensure that the proper amount has been accrued. The general and administrative expenses during the twelve months ended December 30, 2003 also included \$443,000 in accruals to settle outstanding disputes.

In addition, during 2004, the Company collected approximately \$87,000 in receivables that were previously allowed for in the allowance for doubtful accounts. During 2003, the Company increased the allowance for doubtful accounts by \$123,000. General and administrative expense for the twelve months ended December 31, 2003 also included \$259,000 for 1,562,000 shares of common stock issued to settle potential litigation. The Company issued 1,262,000 common shares to six investors due to a dispute arising from a private offering that was completed on January 22, 2003. We agreed to issue the shares to the investors in the offering at \$.25 per share rather than \$.50 per share, the original offering price (or an additional 1,262,000 shares) to resolve a dispute with the investors concerning certain statements made by a former officer in connection with the sale of said shares. The additional 300,000 shares were issued to settle an outstanding dispute with a consultant regarding services performed by such consultant.

Research, development expenses decreased by \$265,000, or 26%, to \$768,000 for the twelve months ended December 31, 2004, from \$1,033,000 for the same period in 2003. Expenses associated with the development of new products during 2004 decreased compared to 2003, as a result of the Company's efforts to reduce costs and focus on products that are fully developed with the highest potential for sales and high margins.

There was no impairment of assets for the twelve months ended December 31, 2004, compared to \$150,000 in 2003. The impairment expense for 2003 was due to a reduction in the value of certain intangible assets based on their then current estimated fair value.

Due to our ongoing cash flow difficulties, most of the Company's vendors and suppliers were contacted during 2003 and 2004 with attempts to

Edgar Filing: PARADIGM MEDICAL INDUSTRIES INC - Form 10KSB/A

negotiate reduced payments and settlement of outstanding accounts payable. While some vendors refused to negotiate and demanded payment in full, some vendors were willing to settle for a reduced amount. The accounts payable forgiven by vendors and suppliers resulted in a gain of \$206,000 and \$436,000 during the years ended December 31, 2004 and 2003, respectively.

Other income mainly consisted of a gain recorded from the sale of the Company's investment in International Bio-Immune Systems, Inc. In July 2004, the Company sold its investment in International Bio-Immune Systems, Inc. for net proceeds of \$505,000 cash. Because, for book purposes, the Company's investment in International Bio-Immune Systems had previously been reduced to \$0, the full amount of \$505,000 was recorded as a gain in 2004.

31

Liquidity and Capital Resources

The Company used \$77,000 cash in operating activities for the twelve months ended December 31, 2004, compared to \$707,000 for the twelve months ended December 31, 2003. The reduction in cash used by operating activities for the twelve months ended December 31, 2004 was primarily attributable to a significant reduction in net loss and decreases in accounts receivable and inventory, partially offset by a decrease in accrued liabilities. The Company's efforts to substantially reduce costs and manage current assets and current liabilities continued to minimize cash used for operating activities. Net cash used in financing activities was \$56,000 for the twelve months ended December 31, 2004, versus cash provided of \$647,000 in the same period in 2003. During the twelve months ended December 31, 2004, the Company did not sell any shares of common or preferred stock. In the past, the Company has relied heavily upon sales of the Company's common and preferred stock to fund operations. There can be no assurance that such equity funding will be available on terms acceptable to the Company in the future.

The Company had working capital deficit of \$84,000 as of December 31, 2004. In the past, the Company has relied heavily upon sales of its common and preferred stock to fund operations. There can be no assurance that such equity funding will be available on terms acceptable to the Company in the future. The Company will continue to seek funding to meet its working capital requirements through collaborative arrangements and strategic alliances, additional public offerings and private placements of the Company's securities; and bank borrowings. In July 2004, the Company sold its investment in International Bio-Immune Systems, Inc. for net proceeds of \$505,000 in cash. The Company is uncertain whether or not the combination of the cash received from the sale of International Bio-Immune Systems, Inc. stock and the benefits from sales of its products will be sufficient to assure its operations through December 31, 2005. The Company will continue to seek funding through the sale of common and preferred stock.

As of December 31, 2004, the Company had net operating loss carry-forwards (NOLs) of approximately \$48 million. These loss carry-forwards are available to offset future taxable income, if any, and have begun to expire in 2001 and extend for twenty years. The Company's ability to use net operating loss carryforwards (NOLs) to offset future income is dependant upon certain limitations as a result of the pooling transaction with Vismed and the tax laws in effect at the time of the NOLs can be utilized. The Tax Reform Act of 1986 significantly limits the annual amount that can be utilized for certain of these carryforwards as a result of change of ownership.

As of December 31, 2004, the Company had accounts payable of \$752,000, a significant portion of which was over 90 days past due. The Company has contacted many of the vendors or companies that have significant amounts of

Edgar Filing: PARADIGM MEDICAL INDUSTRIES INC - Form 10KSB/A

payables past due in an effort to delay payment, renegotiate a reduced settlement payment, or establish a longer-term payment plan. While some companies have been willing to renegotiate the outstanding amounts, others have demanded payment in full. Under certain conditions, including but not limited to judgments rendered against the Company in a court of law, a group of creditors could force the Company into bankruptcy due to its inability to pay the liabilities arising out of such judgments at that time. In addition to the accounts payable noted above, the Company also has non-cancelable capital lease obligations and operating lease obligations that require the payment of approximately \$194,000 in 2005, and \$14,000 in 2006.

The Company has taken numerous steps to reduce costs and increase operating efficiencies. These steps consist of the following:

1. The Company closed its San Diego facility. In so doing, numerous manufacturing, accounting and management responsibilities were consolidated. In addition, such closure resulted in significant headcount reductions as well as savings in rent and other overhead costs.
2. The Company has significantly reduced the use of consultants, which has resulted in a large decrease to these expenses.
3. The Company has reduced its direct sales force to five representatives, which has resulted in less payroll, travel and other selling expenses.

32

Because the Company has significantly fewer sales representatives, its ability to generate sales has been reduced.

The Company has taken measures to reduce the amount of uncollectible accounts receivable such as more thorough and stringent credit approval, improved training and instruction by sales personnel, and frequent direct communication with the customer subsequent to delivery of the system. The allowance for doubtful accounts was 14% of total outstanding receivables as of December 31, 2004 and 40% as of December 31, 2003. The allowance for doubtful accounts has decreased from \$470,000 at December 31, 2003 to \$101,000 at December 31, 2004. The decrease in the allowance for doubtful accounts was the result of the collection of approximately \$87,000 of receivables that was previously allowed as part of the allowance for doubtful accounts and the write off of \$282,000 of receivables against the allowance. The downturn in the economy worldwide has resulted in increased difficulty in collecting certain accounts. Certain international dealers have some aged unpaid invoices that have not been resolved. The Company has addressed its credit procedures and collection efforts and has instituted changes that require more payments at the time of sale through letters of credit and not on a credit term basis.

The Company intends to continue its efforts to reduce the allowance for doubtful accounts as a percentage of accounts receivable. The Company has ongoing efforts to collect a significant portion of the sales price in advance of the sale or in a timely manner after delivery. During the twelve months ended December 31, 2004, the Company had a net recovery of receivables previously allowed for of \$87,000, and during the twelve months ended December 31, 2003, the Company added a net of \$123,000 to the allowance for doubtful. The Company believes that by requiring a large portion of payment prior to shipment, it has greatly improved the collectibility of its receivables.

The Company carried an allowance for obsolete or estimated non-recoverable inventory of \$1,418,000 at December 31, 2004 and \$1,642,000 at December 31, 2003, or approximately 66% and 62% of total inventory,

Edgar Filing: PARADIGM MEDICAL INDUSTRIES INC - Form 10KSB/A

respectively. This inventory reserve was decreased by \$224,000 during the twelve months ended December 31, 2004 due to a direct write-off of inventory against the reserve; therefore, this decrease in the reserve did not impact cost of sales. The Company's means of expansion and development of product has been largely from acquisition of businesses, product lines, existing inventory, and the rights to specific products. Through such acquisitions, the Company has acquired substantial inventory, some of which the eventual use and recoverability was uncertain. In addition, the Company has a significant amount of inventory relating to the Photon(TM) laser system, which does not yet have FDA approval in order to sell the product domestically. Therefore, the allowance for inventory was established to reserve for these potential eventualities.

On a quarterly basis, the Company attempts to identify inventory items that have shown relatively no movement or very slow movement. Generally, if an item has shown little or no movement for over a year, it is determined not to be recoverable and a reserve is established for that item. In addition, if the Company identifies products that have become obsolete due to product upgrades or enhancements, a reserve is established for such products. The Company intends to make efforts to sell these items at significantly discounted prices. If items are sold, the cash received would be recorded as revenue, but there would be no cost of sales on such items due to the reserve that has been recorded. At the time of sale, the inventory would be reduced for the item sold and the corresponding inventory reserve would also be reduced. During the fourth quarter of 2003, the Company sold all inventory and rights associated with the Phaco SISem(TM) and Odyssey(TM) for \$125,000. Because the full amount of inventory related to the SISEm(TM) and Odyssey(TM) had been fully reserved, no cost of sales were recorded in connection with this sale, thus resulting in gross profit equal to the sales price of \$125,000. The Company does not expect the sales of these items, if any, to be significant in the future.

At this time, the Company's Photon(TM) Laser Ocular Surgery Workstation requires regulatory FDA approval in order to be sold in the United States. Any possible future efforts to complete the clinical trials on the Photon(TM) in order to file for FDA approval would depend on the Company obtaining adequate funding. The Company estimates that the funds needed to complete the clinical trials in order to obtain the necessary regulatory approval on the Photon(TM) to be approximately \$225,000.

33

Effect of Inflation and Foreign Currency Exchange

The Company has not realized a reduction in the selling price of its products as a result of domestic inflation. Nor has it experienced unfavorable profit reductions due to currency exchange fluctuations or inflation with its foreign customers. All sales transactions to date have been denominated in U.S. Dollars.

Impact of New Accounting Pronouncements

In December 2003, the FASB issued Interpretation No. 46 ("FIN 46R") (revised December 2003), Consolidation of Variable Interest Entities, an Interpretation of Accounting Research Bulletin No. 51 ("ARB 51"), which addresses how a business enterprise should evaluate whether it has a controlling interest in an entity through means other than voting rights and, accordingly, should consolidate the entity. FIN 46R replaces FASB Interpretation No. 46 (FIN 46), which was issued in January 2003. Before concluding that it is appropriate to apply ARB 51 voting interest consolidation model to an entity, an enterprise must first determine that the entity is not a variable interest entity (VIE). As of the effective date of FIN 46R, an enterprise must evaluate its involvement with all entities or legal structures created before February 1, 2003, to

Edgar Filing: PARADIGM MEDICAL INDUSTRIES INC - Form 10KSB/A

determine whether consolidation requirements of FIN 46R apply to those entities. There is no grandfathering of existing entities. Public companies must apply either FIN 46 or FIN 46R immediately to entities created after January 31, 2003 and no later than the end of the first reporting period that ends after December 15, 2004. The adoption of FIN 46 had no effect on the Company's consolidated financial position, results of operations or cash flows.

In November 2004, the FASB issued SFAS 151 "Inventory Costs--an amendment of ARB No. 43." This statement amends the guidance in ARB No. 43, Chapter 4, "Inventory Pricing," to clarify the accounting for abnormal amounts of idle facility expense, freight, handling costs, and wasted material (spoilage). Paragraph 5 of ARB 43, Chapter 4, previously stated that "[u]nder some circumstances, items such as idle facility expense, excessive spoilage, double freight, and re-handling costs may be so abnormal as to require treatment as current period charges. . . ." This statement requires that those items be recognized as current-period charges regardless of whether they meet the criterion of "so abnormal." In addition, this statement requires that allocation of fixed production overheads to the costs of conversion be based on the normal capacity of the production facilities. The provisions of this statement shall be effective for inventory costs incurred during fiscal years beginning after June 15, 2005. The Company does not believe adoption of SFAS 151 will have any impact on the Company's consolidated financial statements.

In December 2004, FASB issued SFAS 153 "Exchanges of Nonmonetary Assets--an amendment of APB Opinion No. 29." The guidance in APB Opinion No. 29, Accounting for Nonmonetary Transactions, is based on the principle that exchanges of nonmonetary assets should be measured based on the fair value of the assets exchanged. The guidance in that opinion, however, included certain exceptions to that principle. This statement amends Opinion 29 to eliminate the exception for nonmonetary exchanges of similar productive assets and replaces it with a general exception for exchanges of nonmonetary assets that do not have commercial substance. A nonmonetary exchange has commercial substance if the future cash flows of the entity are expected to change significantly as a result of the exchange. The Company does not believe adoption of SFAS 153 will have any impact on the Company's consolidated financial statements.

In December 2004, the FASB issued FASB Statement No. 123 (revised 2004), "Share-Based Payment." Statement 123(R) addresses the accounting for share-based payment transactions in which an enterprise receives employee services in exchange for (a) equity instruments of the enterprise or (b) liabilities that are based on the fair value of the enterprise's equity instruments or that may be settled by the issuance of such equity instruments. Statement 123(R) requires an entity to recognize the grant-date fair-value of stock options and other equity-based compensation issued to employees in the income statement. The revised statement generally requires that an entity account for those transactions using the fair-value-based method, and eliminates the intrinsic value method of accounting in APB Opinion No. 25, "Accounting for Stock Issued to Employees", which was permitted under Statement 123, as originally issued. The revised statement requires entities to disclose information about the nature of the share-based payment transactions and the effects of those transactions on the financial statements.

Statement 123(R) is effective for public companies that do not file as small business issuers as of the beginning of the first interim or annual reporting period that begins after June 15, 2005. For public companies that file as small business issuers, Statement 123(R) is effective as of the beginning of the first interim or annual reporting period that begins after December 15, 2005 (i.e., first quarter 2006 for the Company). All public companies must use either the modified prospective or the modified retrospective transition method. Early

Edgar Filing: PARADIGM MEDICAL INDUSTRIES INC - Form 10KSB/A

adoption of this statement for interim or annual periods for which financial statements or interim reports have not been issued is encouraged. The Company believes that the adoption of this pronouncement may have a material impact on the Company's financial statements.

Item 7A. Quantitative and Qualitative Disclosures about Market Risk

The Company has no activities in derivative financial or commodity instruments. The Company's exposure to market risks (i.e., interest rate risk, foreign currency exchange rate risk and equity price risk) through other financial instruments, including cash equivalents, accounts receivable and lines of credit, is not material.

Item 8. Financial Statements and Supplementary Data

PARADIGM MEDICAL INDUSTRIES, INC.
Financial Statements
December 31, 2004 and 2003

35

PARADIGM MEDICAL INDUSTRIES, INC. Index to Financial Statements

	Page

Report of Chisholm, Bierwolf & Nilson	F-2
Report of Tanner LC	F-3
Balance Sheet	F-4
Statements of Operations	F-5
Statements of Stockholders' Equity	F-6
Statements of Cash Flows	F-7
Notes to Financial Statements	F-8

F-1

Edgar Filing: PARADIGM MEDICAL INDUSTRIES INC - Form 10KSB/A

REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

The Board of Directors
Paradigm Medical Industries, Inc.
Salt Lake City, Utah

We have audited the accompanying balance sheet of Paradigm Medical Industries, Inc. (the Company) as of December 31, 2004, and the related statements of operations, stockholders' equity and cash flows for the year then ended. 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 audit.

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

In our opinion, the financial statements referred to above present fairly, in all material respects, the financial position of Paradigm Medical Industries, Inc. as of December 31, 2004, and the results of their operations and their cash flows for the year then ended, in conformity with accounting principles generally accepted in the United States of America.

The accompanying financial statements have been prepared assuming the Company will continue as a going concern. As discussed in Note 2 to the financial statements, the Company has a working capital deficit and has suffered recurring operating losses, which raises substantial doubt about its ability to continue as a going concern. Management's plans in regard to these matters are also described in Note 2. The financial statements do not include any adjustments that might result from the outcome of these uncertainties.

Chisholm, Bierwolf & Nilson
Bountiful, Utah
April 8, 2005

F-2

REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

To the Board of Directors and stockholders of
Paradigm Medical Industries, Inc.

We have audited the statements of operations, stockholders' equity, and cash flows of Paradigm Medical Industries, Inc. (the Company) for the year ended

Edgar Filing: PARADIGM MEDICAL INDUSTRIES INC - Form 10KSB/A

December 31, 2003. 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 audit.

We conducted our audit in accordance with the standards of the Public Company Accounting Oversight Board (United States). Those standards require that we plan and perform the audit to obtain reasonable assurance about whether the financial statements are free of material misstatement. An audit includes examining, on a test basis, evidence supporting the amounts and disclosures in the financial statements. An audit also includes assessing the accounting principles used and significant estimates made by management, as well as evaluating the overall financial statement presentation. We believe that our audit provides a reasonable basis for our opinion.

In our opinion, the financial statements referred to above present fairly, in all material respects the results of operations and cash flows of Paradigm Medical Industries, Inc. for the year ended December 31, 2003, in conformity with U.S. generally accepted accounting principles.

The accompanying financial statements have been prepared assuming that the Company will continue as a going concern. As discussed in note 2, the Company has incurred significant losses, and has been unable to generate cash flows from operations. These conditions raise substantial doubt about the Company's ability to continue as a going concern. Management's plans in regard to these matters are also described in note 2. The financial statements do not include any adjustments that might result from the outcome of this uncertainty.

Tanner LC
Salt Lake City, Utah
March 5, 2004

F-3

PARADIGM MEDICAL INDUSTRIES, INC. Balance Sheet

December 31, 2004

Assets	

Current assets:	
Cash	\$ 131,000
Receivables, net	657,000
Inventories, net	720,000
Prepaid and other assets	65,000

Total current assets	1,573,000
Intangibles, net	679,000
Property and equipment, net	109,000

Total assets	\$ 2,361,000

Liabilities and Stockholders' Equity

Edgar Filing: PARADIGM MEDICAL INDUSTRIES INC - Form 10KSB/A

Current liabilities:		
Accounts payable	\$	752,000
Accrued liabilities		858,000
Current portion of capital lease obligations		47,000

Total current liabilities		1,657,000

Capital lease obligations, net of current portion		14,000

Commitments and contingencies		-
Stockholders' equity:		
Preferred stock, \$.001 par value, 5,000,000 shares authorized, 1,751,770 shares issued and outstanding (aggregate liquidation preference of \$1,043,000)		2,000
Common stock, \$.001 par value, 80,000,000 shares authorized, 25,627,764 shares issued and outstanding		25,000
Additional paid-in capital		57,470,000
Accumulated deficit		(56,807,000)

Total stockholders' equity		690,000

Total liabilities and stockholders' equity	\$	2,361,000

See accompanying notes to financial statements.

F-4

PARADIGM MEDICAL INDUSTRIES, INC.
Statements of Operations

Years Ended December 31,

		2004		2003

Sales	\$	3,062,000	\$	3,059,000
Cost of sales		1,217,000		2,086,000

Gross profit		1,845,000		973,000

Operating expenses:				
General and administrative		(874,000)		(2,446,000)
Marketing and selling		(801,000)		(920,000)

Edgar Filing: PARADIGM MEDICAL INDUSTRIES INC - Form 10KSB/A

Research and development	(768,000)	(1,033,000)
Impairment of assets	-	(150,000)
Gain on settlement of liabilities	206,000	436,000
	-----	-----
Total operating expenses	(2,237,000)	(4,113,000)
	-----	-----
Operating loss	(392,000)	(3,140,000)
	-----	-----
Other income (expense):		
Interest income	-	3,000
Other expenses	(27,000)	-
Interest expense	(22,000)	(24,000)
Gain on sale of investment	505,000	-
	-----	-----
Total other income (expense)	456,000	(21,000)
	-----	-----
Income (loss) before provision for income taxes	64,000	(3,161,000)
Provision for income taxes	-	-
	-----	-----
Net income (loss)	\$ 64,000	\$ (3,161,000)
	-----	-----
Beneficial conversion feature on Series G preferred stock	-	(217,000)
Series G preferred stock dividend due to registration rights	(54,000)	-
Deemed dividend from Series G preferred detachable warrants	-	(53,000)
	-----	-----
Net income (loss) applicable to common shareholders	\$ 10,000	\$ (3,431,000)
	-----	-----
Earnings (loss) per common share - basic	\$ -	\$ (0.14)
	-----	-----
Earnings (loss) per common share - diluted	\$ -	\$ (0.14)
	-----	-----
Weighted average common shares - basic	25,405,000	24,058,000
	-----	-----
Weighted average common shares - diluted	27,669,000	24,058,000
	-----	-----

See accompanying notes to financial statements.

F-5

PARADIGM M
Statements

Years Ended Dec

Preferred

Additional

Stock

Edgar Filing: PARADIGM MEDICAL INDUSTRIES INC - Form 10KSB/A

	Stock (See Note 8)	Common Shares	Amount	Paid-In Capital	Subscrip Receivab
Balance at January 1, 2003	\$ -	21,954,238	\$ 22,000	\$ 56,775,000	\$ (294,000)
Conversion of preferred stock	-	115,998	-	-	-
Issuance of common stock for:					
Cash	-	1,658,032	2,000	428,000	-
Settlement of litigation	-	1,562,000	1,000	258,000	-
Commission on sale on sale of common stock	-	82,526	-	-	-
Issuance of stock options and warrants for Services	-	-	-	35,000	-
Issuance of Series G preferred stock for:					
Cash	2,000	-	-	268,000	-
Write off of subscription receivable	-	-	-	(294,000)	294,000
Net loss	-	-	-	-	-
Balance at December 31, 2003	2,000	25,372,794	25,000	57,470,000	-
Conversion of preferred stock	-	255,000	-	-	-
Series G preferred stock dividend due to registration rights	-	-	-	-	-
Net income	-	-	-	-	-
Balance at December 31, 2004	\$ 2,000	25,627,764	\$ 25,000	\$ 57,470,000	\$ -

See accompanying notes to financial statements.

PARADIGM MEDICAL INDUSTRIES
Statements of
Years Ended December 31

	2004	
Cash flows from operating activities:		
Net income (loss)	\$ 64,000	\$ -
Adjustments to reconcile net income (loss) to net cash used in operating activities:		

Edgar Filing: PARADIGM MEDICAL INDUSTRIES INC - Form 10KSB/A

Depreciation and amortization	137,000	
Issuance of stock option/warrant for services	-	
Common stock issued for settlement of litigation	-	
Provision for losses on receivables	(369,000)	
Provision for losses on inventory	(224,000)	
Gain on sale of investment	(505,000)	
Impairment of Intangibles and investments		
(Gain) loss on settlement of liabilities	(206,000)	
(Gain) loss on disposal of assets	13,000	
(Increase) decrease in:		
Receivables	420,000	
Inventories	507,000	
Prepaid and other assets	76,000	
Increase (decrease) in:		
Accounts payable	42,000	
Accrued liabilities	(432,000)	

Net cash used in operating activities	(477,000)	-----
Cash flows from investing activities:		
Purchase of property and equipment	-	
Cash proceeds from sales of investment	532,000	

Net cash provided by (used in) investing activities	532,000	-----
Cash flows from financing activities:		
Proceeds from issuance of Series G preferred stock	-	
Principal payments on notes payable and long-term debt	(56,000)	
Proceeds from exercise of common stock warrants and options	-	

Net cash (used in) provided by financing activities	(56,000)	-----
Net change in cash	(1,000)	
Cash, beginning of year	132,000	

Cash, end of year	\$ 131,000	\$

See accompanying notes to financial statements.

December 31, 2004 and 2003

1. Organization
and Significant
Accounting
Policies

Organization

Paradigm Medical Industries, Inc. (the Company) is a Delaware Corporation incorporated in October 1989. The Company is engaged in the design, development, manufacture, and sale of high technology surgical and diagnostic eye care products. Its surgical equipment is designed to perform minimally invasive cataract surgery and is comprised of surgical devices and related instruments and accessories, including disposable products. Its diagnostic products include a blood flow analyzer, a pachymeter, an A-Scan, an A/B Scan, ultrasound biomicroscopes, a perimeter, and a corneal topographer.

Cash Equivalents

For purposes of the statement of cash flows, cash includes all cash and investments with original maturities to the Company of three months or less.

The Company maintains its cash in bank deposit accounts which, at times, may exceed federally insured limits. The Company has not experienced any losses in such account and believes it is not exposed to any significant credit risk on cash and cash equivalents.

Accounts Receivable

Accounts receivable are carried at original invoice amount less an estimate made for doubtful receivables based on a review of all outstanding amounts on a monthly basis. Specific reserves are estimated by management based on certain assumptions and variables, including the customer's financial condition, age of the customer's receivables, and changes in payment histories. Trade receivables are written off when deemed uncollectible. Recoveries of trade receivables previously written off are recorded when received.

A trade receivable is considered to be past due if any portion of the receivable balance has not been received by the contractual pay date. Interest is not charge on trade receivables that are past due.

Inventories

Inventories are stated at the lower of cost or market, cost is determined using the weighted average method.

F-8

PARADIGM MEDICAL INDUSTRIES, INC.
Notes to Financial Statements
Continued

Edgar Filing: PARADIGM MEDICAL INDUSTRIES INC - Form 10KSB/A

1. Organization and Significant Accounting Policies Continued
- Property and Equipment
Property and equipment are recorded at cost, less accumulated depreciation. Depreciation on property and equipment is determined using the straight-line method over the estimated useful lives of the assets or terms of the lease. Expenditures for maintenance and repairs are expensed when incurred and betterments are capitalized. Gains and losses on sale of property and equipment are reflected in operations.

Intangible Assets

As of December 31, 2004, intangible assets consisted of goodwill related to the purchase of Ocular Blood Flow, Ltd., product rights, capitalized payments to manufacturers for engineering and design services and patent costs. The company performed an impairment test on all intangible assets at December 31, 2004. As a result it was not necessary to incur any impairment expense of intangible assets.

Intangible assets determined to have indefinite useful lives are not amortized. The Company tests such intangible assets with indefinite useful lives for impairment annually or more frequently if events or circumstances indicate that an asset might be impaired. Intangible assets determined to have definite lives are amortized on a straight-line basis over their useful lives. Product rights, capitalized engineering, and patents were fully amortized as of December 31, 2004. The Company reviews such intangible assets with definite lives for impairment to ensure they are appropriately valued if conditions exist that may indicate the carrying value may not be recoverable. Such conditions may include an economic downturn in a geographic market or a change in the assessment of future operations.

Goodwill is not amortized. The Company performs tests for impairment of goodwill annually or more frequently if events or circumstances indicate it might be impaired. Such tests include comparing the fair value of a reporting unit with its carrying value, including goodwill.

Impairment assessments are performed using a variety of methodologies, including cash flow analysis and estimates of sales proceeds. Where applicable, an appropriate discount rate is used, based on the Company's cost of capital rate or location-specific economic factors.

F-9

PARADIGM MEDICAL INDUSTRIES, INC.
Notes to Financial Statements
Continued

1. Organization and Significant Accounting Policies Continued

Evaluation of Other Long-Lived Assets

The Company evaluates the carrying value of the unamortized balances of other long-lived assets to determine whether any impairment of these assets has occurred or whether any revision to the related amortization periods should be made. This evaluation is based on management's projections of the undiscounted future cash flows associated with each asset. If management's evaluation were to indicate that the carrying values of these assets were impaired, such impairment would be recognized by a write down of the applicable asset.

Income Taxes

Deferred income taxes are provided in amounts sufficient to give effect to temporary differences between financial and tax reporting, principally related to net operating loss carryforwards, depreciation, impairment of intangible assets, stock compensation expense, and accrued liabilities.

Stock - Based Compensation

For stock options and warrants granted to employees the Company employs the footnote disclosure provisions of Statement of Financial Accounting Standards (SFAS) No. 123, Accounting for Stock-Based Compensation. SFAS No. 123 encourages entities to adopt a fair-value based method of accounting for stock options or similar equity instruments. However, it also allows an entity to continue measuring compensation cost for stock-based compensation using the intrinsic-value method of accounting prescribed by Accounting Principles Board (APB) Opinion No. 25, Accounting for Stock Issued to Employees (APB 25). The Company has elected to continue to apply the provisions of APB 25 and provide pro forma footnote disclosures required by SFAS No. 123. No stock-based employee compensation cost is reflected in net income, as all options granted under those plans had an exercise price equal to or greater than the market value of the underlying common stock on the date of grant.

Stock options and warrants granted to non-employees for services are accounted for in accordance with SFAS No. 123, which requires expense recognition based on the fair value of the options/warrants granted. The Company calculates the fair value of options and warrants granted by use of the Black-Scholes pricing model.

The following table illustrates the effect on net income and earnings per share if the company had applied the fair value recognition provisions of FASB Statement No.

F-10

1. Organization and Significant Accounting Policies Continued Stock - Based Compensation - Continued
 123, "Accounting for Stock-Based Compensation," to
 stock-based employee compensation.

	Years Ended December 31,	
	2004	2003
Net income (loss) applicable to common shareholders- as reported	\$ 10,000	\$ (3,431,000)
Deduct: total stock-based employee compensation determined under fair value based method for all awards, net of related tax effects	(362,000)	(595,000)
Net loss applicable to common shareholders - pro forma	\$ (352,000)	\$ (4,026,000)
Earnings per share:		
Basic and diluted - as reported	\$ -	\$ (.14)
Basic and diluted - pro forma	\$ (.01)	\$ (.17)

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

	December 31,	
	2004	2003
Expected dividend yield	\$ -	\$ -
Expected stock price		
Volatility	112% - 173%	110%-117%
Risk-free interest rate	4%	4%
Expected life of options	2-7 years	2-7 years

The weighted average fair value of options granted during 2004 and 2003 are \$0.09 and \$0.16, respectively.

Earnings Per Share

The computation of basic earnings per common share is based on the weighted average number of shares outstanding during each year.

1. Organization and Significant Accounting Policies Continued

Earnings Per Share- Continued

The computation of diluted earnings per common share is based on the weighted average number of shares outstanding during the year plus the common stock equivalents, which would arise from the conversion of preferred stock to common stock and from the exercise of stock options and warrants outstanding using the treasury stock method and the average market price per share during the year. Options and warrants to purchase 6,036,469 shares of common stock at prices ranging from \$0.16 to \$12.98 per share were outstanding at December 31, 2003, but were not included in the diluted earnings per share calculation for 2003 because the effect would have been antidilutive.

The following table is a reconciliation of basic and diluted weighted average shares for the years ended December 31, 2004 and 2003.

	Years Ended December 31,	
	2004	2003
Basic weighted average shares outstanding	25,405,000	24,058,000
Common stock equivalent-convertible preferred stock	2,047,000	-
Diluted effect of stock options and warrants	217,000	-
Diluted weighted average shares outstanding	27,669,000	24,058,000

Revenue Recognition

Revenues for sales of products that require specific installation and acceptance by the customer are recognized upon such installation and acceptance by the customer. Revenues for sales of other surgical systems, ultrasound diagnostic devices, and disposable products are recognized when the product is shipped. A signed purchase agreement and a deposit or payment in full from customers is required before a product leaves the premises. Title passes at time of shipment (F.O.B. shipping point).

-
1. Organization and Significant Accounting Policies Continued
- Research and Development
Costs incurred in connection with research and development activities are expensed as incurred. These costs consist of direct and indirect costs associated with specific projects as well as fees paid to various entities that perform certain research on behalf of the Company.
- Concentration of Risk
The market for ophthalmic lasers is subject to rapid technological change, including advances in laser and other technologies and the potential development of alternative surgical techniques or new pharmaceutical products. Development by others of new or improved products, processes or technologies may make products developed by the Company obsolete or less competitive.
- The Company's high technology product line requires the Company to deal with suppliers and subcontractors supplying highly specialized parts, operating highly sophisticated and narrow tolerance equipment and performing highly technical calculations and tasks. Although there are a limited number of suppliers and manufacturers that meet the standards required of a regulated medical device, management believes that other suppliers and manufacturers could provide similar components and services.
- The nature of the Company's business exposes it to risk from product liability claims. The Company maintains product liability insurance providing coverage up to \$1 million per claim with an aggregate policy limit of \$2 million. Any losses that the Company may suffer from any product liability litigation could have a material adverse effect on the Company.
- A significant portion of the Company's product sales is in foreign countries. The economic and political instability of some foreign countries may affect the ability of medical personnel to purchase the Company's products and the ability of the customers to pay for the procedures for which the Company's products are used. Such circumstances could cause a possible loss of sales, which would affect operating results adversely.
- During the years ended December 31, 2004 and 2003, no single customer represented more than 10 percent of total net sales.

-
1. Organization and Significant Accounting Policies Continued
- Concentration of Risk - Continued
- Accounts receivable are due from medical distributors, surgery centers, hospitals, optometrists and ophthalmologists located throughout the U.S. and a number of foreign countries. The receivables are generally due within thirty days for domestic customers with extended terms offered for some international customers. The Company maintains an allowance for estimated potentially uncollectible amounts.
- Warranty
- The Company provides product warranties on the sale of certain products that generally extend for one year from the date of sale. The Company maintains a reserve for estimated warranty costs based on historical experience and management's best estimates.
- Use of Estimates in the Preparation of Financial Statements
- The preparation of financial statements in conformity with accounting principles generally accepted in the United States of America requires management to make 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.
- Reclassifications
- Certain amounts in the 2003 financial statements have been reclassified to conform to the presentation of the current year financial statements.
- Series G Preferred Stock Dividends
- Under the terms of the private offering of Series G preferred shares, the Company is required to file a registration statement with the Securities and Exchange Commission to register the common shares issuable to the Series G preferred stockholders upon conversion of their Series G preferred shares and exercise of their warrants. If the registration statement has not been declared effective within 120 days of the initial closing of such offering on August 29, 2003, there is a penalty of 2% per month payable to the Series G preferred. Stockholders in common shares (or 39,631 common shares per month) until the registration statement is declared effective. As of December 31, 2004, the Company had recorded a liability of \$54,000 related to the 356,682 common shares to be issued to the Series G preferred stockholders because a registration

1. Organization and Significant Accounting Policies Continued

Series G Preferred Stock Dividends - Continued statement had not been declared effective as of that date.

2. Going Concern

The accompanying financial statements have been prepared on a going concern basis, which contemplates the realization of assets and the satisfaction of liabilities in the normal course of business. Historically, the Company has not demonstrated the ability to generate sufficient cash flows from operations to satisfy its liabilities and sustain operations, and the Company has incurred significant losses from operations. These factors raise substantial doubt about the Company's ability to continue as a going concern.

The Company's continuation as a going concern is dependent on its ability to generate sufficient income and cash flow to meet its obligations on a timely basis and/or obtain additional financing as may be required. The Company is actively seeking to obtain additional capital and financing.

In addition, the Company has taken significant steps to reduce costs and increase operating efficiencies, including the consolidation of several manufacturing, accounting and management responsibilities. Such consolidation resulted in significant headcount reductions as well as savings in other overhead costs. The Company has also significantly reduced the use of consultants, which has resulted in a large decrease in expenses, and reduced the direct sales force from six to five representatives, which has resulted in less payroll, travel and other selling expenses. Although these cost savings have significantly reduced the Company's losses and ongoing cash flow needs, if the Company is unable to obtain equity or debt financing, it may be unable to continue development of its products and may be required to substantially curtail or cease operations.

Continued

3.	Detail of Certain Balance Sheet Accounts	Receivables	
		Trade receivables	\$ 758,000
		Allowance for doubtful accounts	(101,000)

			\$ 657,000

		Inventories	
		Finished goods	\$ 648,000
		Raw materials	1,490,000
		Reserve for obsolescence	(1,418,000)

			\$ 720,000

		Accrued liabilities:	
		Consulting and litigation reserve	\$ 492,000
		Payroll and employment benefits	84,000
		Sales tax payable	42,000
		Customer deposits	10,000
		Accrued royalties	13,000
		Deferred revenue	7,000
		Warranty and return allowance	149,000
		Other accrued expenses	61,000

			\$ 858,000

4.	Intangible Assets	Intangible assets consist of the following at December 31, 2004:	
		Goodwill, net of accumulated amortization of \$120,000	\$ 679,000

		Other intangible assets:	
		Product and technology rights	769,000
		Engineering and design costs	482,000
		Patents	92,000

			1,343,000
		Accumulated amortization	(1,343,000)

		Total other intangible asstes	-

		Net intangible assets	\$ 679,000

F-16

Edgar Filing: PARADIGM MEDICAL INDUSTRIES INC - Form 10KSB/A

PARADIGM MEDICAL INDUSTRIES, INC.
Notes to Financial Statements
Continued

4. Intangible Assets Continued Amortization expense for the years ended December 31, 2004 and 2003 was \$3,000 and \$79,000, respectively.

During the year ended December 31, 2003, the Company evaluated the carrying value of its unissued patent costs and product and technology rights for recoverability. This analysis, based on the estimated future cash flows associated with such assets, resulted in an impairment expense of \$81,000 related to patents and product and technology rights.

5. Property and Equipment Property and equipment consists of the following:

Office equipment	\$ 750,000
Computer equipment	658,000
Furniture and fixtures	252,000
Leasehold improvements	166,000

	1,826,000
Accumulated depreciation and amortization	(1,717,000)

	\$ 109,000

6. Lease Obligations During the years ended December 31, 2004 and 2003, the Company leased certain equipment under noncancellable capital leases. These leases provide the Company the option to purchase the leased assets at the end of the initial lease term. Assets under capital leases included in fixed assets and are as follows:

Computer and other equipment	\$ 291,000
Less accumulated amortization	(212,000)

	\$ 79,000

Amortization expense on assets under capital leases during the years ended December 31, 2004 and 2003 was \$39,000 and \$56,000, respectively.

6. Lease Obligations Continued
Capital lease obligations have imputed interest rates of approximately 7% to 22%. The leases are secured by equipment. Future minimum payments on the capital lease obligations are as follows:

2005	\$	54,000
2006		14,000

		68,000
Less amount representing interest		(7,200)

Present value of future minimum lease payments		61,000
Less current portion		(47,000)

Long-term portion	\$	14,000

The Company leases office and warehouse space under an operating lease agreement. Future minimum rental payments under the noncancellable operating lease as of December 31, 2004 are approximately as follows:

Year Ending December 31,		Amount
-----		-----
2005	\$	140,000

Total future minimum rental payments	\$	140,000

Rent expense related to noncancelable operating leases was approximately \$137,000 and \$159,000 for the years ended December 31, 2004 and 2003, respectively.

F-18

7. Income Taxes
The provision for income taxes is different than amounts which would be provided by applying the statutory

Edgar Filing: PARADIGM MEDICAL INDUSTRIES INC - Form 10KSB/A

federal income tax rate to loss before provision for income taxes for the following reasons:

	Years Ended December 31,	
	2004	2003
Income tax (provision) benefit at statutory rate	\$ (24,000)	\$ 1,170,000
Expiration of research and development tax credit carryforwards	-	-
Meals and entertainment	(3,000)	(7,000)
Other	-	2,000
Change in valuation allowance	27,000	(1,165,000)
	\$ -	\$ -

Deferred tax assets (liabilities) are comprised of the following:

Net operating loss carryforward	\$ 16,984,000
Depreciation, amortization, and impairment	853,000
Allowance and reserves	828,000
Research and development tax credit carryforwards	56,000

	18,721,000
Valuation allowance	(18,721,000)

	\$ -

A valuation allowance has been established for the net deferred tax asset due to the uncertainty of the Company's ability to realize such asset.

F-19

PARADIGM MEDICAL INDUSTRIES, INC.
Notes to Financial Statements
Continued

7. Income Taxes Continued
- At December 31, 2004, the Company had net operating loss carryforwards of approximately \$48 million and research and development tax credit carryforwards of approximately \$56,000. These carryforwards are available to offset future taxable income and expire in 2004 through 2021. The utilization of the net operating loss

Edgar Filing: PARADIGM MEDICAL INDUSTRIES INC - Form 10KSB/A

carryforwards is dependent upon the tax laws in effect at the time the net operating loss carryforwards can be utilized. The Tax Reform Act of 1986 significantly limits the annual amount that can be utilized for certain of these carryforwards as a result of the change in ownership.

8. Capital
Stock

The Company has established a series of preferred stock with a total of 5,000,000 authorized shares and a par value of \$.001, and one series of common stock with a par value of \$.001 and a total of 80,000,000 authorized shares.

Series A Preferred Stock

On September 1, 1993, the Company established a series of non-voting preferred shares designated as the 6% Series A Preferred Stock, consisting of 500,000 shares with \$.001 par value. The Series A Preferred Stock has the following rights and privileges:

1. The holders of the shares are entitled to dividends at the rate of twenty-four cents (\$.24) per share per annum, payable in cash only from surplus earnings of the Company or in additional shares of Series A Preferred Stock. The dividends are non-cumulative and therefore deficiencies in dividend payments from one year are not carried forward to the next year.
2. Upon the liquidation of the Company, the holders of the Series A Preferred Stock are entitled to receive, prior to any distribution of any assets or surplus funds to the holders of shares of common stock or any other stock, an amount equal to \$1.00 per share, plus any accrued and unpaid dividends related to the fiscal year in which such liquidation occurs. Total liquidation preference at December 31, 2004 was \$6,000.
3. The shares are convertible at the option of the holder at any time into common shares, based on an initial conversion rate of one share of Series A Preferred Stock for 1.2 common shares.
4. The holders of the shares have no voting rights.

F-20

PARADIGM MEDICAL INDUSTRIES, INC.
Notes to Financial Statements
Continued

8. Capital
Stock
Continued

Series A Preferred Stock - Continued

5. The Company may, at its option, redeem all of the then outstanding shares of the Series A Preferred

Edgar Filing: PARADIGM MEDICAL INDUSTRIES INC - Form 10KSB/A

Stock at a price of \$4.50 per share, plus accrued and unpaid dividends related to the fiscal year in which such redemption occurs.

Series B Preferred Stock

On May 9, 1994, the Company established a series of non-voting preferred shares designated as 12% Series B Preferred Stock, consisting of 500,000 shares with \$.001 par value. The Series B Preferred Stock has the following rights and privileges:

1. The holders of the shares are entitled to dividends at the rate of forty-eight cents (\$.48) per share per annum, payable in cash only from surplus earnings of the Company or in additional shares of Series B Preferred Stock. The dividends are non-cumulative and therefore deficiencies in dividend payments from one year are not carried forward to the next year.
2. Upon the liquidation of the Company, the holders of the Series B Preferred Stock are entitled to receive, prior to any distribution of any assets or surplus funds to the holders of shares of common stock or any other stock, an amount equal to \$4.00 per share, plus any accrued and unpaid dividends related to the fiscal year in which such liquidation occurs. Such right, however, is subordinate to the rights of the holders of Series A Preferred Stock to receive a distribution of \$1.00 per share plus accrued and unpaid dividends. Total liquidation preference at December 31, 2004 was \$36,000.
3. The shares are convertible at the option of the holder at any time into common shares, based on an initial conversion rate of one share of Series B Preferred Stock for 1.2 common shares.
4. The holders of the shares have no voting rights.
5. The Company may, at its option, redeem all of the then outstanding share of the Series B Preferred Stock at a price of \$4.50 per share, plus accrued and unpaid dividends related to the fiscal year in which such redemption occurs.

F-21

PARADIGM MEDICAL INDUSTRIES, INC.
Notes to Financial Statements
Continued

Edgar Filing: PARADIGM MEDICAL INDUSTRIES INC - Form 10KSB/A

Stock
Continued

In January 1998, the Company authorized the issuance of a total of 30,000 shares of Series C Preferred Stock, \$.001 par value, \$100 stated value. As of December 31, 2004 there were no Series C Preferred Stock issued and outstanding. The Series C Preferred Stock have the following rights and privileges:

1. The holders of the shares are entitled to dividends at the rate of 12% per share per annum of the aggregate stated value. The dividends are non-cumulative and, therefore, deficiencies in dividend payments from one year are not carried forward to the next year.
2. Upon the liquidation of the Company, the holders of the Series C Preferred Stock are entitled to receive an amount per share equal to the greater of (a) the amount they would have received if they had converted the shares into shares of Common Stock immediately prior to such liquidation plus declared but unpaid dividends; or (b) the stated value, subject to adjustment.
3. Each share was convertible, at the option of the holder at any time until January 1, 2002, into approximately 57.14 shares of common stock at an initial conversion price, subject to adjustments for stock splits, stock dividends and certain combination or recapitalization of the common stock, equal to \$1.75 per share of common stock.
4. The holders of the shares have no voting rights.

Series D Preferred Stock

In January 1999, the Company's Board of Directors authorized the issuance of a total of 1,140,000 shares of Series D Preferred Stock \$.001 par value, \$1.75 stated value. The Series D Preferred Stock has the following rights and privileges:

1. The holders of the shares are entitled to dividends at the rate of 10% per share per annum of the aggregate stated value. The dividends are non-cumulative and, therefore, deficiencies in dividend payments from one year are not carried forward to the next year.
2. Upon the liquidation of the Company, the holders of the Series D Preferred Stock are entitled to receive

F-22

PARADIGM MEDICAL INDUSTRIES, INC.
Notes to Financial Statements
Continued

8. Capital
Stock
Continued

Series D Preferred Stock - Continued

an amount per share equal to the greater of (a) the amount they would have received had they converted the shares into Common Stock immediately prior to such liquidation plus all declared but unpaid dividends; or (b) the stated value, subject to adjustment. Total liquidation preference at December 31, 2004 was \$9,000.

3. Each share was convertible, at the option of the holder at any time until January 1, 2002, into one share of Common Stock at an initial conversion price, subject to adjustment. The Series D Preferred Stock shall be converted into one share of the Common Stock subject to adjustment (a) on January 1, 2002 or (b) upon 30 days written notice by the Company to the holders of the Shares, at any time after (i) the 30-day anniversary of the registration statement on which the shares of Common Stock issuable upon conversion of the Series D Preferred Stock were registered and (ii) the average closing price of the Common Stock for the 20-day period immediately prior to the date on which notice of redemption is given by the Company to the holders of the Series D Preferred Stock is at least \$3.50 per share. The Company in 1999 recorded \$872,000 as a beneficial conversion feature related to the differences in the conversion price of the preferred stock to common stock.

4. The holders of the shares have no voting rights.

Series E Preferred Stock

In May 2001, the Company authorized the issuance of a total of 50,000 shares of Series E Preferred Stock \$.001 par value, \$100 stated value. The Series E Preferred Stock has the following rights and privileges:

1. The holders of the shares are entitled to dividends at the rate of 8% per share per annum of the aggregate stated value. The dividends are non-cumulative and, therefore, deficiencies in dividend payments from one year are not carried forward to the next year.

2. Upon the liquidation of the Company, the holders of the Series E Preferred Stock are entitled to receive an amount per share equal to the greater of (a) the amount they would have received had they converted the shares into Common Stock immediately prior to such liquidation plus all declared but unpaid

F-23

8. Capital
Stock
Continued

Series E Preferred Stock - Continued
dividends; or (b) the stated value, subject to
adjustment. Total liquidation preference at December 31,
2004 was \$100,000.

3. Each share is convertible, at the option of the holder at any time until January 1, 2005, into approximately 53.33 shares of Common Stock at an initial conversion price, subject to adjustment for stock splits, stock dividends and certain combination or recapitalization of the common stock, equal to \$1.875 per share of common stock. The Series E Preferred Stock shall be converted into Common Stock subject to adjustment (a) on January 1, 2005 or (b) upon 30 days written notice by the Company to the holders of the Shares, at any time after (i) the 30-day anniversary of the registration statement on which the shares of Common Stock issuable upon conversion of the Series E Preferred Stock were registered and (ii) the average closing price of the Common Stock for the 20-day period immediately prior to the date on which notice of redemption is given by the Company to the holders of the Series E Preferred Stock is at least \$3.50 per share. The Company in 2001 recorded \$1,482,000 as a beneficial conversion feature related to the differences in the conversion price of the preferred stock to common stock.
4. The holders of the shares have no voting rights.
5. The holders of the shares also were issued warrants to purchase shares of common stock equal to 1,000 warrants for every 200 shares purchased at an exercise price of \$4.00 per share. Each warrant is exercisable until May 23, 2006.

Series F Preferred Stock

In August 2001, the Company authorized the issuance of a total of 50,000 shares of Series F Preferred Stock \$.001 par value, \$100 stated value. The Series F Preferred Stock has the following rights and privileges:

1. The holders of the shares are entitled to dividends at the rate of 8% per share per annum of the aggregate stated value. The dividends are non-cumulative and, therefore, deficiencies in dividend payments from one year are not carried forward to the next year.

F-24

8. Capital
Stock
Continued

Series F Preferred Stock - Continued

2. Upon the liquidation of the Company, the holders of the Series F Preferred Stock are entitled to receive an amount per share equal to the greater of (a) the amount they would have received had they converted the shares into Common Stock immediately prior to such liquidation plus all declared but unpaid dividends; or (b) the stated value, subject to adjustment. Total liquidation preference at December 31, 2004 was \$245,000.
3. Each share is convertible, at the option of the holder at any time until January 1, 2005, into approximately 53.33 shares of Common Stock at an initial conversion price, subject to adjustment for stock splits, stock dividends and certain combination or recapitalization of the common stock, equal to \$1.875 per share of common stock. The Series F Preferred Stock shall be converted into Common Stock subject to adjustment (a) on January 1, 2005 or (b) upon 30 days written notice by the Company to the holders of the Shares, at any time after (i) the 30-day anniversary of the registration statement on which the shares of Common Stock issuable upon conversion of the Series F Preferred Stock were registered and (ii) the average closing price of the Common Stock for the 20-day period immediately prior to the date on which notice of redemption is given by the Company to the holders of the Series F Preferred Stock is at least \$3.50 per share. The Company in 2001 recorded \$1,105,000 as a beneficial conversion feature related to the differences in the conversion price of the preferred stock to common stock.
4. The holders of the shares have no voting rights.

Series G Preferred Stock

In August 2003, the Company authorized the issuance of a total of 2,000,000 shares of Series G Preferred Stock \$.001 par value, \$1.00 stated value. The Series G Preferred Stock has the following rights and privileges:

1. The holders of the shares are entitled to dividends at the rate of 7% per share per annum of the aggregate stated value. The dividends are non-cumulative and, therefore, deficiencies in dividend payments from one year are not carried forward to the next year.

F-25

8. Capital
Stock
Continued

Series G Preferred Stock - Continued

2. Upon the liquidation of the Company, the holders of the Series G Preferred Stock are entitled to receive an amount per share equal to the greater of (a) the amount they would have received had they converted the shares into Common Stock immediately prior to such liquidation plus all declared but unpaid dividends; or (b) the stated value of \$.25 per share plus declared but unpaid dividends. Total liquidation preference at December 31, 2004 was \$432,000.
3. Each share is convertible, at the option of the holder at any time until August 1, 2005, into 1 share of common stock at an initial conversion price, subject to adjustment for dividends, equal to one share of common stock for each share of Series G Preferred Stock. The Series G Preferred Stock shall be converted into common stock subject to adjustment (a) on August 1, 2005 or (b) upon 30 days written notice by the Company to the holders of the shares, at any time after (i) the 30-day anniversary of the registration statement on which the shares of common stock issuable upon conversion of the Series G Preferred Stock were registered and (ii) the average closing price of the common stock for the 15-day period immediately prior to the date in which notice of redemption is given by the Company to the holders of the Series G Preferred Stock is at least \$.50 per share. In 2003, the Company recorded a beneficial conversion feature of \$217,000 related to the differences in the conversion price of the preferred stock to common stock.
4. The holders of the shares have no voting rights.

F-26

PARADIGM MEDICAL INDUSTRIES, INC.
Notes to Financial Statements
Continued

8. Capital
Stock
Continued

The following table summarizes preferred stock activity during the years ended December 31, 2004 and 2003:

Edgar Filing: PARADIGM MEDICAL INDUSTRIES INC - Form 10KSB/A

	Series A		Series B		Series C		Series D		Series E	
	Shares	Amount	Shares	Amount	Shares	Amount	Shares	Amount	Shares	Amount
Balance at January 1, 2003	5,627	\$ -	8,986	\$ -	-	\$ -	5,000	\$ -	1,500	\$ -
Issuance of Series G preferred stock for cash	-	-	-	-	-	-	-	-	-	-
Issuance of Series G preferred stock for commissions	-	-	-	-	-	-	-	-	-	-
Conversion of preferred stock	-	-	-	-	-	-	-	-	(500)	-

Balance at December 31, 2003	5,627	-	8,986	-	-	-	5,000	-	1,000	-
Issuance of Series G preferred stock for cash	-	-	-	-	-	-	-	-	-	-
Conversion of preferred stock	-	-	-	-	-	-	-	-	-	-

Balance at December 31, 2004	5,627	\$ -	8,986	\$ -	-	\$ -	5,000	\$ -	1,000	\$ -

Authorized	500,000		500,000		30,000		1,140,000		50,000	

Liquidation preference		\$ 6,000		\$ 36,000		\$ -		\$ 9,000		\$ 100,000

F-27

PARADIGM MEDICAL INDUSTRIES, INC.
Notes to Financial Statements
Continued

9. Stock Option
Plan and
Warrants

The Company has a Stock Option Plan (the Option Plan), which reserves shares of the Company's authorized but unissued common stock for the granting of stock options. Amendments to the Option Plan increased the number of shares of common stock reserved for issuance thereunder to an aggregate of 3,700,000 shares.

The Option Plan provides for the grant of incentive stock options and non-qualified stock options to employees and directors of the Company. Incentive stock options may be granted only to employees. The Option Plan is administered by the Board of Directors or a Compensation Committee, which determines the terms of options granted including the exercise price, the number of shares subject to the option, and the exercisability of the option.

The Company granted the following options and warrants during the year ended December 31, 2004:

- o Options to officers and the board of directors to purchase 1,775,000 shares of common stock at an exercise price ranging from \$0.10 to \$0.14.

The Company granted the following options and warrants to non-employees during the year ended December 31, 2003:

- o Warrants to purchase 200,000 shares of common stock at an exercise price of \$0.16 per share in return for consulting services.
- o Warrants to investors to purchase 422,633 shares of common stock at an exercise price of \$0.75.
- o In connection with the Series G Preferred Stock offering, the Company issued warrants to purchase, in aggregate 382,353 shares of common stock at exercise prices ranging from \$0.25 to \$0.50.

F-28

PARADIGM MEDICAL INDUSTRIES, INC.
Notes to Financial Statements
Continued

9. Stock Option
Plan and
Warrants
Continued

A schedule of the options and warrants is as follows:

Edgar Filing: PARADIGM MEDICAL INDUSTRIES INC - Form 10KSB/A

	Number of		Exercise Price Per Share
	Options	Warrants	
Outstanding at January 1, 2003	2,486,535	2,565,022 \$	2.00 - 12.98
Granted	2,150,000	1,404,986	0.16 - 0.25
Exercised	-	-	-
Expired	-	(1,162,025)	5.06 - 8.12
Forfeited	(1,008,079)	-	0.21 - 6.00
Outstanding at December 31, 2003	3,628,456	2,807,983	
Granted	1,775,000	-	0.10 - 0.14
Exercised	-	-	-
Expired	(187,500)	(161,019)	2.38 - 4.00
Forfeited	(1,369,750)	(200,000)	0.16 - 5.00
Outstanding at December 31, 2004	3,846,206	2,446,964 \$	0.10 - 12.98

The following table summarizes information about stock options and warrants outstanding at December 31, 2004:

Range of Exercise Prices	Outstanding			Exercisable		
	Number Outstanding	Weighted Average Remaining Contractual Life (Years)	Weighted Average Exercise Price	Number Exercisable	Weighted Average Exercise Price	
\$ 0.16 - 0.75	3,724,986	2.76	\$ 0.20	2,236,653	\$ 0.34	
2.00 - 5.00	2,267,301	2.27	3.62	2,350,676	3.73	
6.00 - 8.13	275,000	1.00	3.27	275,000	6.55	
12.98	25,883	N/A	12.98	25,883	12.98	
\$ 0.16 - 12.98	6,293,170	2.50	\$ 1.63	4,888,212	\$ 2.39	

F-29

PARADIGM MEDICAL INDUSTRIES, INC.
Notes to Financial Statements
Continued

Edgar Filing: PARADIGM MEDICAL INDUSTRIES INC - Form 10KSB/A

10. Sale of Investment In July 2004, the Company sold its investment in International Bioimmune Systems, Inc. (IBS) for \$532,000 cash. Because, for book purposes, the Company's investment in IBS had previously been reduced to \$0, the net sales price was recorded as a gain as follows.

Sale of IBS stock	\$532,000
Less commissions	27,000

Net gain	\$505,000

11. Gain on Settlement of Liabilities Due to the Company's ongoing cash flow difficulties, during 2003 and 2004 most vendors and suppliers were contacted with attempts to negotiate reduce payments and settlements of settlements of outstanding accounts payable and accrued expenses. While some vendors refused to negotiate and demanded payment in full, some vendors were willing to settle for a reduced amount. The accounts payable forgiven by vendors and suppliers and accrued expenses settled resulted in a gain of \$206,000 and \$436,000 in 2004 and 2003, respectively.

12. Related Party Transactions A law firm, of which the chairman of the board of directors of the Company is a shareholder, has rendered legal services to the Company. The Company paid this firm \$100,000 and \$97,000, for the years ended December 31, 2004 and 2003, respectively. As of December 31, 2004, the Company owed this firm \$197,000, which is included in accounts payable.

During the year ended December 31, 2004, the Company increased accrued liabilities and increased accumulated deficit for \$54,000 for accrued preferred stock dividends related to registration rights on the Series G preferred stock.

13. Supplemental Cash Flow Information During the year ended December 31, 2003, the Company:
- o Granted 200,000 warrants for consulting services, which is recorded as an increase to general and administrative expense and additional paid-in capital of \$35,000.
 - o Issued 1,562,000 shares of common stock, valued at \$258,000 based on the trading prices on the date of issuance, as settlement of potential litigation. This amount is included in general and administrative expenses and additional paid-in capital.

F-30

PARADIGM MEDICAL INDUSTRIES, INC.
Notes to Financial Statements
Continued

Edgar Filing: PARADIGM MEDICAL INDUSTRIES INC - Form 10KSB/A

13. Supplemental Cash Flow Information Continued
- o Incurred an obligation of approximately \$46,000 for the settlement of accrued liabilities of approximately \$83,000 and recorded a corresponding gain of \$37,000.
 - o Reduced subscription receivable and additional paid-in capital for \$294,000.

Actual amounts paid for interest and income taxes are as follows:

	Years Ended December 31,	
	2004	2003
Interest	\$ 22,000	\$ 24,000
Income taxes	\$ -	\$ -

14. Export Sales
- Total sales include export sales by major geographic area as follows:

Geographic Area	Years Ended December 31,	
	2004	2003
Far East	\$ 529,000	\$ 272,000
South America	50,000	9,000
Middle East	233,000	228,000
Europe	684,000	363,000
Canada	68,000	62,000
Mexico	-	9,000
Africa	9,000	-
	\$ 1,573,000	\$ 943,000

F-31

PARADIGM MEDICAL INDUSTRIES, INC.
Notes to Financial Statements
Continued

15. Savings Plan
- In November 1996, the Company established a 401(k)

Edgar Filing: PARADIGM MEDICAL INDUSTRIES INC - Form 10KSB/A

Retirement Savings Plan for the Company's officers and employees. The Plan provisions include eligibility after six months of service, a three year vesting provision and matching contributions at the Company's discretion. During the years ended December 31, 2004 and 2003, the Company contributed approximately zero and \$1,000 to the Plan, respectively.

16. Commitments and Contingencies

Consulting Agreements

On April 3, 2003, the Company entered into a consulting agreement with Kinexsys Corporation ("Kinexsys"). Under the terms of the agreement, Kinexsys through its Senior Partner, Timothy R. Forstrom, is to prepare a capital markets plan and a corporate positioning and communications plan for the Company, for which Kinexsys is to receive warrants to purchase up to 200,000 shares of the Company's common stock at an exercise price of \$.16 per share. The capital markets plan is to include a detailed analysis of the Company's capital market structure in relation to current investors, market trends and projected equity movements, and recommendations on capital management strategies. The corporate positioning and communications plan is to include a corporate positioning matrix for markets, analysts, customers and partners, and a communications plan. The agreement is for a one-year term but may be renewed at the option of both parties. The Agreement expired on April 3, 2004.

During the year ended December 31, 1999 the Company entered a consulting agreement with a former officer of the Company, which expired in 2004 and requires annual payments of \$25,000 through 2003 and a payment of \$12,500 in 2004.

During the year ended December 31, 2000, in connection with the acquisition of OBF, the Company entered a consulting agreement with the former owner of OBF, which required monthly payments of \$6,000 through June 2003. As of December 31, 2003, this agreement was settled in conjunction with the royalty agreement for the Blood Flow Analyzer (see Royalty Agreements in Note 14).

F-32

PARADIGM MEDICAL INDUSTRIES, INC.
Notes to Financial Statements
Continued

16. Commitments and Contingencies
Continued

Litigation

An action was brought against the Company in March 2000 by George Wiseman, a former employee, in the Third District Court of Salt Lake County, State of Utah. The complaint alleges that the Company owes Mr. Wiseman 6,370 shares of its common stock plus costs, attorney's

fees and a wage penalty (equal to 1,960 additional shares of its common stock) pursuant to Utah law. The action is based upon an extension of a written employment agreement. The Company disputes the amount allegedly owed and intends to vigorously defend against the action.

An action was brought against the Company on September 11, 2000 by PhotoMed International, Inc. and Daniel M. Eichenbaum, M.D. in the Third District Court of Salt Lake County, State of Utah. The action involves an amount of royalties that are allegedly due and owing to PhotoMed International, Inc. and Dr. Eichenbaum under a license agreement dated July 7, 1993, with respect to the sale of certain equipment, plus costs and attorneys' fees. Certain discovery has taken place and the Company has paid royalties of \$16,000, which the Company believes brings all payments current as of the date of last payment on January 7, 2005. The Company has been working with PhotoMed and Dr. Eichenbaum to ensure that the calculations have been correctly made on the royalties paid as well as the proper method of calculation for the future.

It is anticipated that once the parties can agree on the correct calculations on the royalties, the legal action will be dismissed. An issue in dispute concerning the method of calculating royalties is whether royalties should be paid on returned equipment. Since July 1, 2001, only one Photon(TM) laser system has been sold and no systems returned. However, if the parties are unable to agree on a method for calculating royalties, there is a risk that PhotoMed and Dr. Eichenbaum might amend their complaint to request termination of the license agreement and, if successful, the Company would lose its right to manufacture and sell the Photon(TM) laser system.

On May 14, 2003, a complaint was filed in the United States District Court, District of Utah, captioned Richard Meyer, individually and on behalf of all others similarly suited v. Paradigm Medical Industries, Inc., Thomas Motter, Mark Miehle and John Hemmer, Case No. 2:03 CV00448TC. The complaint also indicates that it is a "Class Action Complaint for Violations of Federal

F-33

PARADIGM MEDICAL INDUSTRIES, INC.
Notes to Financial Statements
Continued

16. Commitments and Contingencies Continued Litigation - Continued
Securities Law and Plaintiffs Demand a Trial by Jury."
The Company has retained legal counsel to review the

complaint, which appears to be focused on alleged false and misleading statements pertaining to the Blood Flow Analyzer(TM) and concerning a purchase order from Valdespino Associates Enterprises and Westland Financial Corporation.

More specifically, the complaint alleges that the Company falsely stated in its Securities and Exchange Commission filings and press releases that it had received authorization to use an insurance reimbursement CPT code from the CPT Code Research and Development Division of the American Medical 16. Commitments and Association for reimbursement to doctors in connection with the Blood Flow Contingencies Analyzer(TM), adding that the CPT code provides for a reimbursement to doctors Continued of \$57.00 per patient for use of the Blood Flow Analyzer(TM). According to the complaint, the CPT code was critical. Without a reimbursement code, physicians would not purchase the Blood Flow Analyzer(TM) because they could not receive compensation for performance of medical procedures using the medical device. The complaint further contends that the Company never received the CPT code from the American Medical Association at any time. Nevertheless, it is alleged that the Company continued to misrepresent in its SEC filings and press releases that it had received the CPT code. It is also alleged that the Company has never made a full, corrective disclosure with respect to this alleged misstatement.

The complaint also alleges that on July 11, 2002, the Company issued a press release falsely announcing that it had received a purchase order from Valdespino Associates Enterprises and Westland Financial Corporation for 200 sets of its entire portfolio of products, with \$70 million in systems to be delivered over a two-year period, then another \$35 million of orders to be completed in the third year. The complaint further alleges that the Company had never received a true purchase order for its products. As a result of these alleged misstatements, the complaint contends that the price of the Company's shares of common stock was artificially inflated during the period from April 25, 2001 through May 14, 2003, and the persons who purchased or retained the Company's common shares during that period suffered substantial damages. The complaint requests judgment for unspecified damages, together with interest and attorney's fees.

F-34

PARADIGM MEDICAL INDUSTRIES, INC.
Notes to Financial Statements
Continued

16. Commitments and Contingencies Continued

Litigation - Continued

The Company disputes having issued false and misleading statements concerning the Blood Flow Analyzer™ and a purchase order from Westland Financial Corporation and Valdespino Associates Enterprises. On April 25, 2001, the Company issued a press release that stated it had received authorization to use common procedure terminology or CPT code number 92120 for the Blood Flow Analyzer™. This press release was based on a letter the Company received from the CPT Editorial Research and Development Department of the American Medical Association stating that CPT code number 92120 was the appropriate common procedure terminology or CPT code number for doctors to use when reporting certain procedures performed with the Blood Flow Analyzer™.

Currently, there is reimbursement by insurance payors to doctors using the Blood Flow Analyzer(TM) in 22 states and partial reimbursement in four other states. The amount of reimbursement to doctors using the Blood Flow Analyzer(TM) generally ranges from \$56.00 to \$76.00 per patient, depending upon the insurance payor. Insurance payors providing reimbursement for the Blood Flow Analyzer(TM) have the discretion to increase or reduce the amount of reimbursement. The Company is endeavoring to obtain reimbursement by insurance payors in other states where there is currently no reimbursement being made. The Company believes it has continued to correctly represent in its Securities and Exchange Commission filings that the CPT Editorial Research and Development Department of the American Medical Association has informed the Company that CPT code number 92120 is the appropriate code for doctors to use when reporting certain procedures performed with the Blood Flow Analyzer(TM).

On July 11, 2002, the Company issued a press release that stated it received a purchase order from Valdespino Associates Enterprises and Westland Financial Corporation for 200 complete sets of the Company's entire product portfolio of diagnostic and surgical equipment for Mexican ophthalmic practitioners, to be followed by a second order of 100 sets of equipment. The press release was based on a purchase order dated July 10, 2002 that the Company entered into with Westland Financial Corporation for the sale of 200 complete sets of the Company's surgical and diagnostic equipment to Mexican ophthalmic practitioners. The press release also stated that the initial order was for \$70 million of the

F-35

PARADIGM MEDICAL INDUSTRIES, INC.
Notes to Financial Statements
Continued

16. Commitments and Contingencies Continued Litigation - Continued
Company's equipment to be filled over a two-year period followed by the second order of \$35 million in equipment to be completed in the third year. The press release further stated that delivery would be made in tranches of 25 complete sets of the Company's equipment, beginning in 30 days from the date of the purchase order.

On September 13, 2002, the board of directors issued a press release updating the status of its product sales to the Mexican ophthalmic practitioners. In that press release the board stated that the Company had been in discussions for the prior nine months with Westland Financial Corporation, aimed at supplying its medical device products to the Mexican market. In the past, the Company has had a business relationship with Westland Financial. Upon investigation, the board of directors had determined that the purchase order referenced in the July 11, 2002 press release was not of such a nature as to be enforceable for the purpose of sales or revenue recognition. In addition, the Company had not sent any shipment of medical products to Mexican ophthalmic practitioners nor received payment for those products pursuant to those discussions. The September 13, 2002 press release also stated that discussions were continuing with Westland Financial Corporation regarding sales and marketing activities for the Company's medical device products in Mexico, but the Company could not, at the time, predict or provide any assurance that any transactions would result.

On June 2, 2003, a complaint was filed in the United States District Court, captioned Michael Marrone v. Paradigm Medical Industries, Inc., Thomas Motter, Mark Miehle and John Hemmer, Case No. 2:03 CV00513 PGC. On July 11, 2003, a complaint was filed in the same United States District Court, captioned Lidia Milian v. Paradigm Medical Industries, Inc., Thomas Motter, Mark Miehle and John Hemmer, Case No. 2:03 CV00617PGC. Both complaints seek class action status. These cases are substantially similar in nature to the Meyer case, including the contention that as a result of allegedly false statements regarding the Blood Flow AnalyzerTM and the purchase order from Westland Financial Corporation and Valdespino Associates Enterprises, the price of the Company's common stock was artificially inflated and the persons who purchased the Company's common shares during the class period suffered substantial damages. In a press release dated July 11, 2003, captioned "Milberg

F-36

PARADIGM MEDICAL INDUSTRIES, INC.
Notes to Financial Statements
Continued

16. Commitments and
Contingencies
Continued

Litigation - Continued

Weiss announces the filing of a class action suit against Paradigm Medical Industries, Inc. on behalf of investors," the law firm of Milberg Weiss Bershad Hynen & Levach LLP, which represents purchasers of the Company's securities in the class action suit filed on July 11, 2003, stated that the Company alleged misrepresentations caused the market price of the stock to be artificially inflated during the class period. As a result, it is alleged that investors suffered millions of dollars in damages from the Company's alleged misstatements.

The cases request judgment for unspecified damages, together with interest and attorney's fees. These cases have now been consolidated with the Meyer case into a single action, captioned In re: Paradigm Medical Industries Securities Litigation, Case No. 03-CV-448TC. The law firm of Milberg Weiss Bershad & Schulman LLP is representing purchasers of the Company's securities in the consolidated class action. On June 28, 2004, a consolidated amended class action complaint was filed on behalf of purchasers of the Company's securities. The consolidated complaint is similar to the three class action complaints and alleges that the Company made false representations regarding the CPT code for the Blood Flow Analyzer(TM), but it includes additional allegations that the Company failed to disclose in a timely manner that doctors were being denied reimbursement for procedures performed with the Blood Flow Analyzer(TM). The consolidated complaint also alleges that the Company made false statements regarding the purchase order from Westland Financial Corporation and Valdespino Associates Enterprises. The Company believes the consolidated complaint is without merit and intends to vigorously defend and protect its interests in the case.

The Company was issued a Directors and Officers Liability and Company Reimbursement Policy by United States Fire Insurance Company for the period from July 10, 2002 to July 10, 2003 that contains a \$5,000,000 limit of liability, which is excess of a \$250,000 retention. The officers and directors named in the consolidated cases have requested coverage under the policy. U.S. Fire is currently investigating whether it may have a right to deny coverage for the consolidated cases based upon policy terms, conditions and exclusions or to rescind the policy based upon misrepresentations contained in its application for insurance.

F-37

16. Commitments and
Contingencies
Continued

Litigation - Continued

The Company has paid \$30,000 to U.S. Fire toward satisfaction of the \$250,000 retention that is applicable to the consolidated cases. The Company has advised U.S. Fire that it cannot pay the \$250,000 retention due to its current financial circumstances. As a consequence, on January 8, 2004, the Company entered into a non-waiver agreement with U.S. Fire in which U.S. Fire agreed to fund and advance the Company's retention obligation in consideration for which the Company has agreed to reimburse U.S. Fire the sum of \$5,000 a month, for a period of six months, with the first of such payments due on February 15, 2004. Thereafter, commencing on August 15, 2004, the Company is currently required to reimburse U.S. Fire the sum of \$10,000 per month until the entire amount of \$250,000 has been reimbursed to U.S. Fire. The Company has made payments to U.S. Fire in the aggregate amount of \$30,000 of which its last payment of \$10,000 was made on October 11, 2004. These payments were for the \$5,000 monthly payments due during the six month period from February 15 to July 15, 2004, leaving a remaining retention obligation to U.S. Fire of \$220,000.

In the event U.S. Fire determines that the Company or the former officers and directors named in the consolidated cases are not entitled to coverage under the policy, or that it is entitled to rescind the policy, or should the Company be declared in default under the non-waiver agreement on account of its failure to make the monthly payments owed to U.S. Fire for funding the Company's retention obligation, then the Company agrees to pay U.S. Fire, on demand, the full amount of all costs advanced by U.S. Fire, except for those amounts that the Company may have reimbursed to U.S. Fire pursuant to the monthly payments due under the non-waiver agreement. Moreover, if U.S. Fire denies coverage for the consolidated cases under the policy, the Company would owe its litigation counsel in the class action lawsuits, for any legal fees not paid by U.S. Fire. However, U.S. Fire has currently agreed to pay the legal fees relating to the class action lawsuits.

The Company will be in default under the non-waiver agreement if it fails to make any payment due to U.S. Fire thereunder when such payment is due, or institute proceedings to be adjudicated as bankrupt or insolvent. U.S. Fire's obligation to advance defense costs under the agreement will terminate in the event that the \$5,000,000 policy limit of liability is exhausted. If

16. Commitments and
Contingencies
Continued

Litigation - Continued

U.S. Fire denies coverage for the consolidated cases under the policy and the Company is not successful in defending and protecting its interests in the cases, resulting in a judgment against the Company for substantial damages, the Company would not be able to pay such liability and, as a result, would be forced to seek bankruptcy protection.

On July 10, 2003, an action was filed in the United States District Court, District of Utah, by Innovative Optics, Inc. and Barton Dietrich Investments, L.P. Defendants include us, Thomas Motter, Mark Miehle and John Hemmer, former officers of the company. The complaint claims that Innovative and Barton entered into an asset purchase agreement with the Company on January 31, 2002, in which the Company agreed to purchase all the assets of Innovative in consideration for the issuance of 1,310,000 shares of the Company's common stock to Innovative. The complaint claims the Company breached the asset purchase agreement. The complaint also claims that the Company allegedly made false and misleading statements pertaining to the Blood Flow Analyzer(TM) and concerning a purchase order from Valdespino Associates Enterprises and Westland Financial Corporation. The purpose of these statements, according to the complaint, was to induce Innovative to sell its assets and purchase the shares of the Company's common stock at artificially inflated prices while simultaneously deceiving Innovative and Barton into believing that the Company's shares were worth more than they actually were. The complaint contends that had Innovative and Barton known the truth they would not have sold Innovative to us, would not have purchased the Company's stock for the assets of Innovative, or would not have purchased the stock at the inflated prices that were paid. The complaint further contends that as a result of the allegedly false statements, Innovative and Barton suffered substantial damages in an amount to be proven at trial.

The complaint also claims that 491,250 of the shares to be issued to Innovative in the asset purchase transaction were not issued on a timely basis and the Company also did not file a registration statement with the Securities and Exchange Commission within five months of the closing date of the asset purchase transaction. As a result, the complaint alleges that the value of the shares of the Company's common stock issued to Innovative in the transaction declined, and

16. Commitments and Contingencies Continued
- Litigation - Continued
- Innovative and Barton suffered damages in an amount to be proven at trial. The Company filed an answer to the complaint and also filed counterclaims against Innovative and Barton for breach of contract. The Company believes the complaint is without merit and intends to vigorously defend and protect its interests in the action. If the Company is not successful in defending and protecting its interests in this action, resulting in a judgment against the Company for substantial damages, and U.S. Fire denies coverage in the litigation under the Directors and Officers Liability and Company Reimbursement Policy, the Company would not be able to pay such liability and, as a result, would be forced to seek bankruptcy protection.
- On October 14, 2003, an action was filed in the Third Judicial District Court, Salt Lake County, State of Utah, captioned Albert Kinzinger, Jr., individually and on behalf of all others similarly situated vs. Paradigm Medical Industries, Inc., Thomas Motter, Mark Miehle, Randall A. Mackey, and John Hemmer, Case No. 030922608. The complaint also indicates that it is a "Class Action Complaint for Violations of Utah Securities Laws and Plaintiffs Demand a Trial by Jury." The Company has retained legal counsel to review the complaint, which appears to be focused on alleged false or misleading statements pertaining to the Blood Flow Analyzer(TM). More specifically, the complaint alleges that the Company falsely stated in Securities and Exchange Commission filings and press releases that it had received authorization to use an insurance reimbursement CPT code from the CPT Code Research and Development Division of the American Medical Association in connection with the Blood Flow Analyzer(TM), adding that the CPT code provides for a reimbursement to doctors of \$57.00 per patient for the Blood Flow Analyzer(TM).
- The purpose of these statements, according to the complaint, was to induce investors to purchase shares of the Company's Series E preferred stock in a private placement transaction at artificially inflated prices. The complaint contends that as a result of these statements, the investors that purchased shares of its Series E preferred stock in the private offering suffered substantial damages to be proven at trial. The complaint also alleges that the Company sold Series E preferred shares without registering the sale of such shares or obtaining an exemption from registration. The complaint requests rescission, compensatory damages and treble damages, including interest and attorneys' fees.

PARADIGM MEDICAL INDUSTRIES, INC.
Notes to Financial Statements
Continued

16. Commitments and
Contingencies
Continued

Litigation - Continued

The Company filed an answer to the complaint. The Company believes the complaint is without merit and intends to vigorously defend its interests in the action. If the Company is not successful in defending and protecting its interests in the action, resulting in a judgment against it for substantial damages, and U.S. Fire denies coverage in the litigation under the Directors and Officers Liability and Company Reimbursement Policy, the Company would not be able to pay such liability and, as a result, would be forced to seek bankruptcy protection.

On January 26, 2005, the Company completed a written settlement agreement to settle the lawsuit that Innovative Optics, Inc. and Barton Dietrich Investments, L.P. brought against the Company and its former executive officers. Under the terms of the settlement, U.S. Fire agreed to pay Innovative Optics, Inc. and Barton Dietrich Investments, L.P. the sum of \$367,500 in cash. Payment of this amount is contingent, however, upon the courts in the federal and state class action lawsuits granting final approval of the settlements reached in those respective actions, and such orders becoming final and non-appealable.

On February 23, 2005, the Company executed written settlement agreements to settle the federal and state court class action lawsuits that were filed against the Company and its former executive officers. Under the terms of settlement of the federal court class action lawsuit, U.S. Fire agreed to pay the sum of \$1,507,500 in cash to the class members that purchased the Company's securities during the period between April 17, 2002 and November 4, 2002. Under the terms of settlement of the state court class action lawsuit, U.S. Fire agreed to pay the sum of \$625,000 in cash to the class members that purchased shares of Series E Convertible preferred stock on or about July 11, 2001.

As a condition to the settlement agreements to settle the federal and state court class action lawsuits, the courts in such lawsuits must have entered orders granting final approval of the settlements reached in those respective actions, and such orders must have become final and non-appealable. On March 3, 2005, the federal court entered an order granting preliminary approval of the settlement in the federal court class action lawsuit and providing for notice to be sent to potential class members. On April 18, 2005, a hearing

was held in the state court and the court entered a

F-41

PARADIGM MEDICAL INDUSTRIES, INC.
Notes to Financial Statements
Continued

16. Commitments and Contingencies
Continued
- Litigation - Continued
- minute entry granting preliminary approval of the settlement in the state court class action lawsuit.

As a further condition to the settlement agreements to settle the federal and state court class action lawsuits, both settlement agreements provide that U.S. Fire must not have exercised its option to terminate the settlement agreements. U.S. Fire has the option to terminate the settlement agreements if the cumulative dollar value of the claims held by individuals or entities that "opt out" of the federal and state class action lawsuits exceeds \$250,000. If such "opt outs" exceed \$250,000, however, plaintiffs in the federal and state court class action lawsuits will have five days to cure by reducing the amount of "opt outs" to less than \$250,000.

If U.S. Fire exercises its option to terminate the settlement agreements, then all parties to the settlement agreements will be restored to their respective positions in the various actions as of the date of the settlement agreements. In addition, the terms and provisions of the settlement agreements will have no further force and effect on the various parties and will be deemed null and void in their entirety.

Under the terms of the settlement agreements regarding the federal and state court class action lawsuits and the lawsuit that Innovative Optics, Inc. and Barton Dietrich Investors, L.P. brought against the Company and its former executive officers, U.S. Fire has agreed to pay a total of \$2,500,000 in cash to the classes in the class action lawsuits and to Innovative Optics, Inc. and Barton Dietrich Investments, L.P. in settlement of these lawsuits. Under the terms of settlement, Paradigm Medical is to pay U.S. Fire the sum of \$220,000 representing the remaining amount owing under the \$250,000 retention obligation in the insurance policy, and to execute a policy release in favor of U.S. Fire as to coverage under the insurance policy.

An action was filed on June 20, 2003, in the Third Judicial District Court, Salt Lake County, State of Utah (Civil No. 030914195) by CitiCorp Vendor Finance, Inc., formerly known as Copelco Capital, Inc. The complaint claims that \$50,000 plus interest is due for the leasing of three copy machines that were delivered to the

Company's Salt Lake City facilities on or about April of

F-42

PARADIGM MEDICAL INDUSTRIES, INC.
Notes to Financial Statements
Continued

16. Commitments and
Contingencies
Continued

Litigation - Continued

2000. The action also seeks an award of attorney's fees and costs incurred in the collection. The Company disputes the amounts allegedly owed, asserting that two of the machines were returned to the leasing company because they did not work properly. A responsive pleading has been filed. The Company was engaged in settlement discussions with CitiCorp until counsel for CitiCorp withdrew from the case. New counsel for CitiCorp has been appointed and it is anticipated that settlement discussions will resume.

An action was filed in June, 2003 in the Third Judicial District Court, Salt Lake County, State of Utah (Civil No. 030914719) by Franklin Funding, Inc. in which it alleges that the Company had entered into a lease agreement for the lease of certain equipment for which payment is due. It is claimed that there is due and owing approximately \$89,988 after accruing late fees, interest, repossession costs, collection costs and attorneys' fees. On August 28, 2003, the Company agreed to a settlement of the case with Franklin Funding by agreeing to make 24 monthly payments of \$2,000 to Franklin Funding, with the first monthly payment due on August 29, 2003. As of March 31, 2005, the Company has made 19 monthly payments of \$2,000 each to Franklin Funding.

The Company received demand letters dated July 18, 2003, September 26, 2003 and November 10, 2003 from counsel for Douglas A. MacLeod, M.D., a shareholder of the company. In the July 18, 2003 letter, Dr. MacLeod demands that he and certain entities with which he is involved or controls, namely the Douglas A. MacLeod, M.D. Profit Sharing Trust, St. Marks' Eye Institute and Milan Holdings, Ltd., be issued a total of 2,296,667 shares of the Company's common stock and warrants to purchase 1,192,500 shares of its common stock at an exercise price of \$.25 per share. Dr. MacLeod claims that these common shares and warrants are owing to him and the related entities under the terms of a mutual release dated January 16, 2003, which he and the related entities entered into with us. Dr. MacLeod renewed his request for these additional common shares and warrants in the September 26, 2003 and November 10, 2003 demand letters. The Company believes that Dr. MacLeod's claims and assertions are without merit and that neither he nor

the related entities are entitled to any additional shares of its common stock or any additional warrants under the terms of the mutual release. The Company

F-43

PARADIGM MEDICAL INDUSTRIES, INC.
Notes to Financial Statements
Continued

16. Commitments and Contingencies Continued Litigation - Continued
intends to vigorously defend against any legal action that Dr. MacLeod may bring.

On August 3, 2003, a complaint was filed against the Company by Corinne Powell, a former employee, in the Third Judicial District Court, Salt Lake County, State of Utah (Civil No. 030918364). Defendants consist of the Company and Randall A. Mackey, Dr. David M. Silver and Keith D. Ignatz, directors of the Company. The complaint alleges that at the time the Company laid off Ms. Powell on March 25, 2003, she was owed \$2,000 for business expenses, \$11,000 for accrued vacation days, \$13,000 for unpaid commissions, the fair market value of 50,000 stock options exercisable at \$5.00 per share that she claims she was prevented from exercising, attorney's fees and a continuing wage penalty under Utah law. On March 29, 2005, the Company agreed to a settlement with Ms. Powell of her claims for unpaid business expenses, accrued vacation days, and unpaid commissions by agreeing to pay her \$13,000. The Company has not yet made payment to Ms. Powell for the agreed upon settlement amount.

On September 10, 2003, an action was filed against the Company by Larry Hicks in the Third Judicial District Court, Salt Lake County, State of Utah, (Civil No. 030922220), for payments due under a consulting agreement with us. The complaint claims that monthly payments of \$3,083 are due for the months of October 2002 to October 2003 under a consulting agreement and, if the agreement is terminated, for the sum of \$110,000 minus whatever the Company has paid Mr. Hicks prior to such termination, plus costs, attorney's fees and a wage penalty pursuant to Utah law. The Company has filed an answer in which it denies any liability to Mr. Hicks. Formal discovery in the matter has commenced. The Company disputes the amount allegedly owed and intends to vigorously defend against such action.

On November 7, 2003, a complaint was filed against the Company by Todd Smith, a former employee, in the Third Judicial District Court, Salt Lake County, State of Utah (Civil No. 030924951 CN). Defendants consist of the Company and Randall Mackey, a director of the Company.

The complaint alleges that while an employee of the Company, Mr. Smith was granted stock options to purchase 16,800 shares of common stock exercisable at \$5.00 per share. Mr. Smith claims unpaid wages in the amount of

F-44

PARADIGM MEDICAL INDUSTRIES, INC.
Notes to Financial Statements
Continued

16. Commitments and
Contingencies
Continued

Litigation - Continued

the fair market value of the stock options he claims he was prevented from exercising, attorney's fees, and a continuing wage penalty under Utah law. The Company believes the claims are without merit and intends to vigorously defend against such action.

On May 25, 2004, an action was brought against the Company by Jeffrey F. Poore, former President and Chief Executive Officer of the Company, in the Third Judicial District Court of Salt Lake County, State of Utah (Civil No. 040910875). The complaint alleges that the Company unlawfully terminated the written employment agreement between Mr. Poore and the Company. As a result, Mr. Poore demands judgment against the Company for \$350,000, representing his annual salary for the two remaining years under the employment agreement, for money judgment based on the value of his benefits for the two remaining years under the employment agreement, including profit sharing plans, 401(k) and cafeteria plans, health, hospitalization, dental, disability and other insurance plans canceled by the Company, and for money judgment equal to the value of the stock options granted to him under the employment agreement. The Company disputes the amounts allegedly owed in the complaint and believes that there was a sufficient basis to terminate Mr. Poore's employment for cause under the terms of the employment agreement. Accordingly, the Company intends to vigorously defend against the action.

On August 9, 2004, a third party complaint was brought against the Company by Wakefield Eye Center and Dr. Kenneth C. Westfield (collectively "Westfield"). The original action was brought by American Express Business Finance Corporation against Westfield on May 27, 2004 in the District Court, Clark County, State of Nevada (Civil No. A486307, Dept. No. XXI) concerning the financing of the purchase of a Blood Flow Analyzer(TM) involving Westfield Eye Center. The transaction took place during the latter half of 2001. Westfield takes the position that if there is liability of Westfield to American Express this liability is ultimately ours and the other third-party defendants. The amount being sought against Westfield by American Express in the original action includes the sum of \$30,000, together with interest and

attorney's fees. Westfield's alleged claims against the Company include fraud, breach of contract, promissory estoppel, declaratory relief, negligence, negligent supervision, damages for injuries resulting from actions

F-45

PARADIGM MEDICAL INDUSTRIES, INC.
Notes to Financial Statements
Continued

16. Commitments and
Contingencies
Continued

Litigation - Continued
of employee/contractor, wilful and wanton misconduct, conspiracy, and breach of fiduciary duty as well as costs and attorney's fees. Westfield also seeks punitive damages. The Company has filed an answer to the third party complaint in which the Company denies liability. Formal discovery in the matter involving us has commenced. The case has been referred to arbitration. The Company intends to vigorously defend the action.

On March 31, 2005, an action was filed against the Company by Joseph W. Spadafora in the United States District Court, District of Utah (Civil No. 2:05CV00278 TS). The complaint alleges that Dr. Spadafora was a clinical investigator in the study for the FDA involving the Company's Photon(TM) laser system where he performed numerous surgeries using the Photon(TM). Dr. Spadafora contends that in meetings with Company personnel he suggested ways in which the handpiece on the Photon(TM) could be improved. Dr. Spadafora further contends that on August 5, 1999, the Company filed a patent application for an improved handpiece with the United States Patent and Trademark Office but he was not named as one of the inventors or a co-inventor on the patent application.

On September 24, 2004, the Company was issued a patent entitled, "Laser Surgival Handpiece with Photon Trap." Because the Company did not list Dr. Spadafora as one of the inventors or a co-inventor on the patent, Dr. Spadafora is requesting in his complaint that a court order be entered declaring that he is the inventor or co-inventor of the patent and, as a result, is entitled to all or part of the royalties and profits that the Company earned or will earn from the sale of any product incorporating or using the improved handpiece, plus interest and attorney's fees. The Company disputes the claims made by Dr. Spadafora and intends to vigorously defend against such action.

The Company is not a party to any other material legal proceedings outside the ordinary course of its business or to any other legal proceedings, which, if adversely determined, would have a material adverse effect on its financial condition or results of operations.

Royalty Agreements

The Company had a royalty agreement with the president of OBF. The agreement provided for the payment of 10% royalty of the net sales related to the Blood Flow Analyzer.

F-46

PARADIGM MEDICAL INDUSTRIES, INC.
Notes to Financial Statements
Continued

16. Commitments and Contingencies Continued
- Royalty Agreements - Continued
- During 2003, a settlement was reached with the president of OBF whereby the royalty payments were forfeited and no longer are an obligation of the Company. The over-accrued amount of \$147,000 was reversed during 2003 to reflect the settlement agreement.
- The Company has an amended exclusive patent license agreement with a company which owns the patent for the laser-probe used on the Photon machine. The agreement provides for the payment of a 1% royalty on all sales proceeds related directly or indirectly, to the Photon machine. The agreement expires when the United States patent rights expire in September 2004. Through December 31, 2003, no significant royalties have been paid under this agreement.
- The Company has a royalty agreement with another company that developed a promotional CD for the Company. Through the promotion of the CD, the Company hopes to increase sales in the Autoperimeter and assist doctors currently using the unit with the interpretation of visual fields. The royalty base is 50% each until the Company's share equals the production costs related to development of the disk. Thereafter, the developer will receive 70% and the Company will receive 30% of the royalty base. Royalties paid during the year relating to this agreement were not significant.
17. Fair Value of Financial Instruments
- The Company's financial instruments consist of cash, receivables, payables, and notes payable. The carrying amount of cash, receivables and payables approximates fair value because of the short-term nature of these items. The carrying amount of the notes payable approximates fair value as the individual borrowings bear interest at market interest rates.
18. Recent Accounting Pronouncements
- In December 2003, the FASB issued Interpretation No. 46 ("FIN 46R") (revised December 2003), Consolidation of Variable Interest Entities, an Interpretation of Accounting Research Bulletin No. 51 ("ARB 51"), which addresses how a business enterprise should evaluate whether it has a controlling interest in an entity

though means other than voting rights and accordingly should consolidate the entity. FIN 46R replaces FASB Interpretation No. 46 (FIN 46), which was issued in January 2003. Before concluding that it is appropriate to apply ARB 51 voting interest consolidation model to an entity, an enterprise must first determine that the entity is not a variable interest entity (VIE). As of the effective date of FIN 46R, an enterprise must

F-47

PARADIGM MEDICAL INDUSTRIES, INC.
Notes to Financial Statements
Continued

18. Recent
Accounting
Pronounce-
ments

evaluate its involvement with all entities or legal structures created before February 1, 2003, to determine whether consolidation requirements of FIN 46R apply to those entities. There is no grandfathering of existing entities. Public companies must apply either FIN 46 or FIN 46R immediately to entities Continued created after January 31, 2003 and no later than the end of the first reporting period that ends after December 15, 2004. The adoption of FIN 46 had no effect on the Company's consolidated financial position, results of operations or cash flows.

In December 2004, FASB issued SFAS 153 "Exchanges of Nonmonetary Assets--an amendment of APB Opinion No. 29". The guidance in APB Opinion No. 29, Accounting for Nonmonetary Transactions, is based on the principle that exchanges of nonmonetary assets should be measured based on the fair value of the assets exchanged. The guidance in that Opinion, however, included certain exceptions to that principle. This Statement amends Opinion 29 to eliminate the exception for nonmonetary exchanges of similar productive assets and replaces it with a general exception for exchanges of nonmonetary assets that do not have commercial substance. A nonmonetary exchange has commercial substance if the future cash flows of the entity are expected to change significantly as a result of the exchange. The Company does not believe adoption of SFAS 153 will have any impact on the Company's consolidated financial statements.

In November 2004, the FASB issued SFAS 151 "Inventory Costs--an amendment of ARB No. 43". This Statement amends the guidance in ARB No. 43, Chapter 4, "Inventory Pricing," to clarify the accounting for abnormal amounts of idle facility expense, freight, handling costs, and wasted material (spoilage). Paragraph 5 of ARB 43, Chapter 4, previously stated that ". . . under some circumstances, items such as idle facility expense, excessive spoilage, double freight, and re-handling costs may be so abnormal as to require treatment as current period charges. . . ." This Statement requires

that those items be recognized as current-period charges regardless of whether they meet the criterion of "so abnormal." In addition, this Statement requires that allocation of fixed production overheads to the costs of conversion be based on the normal capacity of the production facilities. The provisions of this Statement shall be effective for inventory costs incurred during fiscal years beginning after June 15, 2005. The Company does not believe adoption of SFAS 151 will have any impact on the Company's consolidated financial statements.

F-48

PARADIGM MEDICAL INDUSTRIES, INC.
Notes to Financial Statements
Continued

18. Recent
Accounting
Pronounce-
ments
Continued

In December 2004, the FASB issued FASB Statement No. 123 (revised 2004), "Shared-Based Payment." Statement 123(R) addresses the accounting for share-based payment transactions in which an enterprise receives employee services in exchange for (a) equity instruments of the enterprise or (b) liabilities that are based on the fair value of the enterprise's equity instruments or that may be settled by the issuance of such equity instruments. Statement 123(R) requires an entity to recognize the grant-date fair-value of stock options and other equity-based compensation issued to employees in the income statement. The revised Statement generally requires that an entity account for those transactions using the fair-value-based method, and eliminates the intrinsic value method of accounting in APB Opinion No. 25, "Accounting for Stock Issued to Employees", which was permitted under Statement 123, as originally issued. The revised Statement requires entities to disclose information about the nature of the share-based payment transactions and the effects of those transactions on the financial statements. Statement 123(R) is effective for public companies that do not file as small business issuers as of the beginning of the first interim or annual reporting period that begins after June 15, 2005. For public companies that file as small business issuers, Statement 123(R) is effective as of the beginning of the first interim or annual reporting period that begins after December 15, 2005 (i.e., first quarter 2006 for the Company). All public companies must use either the modified prospective or the modified retrospective transition method. Early adoption of this Statement for interim or annual periods for which financial statements or interim reports have not been issued is encouraged. The Company believes that the adoption of this pronouncement may have a material impact on the Company's financial statements.

Item 9. Changes in and Disagreements with Accountants on Accounting and Financial Disclosures

None.

Item 8A. Controls and Procedures

Under the supervision and with the participation of the Company's management, including its principal executive officer and principal financial officer, the Company evaluated the effectiveness of the design and operation of its disclosure controls and procedures (as defined in Rule 13a-15(e) or 15d-15(e) under the Securities Exchange Act of 1934 (the "Exchange Act")). Based upon that evaluation, the principal executive officer and principal financial officer concluded that, as of the end of the period covered by this report, the Company's disclosure controls and procedures were effective and adequately designed to ensure that information required to be disclosed by the Company in the reports it files or submits under the Exchange Act is recorded, processed, summarized and reported within the time periods specified in applicable rules and forms.

During the fourth fiscal quarter, there has been no change in the Company's internal control over financial reporting (as defined in Rule 13a-15(f) or 15d-15(f) under the Exchange Act) that has materially affected, or is reasonably likely to materially affect, the Company's internal control over financial reporting.

PART III

Item 9. Directors, Executive Officers, Promoters and Control Persons; Compliance with Section 16(a) of the Exchange Act.

As of March 31, 2005, the Company's executive officers and directors, their ages and their positions are set forth below:

Name	Age	Position
John Y. Yoon	41	President and Chief Executive Officer
Aziz A. Mohabbat	45	Vice President of Operations and Chief Operating Officer
Randall A. Mackey, Esq.	59	Chairman of the Board and Director
David M. Silver, PhD.	63	Director
Keith D. Igotz	57	Director
John C. Pingree	64	Director

The directors are elected for one-year terms that expire at the next annual meeting of shareholders. Executive officers are elected annually by the Board of Directors to hold office until the first meeting of the Board following the next annual meeting of shareholders and until their successors have been elected and qualified.

Edgar Filing: PARADIGM MEDICAL INDUSTRIES INC - Form 10KSB/A

John Y. Yoon has served as the Company's President and Chief Executive Officer since March 19, 2004. From June 2003 to March 19, 2004, Mr. Yoon served as Senior Director of Marketing, Enterprise Voice Solutions Division of 3Com Corporation. From 1997 to June 2003, he served as Senior Director of Product Management and Director of Product Management of 3Com Corporation. During the period from 1996 to 1997, Mr. Yoon was Director of Strategic Planning and Product Development of US Robotics. During the period from 1993 to 1996, he served as Manager of Marketing and Strategic Planning, Senior Director of Product Management and Management of Product Development for Ericsson, Inc. From 1990 to 1993, Mr. Yoon was Manager of Public Service Marketing and Product Line Manager Mobile Radios for Ericsson, Inc. During the period from 1986 to 1988, he was Product Planner of Business and Industrial Trucking and Marketing Research Analyst for General Electric Mobile Communications. Mr. Yoon received a B.A. degree in Economics from Harvard College in 1985 and an M.B.A. degree from Duke University in 1992.

36

Aziz A. Mohabbat has served as Chief Operating Officer of the Company since March 23, 2004 and from August 2002 to March 2003, and as Vice President of Operations since March 23, 2004 and from 2001 to March 2003. From 2000 to 2001, he served as Managing Director of the San Diego Division of the Company and from 1999 to 2000 as its Regulatory Affairs and Quality Assurance Manager. From March 2003 to March 2004, Mr. Mohabbat served as Division Manager of the Medical Division of TUV Rheiland of North America, a medical products safety and compliance services company. From 1997 to 1999, he served as Operations and Regulatory Affairs and Quality Assurance Manager of Codan U.S., a subsidiary of Codan GmbH, a manufacturer of disposable sterile and non-sterile medical devices. Prior to 1989, Mr. Mohabbat held various management and bioengineering positions in the medical laboratory and diagnostics field in the Eye Care Clinic of the University Hospital-Eppendorf and the General Hospital of Barmbek in Hamburg, Germany. Mr. Mohabbat received a B.S. degree in Medical Laboratory Technology in 1986 from St. George Hospital College in Hamburg, Germany. He is a member of the American Society for Quality Assurance.

Randall A. Mackey, Esq. has been the Company's Chairman of the Board since August 20, 2002, and a director since January 2000. He had served as a director of the Company from November 1995 to September 1998. Mr. Mackey has been President of the Salt Lake City law firm of Mackey Price & Thompson since 1992, and a shareholder and director of the firm and its predecessor firms since 1989. Mr. Mackey received a B.S. degree in Economics from the University of Utah in 1968, an M.B.A. degree from the Harvard Business School in 1970, a J.D. degree from Columbia Law School in 1975 and a B.C.L. degree from Oxford University in 1977. Mr. Mackey has also served as Chairman of the Board from June 2001 to May 2003, and as a director from 1998 to May 2003 of Cimatrix, Incorporated, a software development company. Mr. Mackey has additionally served as Chairman of the Board from July 2000 to July 2003 and as a trustee from 1993 to July 2003 of Salt Lake Community College.

David M. Silver, Ph.D. has been a director since January 2000. He had served as a director of the company from November 1995 to September 1998. Dr. Silver is a Principal Senior Scientist in the Milton S. Eisenhower Research and Technology Development Center at the Johns Hopkins University Applied Physics Laboratory, where he has been employed since 1970. He served as the J. H. Fitzgerald Dunning Professor of Ophthalmology in the Johns Hopkins Wilmer Eye Institute in Baltimore during 1998-99. He received a B.S. degree from Illinois Institute of Technology, an M.A. degree from Johns Hopkins University and a Ph.D. degree from Iowa State University before holding a postdoctoral fellowship at Harvard University and a visiting scientist position at the University of Paris.

Edgar Filing: PARADIGM MEDICAL INDUSTRIES INC - Form 10KSB/A

Keith D. Ignatz has been a director since November 2000. He has been President and Chief Operating Officer of SpectRx, Inc., a medical technology company that he founded in 1992, which develops, manufactures and markets alternatives to traditional blood-based medical tests. From 1986 to 1992, Mr. Ignatz was Senior Vice President of Allergan Humphrey, Inc., a medical electronics company. From 1985 to 1986, he was President of Humphrey Instruments Limited-SKB, a medical electronics company, and from 1980 to 1985, Mr. Ignatz was President of Humphrey Instruments GmbH, also a medical electronics company. Mr. Ignatz also served on the Board of Directors of Vismed, Inc., d/b/a Dicon from 1992 to June 2000. Mr. Ignatz received a B.A. degree in Sociology and Political Science from San Jose University and an M.B.A. degree from Pepperdine University. Mr. Ignatz has served as a trustee of Pennsylvania College of Optometry since 1990 and as a member of the American Marketing Association of the American Association of Diabetes Education.

John C. Pingree has been a director since April 2004. He has been the Executive Director of the Semnani Foundation since August 2001, which funds projects to assist women and children in developing countries. From July 1998 to July 2001, Mr. Pingree was a Mission President for the Church of Jesus Christ of Latter-day Saints, serving in Mexico City, Mexico. From 1977 to 1997, Mr. Pingree was General Manager and Chief Executive Officer of Utah Transit Authority. From 1970 to 1975, he was Director of Marketing for Memorex Corporation. From 1967 to 1970, Mr. Pingree was Regional Manager, Sales Planning at Xerox Corporation. He also currently serves as a member of the Utah State Board of Education. Mr. Pingree received a B.A. degree in Economics from the University of Utah and an M.B.A. degree from the Harvard Business School.

Appointment of New President and Chief Executive Officer

On March 18, 2004, John Y. Yoon was appointed as the Company's President and Chief Executive Officer, replacing Jeffrey F. Poore who had served in those positions from March 19, 2003 to March 18, 2004.

37

Appointment of New Chief Operating Officer

On March 23, 2004, Aziz A. Mohabbat was appointed as the Company's Vice President of Operations and Chief Operating Officer, replacing David I. Cullumber who had served as Chief Operating Officer since November 6, 2003. Mr. Mohabbat had previously served as the Company's Chief Operating Officer from August 2002 to March 2003, and as Vice President of Operations from 2001 to March 2003.

Board Meetings and Committees

The Board of Directors held a total of six meetings during the fiscal year ended December 31, 2004. No director attended fewer than 75% of all meetings of the Board of Directors during the 2004 fiscal year. The Audit Committee of the Board of Directors consists of directors Dr. David M. Silver, Randall A. Mackey, Keith D. Ignatz and John C. Pingree. The Audit Committee met one time during the fiscal year. The Audit Committee is primarily responsible for reviewing the services performed by its independent public accountants and internal audit department and evaluating its accounting principles and its system of internal accounting controls. The Compensation Committee of the Board of Directors consists of directors Dr. David M. Silver, Randall A. Mackey, Keith D. Ignatz and John C. Pingree. The Compensation Committee met one time during the fiscal year. The Compensation Committee is primarily responsible for reviewing compensation of executive officers and overseeing the granting of stock options.

Edgar Filing: PARADIGM MEDICAL INDUSTRIES INC - Form 10KSB/A

Pursuant to Item 406 of Regulation S-K under the Securities Exchange Act of 1934, the Company has not yet adopted a code of ethics that applies to its principle executive officer, principal financial officer, controller or persons performing similar functions. The Company is still in the process of studying this issue and intends to adopt a code of ethics in the near future.

The Company's Board of Directors has determined that Keith D. Ignatz and John C. Pingree, who currently serve as directors of the Company as well as a member of the Company's audit committee, are independent audit committee financial experts.

Item 10. Executive Compensation

The following table sets forth, for each of the last three fiscal years, the compensation received by Thomas F. Motter, former Chairman of the Board and Chief Executive Officer, and other executive officers whose salary and bonus for all services in all capacities exceed \$100,000 for the fiscal years ended December 31, 2004, 2003 and 2002.

38

Summary Compensation Table

Name and Principal Position -----	Year ----	Salary\$ -----	Annual Compensation			Long Awards
			Bonus (\$) -----	Other Annual Compen- sation (\$) -----	Restricted Stock Awards (\$) -----	
John Y. Yoon President and Chief Executive Officer	2004(1)	\$110,961(4)	0	\$18,494(4)	0	1,000
Aziz A. Mohabbat Vice President of Operations and Chief Operating Officer(6)	2004(1) 2003(2) 2002(3)	\$106,244 \$ 24,219 \$126,878	0 0 0	0 0 0	0 0 0	
Jeffrey F. Poore Former President and Chief Executive Officer	2004(1) 2003(2)	\$ 41,052 \$136,015	0 0	0 0	0 0	1,000
David I. Cullumber, Former Chief Operating Officer and Chief Technical Officer	2004(1) 2003(2)	\$ 15,894 \$ 22,312	0 0	\$18,059(9) \$16,616(9)	0 0	15,000
Gregory C. Hill Former Vice President of Finance and Chief Financial Officer	2004(1) 2003(2)	0 \$ 34,000	0 0	0 0	0 0	

Edgar Filing: PARADIGM MEDICAL INDUSTRIES INC - Form 10KSB/A

Thomas F. Motter	2004(1)	0	0	0	0
Former Chairman of	2003(2)	0	0	0	0
the Board and Chief	2002(3)	\$187,483(11)	0	0	0
Executive Officer					
Mark R. Miehle	2004(1)	0	0	0	0
Former President and	2003(2)	0	0	0	0
Chief Operating	2002(3)	\$134,202	0	0	0
Officer					
Heber C. Maughan	2004(1)	0	0	0	0
Former Vice President	2003(2)	\$ 36,855	0	0	0
of Finance and Chief	2002(3)	\$114,416	0	0	0
Financial					
Officer(16)					

-
- (1) For the fiscal year ended December 31, 2004
 - (2) For the fiscal year ended December 31, 2003
 - (3) For the fiscal year ended December 31, 2002
 - (4) Of the salary payable to Mr. Yoon pursuant to his employment agreement, \$110,961 was paid to him during 2004 and the remaining amount of \$18,494 payable in 2004 was deferred until the Company's board of directors has determined that its financial condition is improved.
 - (5) On March 18, 2004, the Company's board of directors granted Mr. Yoon options to purchase 1,000,000 shares of the Company's common stock at an exercise price of \$.13 per share.
 - (6) Mr. Mohabbat has served a Vice President of Operations and Chief Operating Officer since March 22, 2004 and as Chief Operating Officer from August 30, 2002 to March 2003. He was not an officer in prior years.
 - (7) The amounts under "All Other Compensation" for 2004 consist of payments to Mr. Mohabbat for accrued vacation days prior to his resignation from the Company in March 2003.
 - (8) On March 19, 2003, the Company's board of directors granted Mr. Poore options to purchase 1,000,000 shares of its common stock at an exercise price of \$.16 per share. These options were terminated on March 18, 2003 when the Company's board of directors terminated Mr. Poore's employment for cause as defined in the employment agreement.
 - (9) the Company paid A-Mech Engineering, Inc. a total of \$16,616 and \$18,059 for consulting services during 2003 and 2004, respectively. From 1982 to March 2004, Mr. Cullumber served as President of A-Mech Engineering, Inc.
 - (10) On November 6, 2003, the Company's board of directors granted Mr. Cullumber options to purchase 150,000 shares of the Company's common stock at an exercise price of \$.21 per share. These options were terminated on June 20, 2003, 90 days after Mr. Cullumber resigned as the Company's Chief Operating Officer and Chief Technical Officer.
 - (11) Although Mr. Motter resigned as Chairman and Chief Executive Officer on August 30, 2002, he continued to receive his salary under the terms of his employment agreement through December 16, 2002.
 - (12) The amounts under "All Other Compensation" for 2004, 2003 and 2002 include payments related to the operation of automobiles and/or automobiles and insurance by the named executives.

- (13) The amounts under "All Other Compensation" for 2002 include payments related to the residential housing accommodations for the Company's

Edgar Filing: PARADIGM MEDICAL INDUSTRIES INC - Form 10KSB/A

employees, living outside of Utah while they were working at its corporate headquarters in Salt Lake City, leased from Mr. Motter at \$2,500 per month.

- (14) On January 29, 2002, the Company's Board of Directors granted Mr. Miehle options to purchase the 55,000 shares of the Company's common stock at an exercise price of \$2.75 per share. These options were terminated on February 28, 2004, one year after expiration of a six-month consulting agreement with the Company, which expired on February 28, 2003.
- (15) On September 3, 2002, the Company entered into a consulting agreement with Mr. Miehle in which the Company is required to pay him monthly consulting fees of \$5,000 over a period of six months. The Company paid him a total of \$15,000 for consulting services during the months of September, October and November of 2002.
- (16) Mr. Maughan served as Interim Chief Executive Officer from August 30, 2002 to March 19, 2003. He served as Vice President of Finance, Treasurer and Chief Financial Officer from October 1, 2001 until his resignation on May 31, 2003.
- (17) On May 13, 2003, the Company's Board of Directors granted Mr. Maughan options to purchase 150,000 shares of its common stock at an exercise price of \$.16 per share. These options were terminated on August 29, 2003, 90 days after Mr. Maughan resigned as Vice President of Finance and Chief Financial Officer.

Options

The following table sets forth information regarding stock options granted during the fiscal year ended December 31, 2004, to each named executive officer.

Option Grants in Last Fiscal Year

Name	Number of Securities Underlying Options Granted (#)	Individual Grants	
		Percentage of Total Options Granted to Employees in Fiscal Year(%)	Exercise Price Per Share (\$/Sh)
John Y. Yoon.....	1,000,000 (1)	56.3%	\$.13
Aziz A. Mohabbat.....	200,000 (2)	11.3%	\$.12

- (1) Options vest in 36 monthly installments of 27,778 shares, beginning on April 30, 2004, until such shares are vested.
- (2) Options vest in 36 monthly installments of 5,556 shares, beginning on April 30, 2004, until such shares are vested.

The following table sets forth information regarding unexercised options to acquire shares of the Company's common stock held as of December 31, 2004, by each named executive officer.

Aggregated Option Exercises in Last Fiscal Year and Fiscal Year-End Option Value

Number of Securities
Underlying
Unexercised Options
at December 31, 2004 (#)

Edgar Filing: PARADIGM MEDICAL INDUSTRIES INC - Form 10KSB/A

Name	Shares Acquired on Exercise	Value Realized(\$)	Exercisable	Unexercisable	Ex
John Y. Yoon	0	0	250,002	749,998	
Aziz A. Mohabbat	0	0	50,004	149,996	

The following table sets forth information regarding unexercised options to acquire shares of the Company's common stock held as of December 31, 2004 by each named executive officer.

40

Director Compensation

On April 19, 2004, John C. Pingree, a director of the Company, was granted options to purchase 125,000 shares of its common stock at an exercise price of \$.12 per share. On September 30, 2004, Messrs. Randall A. Mackey, Dr. David M. Silver and Keith D. Ignatz, directors of the company, were each granted options to purchase 125,000 shares of the Company's common stock at an exercise price of \$.13 per share. In addition, outside directors are also reimbursed for their expenses in attending board and committee meetings. Directors are not precluded from serving us in any other capacity and receiving compensation therefore. The options were not issued at a discount to the then market price.

Employee 401(k) Plan

In October 1996, the Company's board of directors adopted a 401(k) Retirement Savings Plan. Under the terms of the 401(k) plan, effective as of November 1, 1996, the Company may make discretionary employer matching contributions to its employees who choose to participate in the plan. The plan allows the board to determine the amount of the contribution at the beginning of each year. The Board adopted a contribution formula specifying that such discretionary employer matching contributions would equal 100% of the participating employee's contribution to the plan up to a maximum discretionary employee contribution of 3% of a participating employee's compensation, as defined by the plan. All persons who have completed at least six months' service with the Company and satisfy other plan requirements are eligible to participate in the plan.

1995 Stock Option Plan

The Company adopted a 1995 Stock Option Plan, for the officers, employees, directors and consultants of its company on November 7, 1995. The plan authorized the granting of stock options to purchase an aggregate of not more than 300,000 shares of its common stock. On February 16, 1996, options for substantially all 300,000 shares were granted. On June 9, 1997, its shareholders approved an amendment to the plan to increase the number of shares of common stock reserved for issuance thereunder from 300,000 shares to 600,000 shares. On September 3, 1998, its shareholders approved an amendment to the plan to increase the number of shares of common stock reserved for issuance thereunder from 600,000 shares to 1,200,000 shares. On November 29, 2000, its shareholders approved an amendment to the plan to increase the number of shares of common stock reserved for issuance thereunder from 1,200,000 shares to 1,700,000 shares. On September 11, 2001, its shareholders approved an amendment to the 1995 plan to increase the number of shares of common stock reserved for issuance thereunder from 1,700,000 shares to 2,700,000 shares. On June 13, 2003, its shareholders approved an amendment to the plan to increase the member of shares

Edgar Filing: PARADIGM MEDICAL INDUSTRIES INC - Form 10KSB/A

of common stock reserved for issuance thereunder from 2,700,000 shares to 3,700,000 shares.

The compensation committee administers the 1995 Stock Option Plan. In general, the compensation committee will select the person to whom options will be granted and will determine, subject to the terms of the plan, the number, exercise, and other provisions of such options. Options granted under the plan will become exercisable at such times as may be determined by the compensation committee. Options granted under the plan may be either incentive stock options, as such term is defined in the Internal Revenue Code, or non-incentive stock options. Incentive stock options may only be granted to persons who are employees. Non-incentive stock options may be granted to any person, including, but not limited to, its employees, independent agents, consultants as the compensation committee believes has contributed, or will contribute, to its success as the compensation committee believes has contributed, or will contribute, to its success. The compensation committee determines the exercise price of options granted under the 1995 Stock Option Plan, provided that, in the case of incentive stock options, such price is not less than 100% (110% in the case of incentive stock options granted to holders of 10% of voting power of its stock) of the fair market value (as defined in the plan) of the common stock on the date of grant. The aggregate fair market value (determined at the time of option grant) of stock with respect to which incentive stock options become exercisable for the first time in any year cannot exceed \$100,000.

The term of each option shall not be more than ten years (five years in the case of incentive stock options granted to holders of 10% of the voting power of its stock) from the date of grant. The Board of Directors has a right to amend, suspend or terminate the 1995 Stock Option Plan at any time; provided, however, that unless ratified by its shareholders, no amendment or change in the plan will be effective that would increase the total number of shares that may be issued under the plan, materially increase the benefits accruing to persons granted under the plan or materially modify the requirements as to eligibility and participation in the plan. No amendment, supervision or termination of the plan shall, without the consent of an employee to whom an option shall heretofore have been granted, affect the rights of such employee under such option.

41

Employment Agreements

The Company entered into an employment agreement with Thomas F. Motter, which commenced on January 1, 1998 and expires on December 31, 2002. The employment agreement requires Mr. Motter to devote substantially all of his working time as the Company's Chairman and Chief Executive Officer, provided that he may be terminated for "cause" (as provided in the agreements) and prohibits him from competing with the Company for two years following the termination of his employment agreement. The employment agreement provides for the payment of an initial base salary of \$135,000, effective as of January 1, 1998. The employment agreement also provides for salary increases and bonuses as shall be determined at the discretion of the Board of Directors. Effective as of October 1, 1999, the Board of Directors approved an increase in Mr. Motter's annual base salary to \$160,000, and effective as of July 1, 2000, the board approved an increase in his annual base salary to \$200,000, which remained in effect during 2002. Mr. Motter resigned as Chairman and Chief Executive Officer on August 30, 2002. He continued to receive his salary under the terms of the employment agreement through December 16, 2002.

The Company entered into an employment agreement with Mark R. Miehle, which commenced on June 5, 2000, and was to expire on June 4, 2003. The employment agreement required Mr. Miehle to devote substantially all of his

Edgar Filing: PARADIGM MEDICAL INDUSTRIES INC - Form 10KSB/A

working time as the Company's President and Chief Operating Officer, provided that he may be terminated for "cause" (as provided in the agreement) and prohibited him from competing with the Company for two years following the termination of his employment agreement. The employment agreement provided for the payment of an initial annual base salary of \$150,000, effective as of June 5, 2000, and the issuance of stock options to purchase 150,000 shares of the Company's common stock at \$6.00 per share, to be vested in equal annual amounts over a three year period. The employment agreement also provided for salary increases and bonuses as to be determined at the discretion of the Board of Directors. The stated annual compensation remained in effect through December 31, 2001 and into 2002. The Board of Directors terminated the employment agreement with Mr. Miehle on August 30, 2002. He entered into a six month consulting agreement, which expired on February 28, 2003, for \$5,000 per month. Mr. Miehle was paid \$15,000 in 2002 under the terms of the consulting agreement.

The Company entered into an employment agreement with Jeffrey F. Poore, which commenced on March 19, 2003 and expires on March 19, 2006. The employment agreement requires Mr. Poore to devote substantially all of his working time as the Company's President and Chief Executive Officer, provided that he may be terminated for "cause" (as provided in the agreement) and prohibits him from competing with the Company for two years following the termination of his employment agreement. The employment agreement provides for the payment of an initial base salary of \$175,000, effective as of March 19, 2003. The employment agreement also provides for salary increases and bonuses as shall be determined at the discretion of the Board of Directors. The employment agreement further provides for the issuance of stock options to purchase 1,000,000 shares of the Company's common stock at \$.16 per share, of which options to purchase 800,000 shares of common stock shall vest on March 19, 2003, options for an additional 100,000 shares of common stock shall vest on March 19, 2004, and options for an additional 100,000 shares of common stock shall vest on March 19, 2005.

The Company entered into an employment agreement with John Y. Yoon, which commenced on March 18, 2004 and expires on March 18, 2007. The employment agreement requires Mr. Yoon to devote substantially all of his working time as the Company's President and Chief Executive Officer, providing that he may be terminated for "cause" (as provided in the agreement) and prohibits him from competing with the Company for two years following the termination of his employment agreement. The employment agreement provides for the payment of an initial base salary of \$175,000, effective as of April 1, 2004. The employment agreement also provides for salary increases and bonuses as shall be determined at the discretion of the Board of Directors. The employment agreement further provides for the issuance of stock options to purchase 1,000,000 shares of the Company's common stock at \$.13 per share. The options vest in 36 equal monthly installments of 27,778 shares, beginning on April 30, 2004 until such shares are vested.

In the event of a change of control of the Company, then all outstanding stock options granted to Mr. Yoon shall be immediately vested. A change of control shall be deemed to have occurred if (i) a tender offer shall be made and consummated for the ownership of more than 25% of the Company's outstanding shares; (ii) the Company shall be merged or consolidated with another corporation and, as a result, less than 25% of the outstanding common shares of the surviving corporation shall be owned in the aggregate by the Company's former shareholders, as the same shall have listed prior to such merger or consolidation; (iii) the Company shall sell all or substantially all of its assets to another corporation that is not a wholly-owned subsidiary or affiliate; (iv) as a result of any contested election for the Board of Directors, or any tender or exchange offer, merger of business combination or sale of assets, the persons who were directors of the Company before such a transaction shall cease to constitute a majority of the Board of Directors; or (v) a person other than an officer or director of the Company shall acquire more than 20% of the outstanding shares of common stock of the Company.

The Company entered into an employment agreement with Aziz A. Mohabbat on October 5, 2004, which is effective as of April 1, 2004, and expires on March 18, 2006. However, the term shall be extended an additional one year period to March 18, 2007 in the event Mr. Mohabbat moves from San Diego, California to Salt Lake City, Utah and becomes a resident of the state of Utah. The employment agreement requires Mr. Mohabbat to devote substantially all of his working time as the Company's Vice President of Operations and Chief Operating Officer, provided that he may be terminated for "cause" (as provided in the agreement) and prohibits him from competing with us for two years following the termination of the employment agreement. The employment agreement provides for the payment of an initial base salary of \$144,500, effective as of April 1, 2004. The employment agreement also provides for salary increases and bonuses as shall be determined at the discretion of the Company's Board of Directors. The employment agreement further provides for the issuance of stock options to purchase 200,000 shares of the Company's common stock at \$.12 per share. These options vest in 36 equal monthly installments of 5,556 shares, beginning on April 30, 2004, until such shares are vested.

In the event of a change of control of the Company, then all outstanding stock options granted to Mr. Mohabbat shall be immediately vested. A change of control shall be deemed to have occurred if (i) a tender offer shall be made and consummated for the ownership of more than 25% of the Company's outstanding shares; (ii) the Company is merged or consolidated with another corporation and, as a result, less than 25% of the outstanding common shares of the surviving corporation shall be owned in the aggregate by the Company's former shareholders, as the same shall have listed prior to such merger or consolidation; (iii) the Company sells all or substantially all of its assets to another corporation that is not a wholly-owned subsidiary or affiliate; (iv) as a result of any contested election for the Company's Board of Directors, or any tender or exchange offer, merger of business combination or sale of assets, the persons who were the directors before such a transaction shall cease to constitute a majority of the Company's Board of Directors; or (v) a person other than an officer or director of the Company shall acquire more than 20% of the outstanding shares of the Company's common stock.

Severance Agreement

On August 30, 2002, the Board of Directors terminated the employment agreement with Mark R. Miehle who had been serving as its President and Chief Operating Officer. Under the terms of the termination of Mr. Miehle's employment agreement, the stock options issued to him on April 19, 2000 to purchase 150,000 shares of its common stock at \$6.00 per share, on September 11, 2001 to purchase 110,000 shares of its common stock at \$2.75 per share, and on January 28, 2002 to purchase 55,000 shares of its common stock at \$2.75 per share were fully vested as of the date of such termination and continue to be exercisable for a period of one year following the termination of a consulting agreement, at which time such options would expire.

The termination of the employment agreement also required the Company to enter into a consulting agreement with Mr. Miehle. Under the terms of the consulting agreement, Mr. Miehle is to provide consulting services to the Company for a period of six months for a fee of \$5,000 per month. The consulting agreement is to be automatically renewed for an additional six months at a fee of \$3,000 per month unless the Company deliver written notice to Miehle at least 30 days prior to the end of the initial six month term that the Company will not renew the agreement. The Company paid Mr. Miehle a total of \$15,000 under the consulting agreement for consulting services during the months of September,

Edgar Filing: PARADIGM MEDICAL INDUSTRIES INC - Form 10KSB/A

October and November of 2002. The Company also provided written notice to Mr. Miehle more than 30 days prior to the end of the initial six month term of the consulting agreement of its intention not to renew the agreement.

Consulting Agreement

On April 3, 2003, the Company entered into a consultant agreement with Kinexsys Corporation ("Kinexsys"). Under the terms of the agreement, Kinexsys through its Senior Partner, Timothy R. Forstrom, is to prepare a capital markets plan and a corporate positioning and communications plan for the Company, for which Kinexsys is to receive warrants to purchase up to 200,000 shares of the Company's common stock at an exercise price of \$.16 per share. The capital markets plan is to include a detailed analysis of the Company's capital market structure in relation to current investors, market trends and projected equity movements, and recommendations on capital management strategies. The corporate positioning and communications plan is to include a corporate positioning matrix for markets, analysts, customers and partners, and a communications plan. The agreement is for a one-year term but may be renewed at the option of both parties. The Agreement expired on April 3, 2004.

43

Item 11. Security Ownership of Certain Beneficial Owners and Management

The following table sets forth certain information with respect to beneficial ownership of the Company's common stock as of March 31, 2005 for (i) each executive officer (ii) each director, (iii) each person known to the Company to be the beneficial owner of more than 5% of the outstanding shares, and (iv) all directors and officers as a group.

Name and Address(1)	Number of Shares	Percent of Ownership
-----	-----	-----
Douglas A. MacLeod, M.D. (2) 502 South M Street Tacoma Washington 98405	3,068,451	11.1%
Dr. David M. Silver (3)	761,166	2.7%
Randall A. Mackey (3)	725,000	2.6%
Keith D. Ignotz (3)	454,560	1.6%
John Y. Yoon (3)	222,224	*
John C. Pingree (3)	231,500	*
Aziz A. Mohabbat (3)	44,448	*

Executive officers and directors as a group (six persons)	2,438,898	8.8%

*Less than 1%.

- (1) Unless otherwise indicated, the address of each listed stockholder is c/o Paradigm Medical Industries, Inc., 2355 South 1070 West, Salt Lake City, Utah, 84119.
- (2) Based on the Company's shareholder records, Dr. McLeod owns 1,218,451 shares and is the Company's largest sole shareholder. Dr. McLeod's beneficial ownership is believed to also include 400,000 shares held by the Douglas A. MacLeod, M.D. Profit Sharing Trust, 200,000 shares held by St. Mark's Eye Institute and 720,000 shares held by Milan Holdings, Ltd., which the Company believes Dr. MacLeod to have sole or shared voting and dispositive powers with regard to such shares. Dr. McLeod's beneficial ownership further includes shares that may be acquired currently or within 60 days after March 31, 2005 through the exercise of warrants as follows: Dr. MacLeod, 200,000 shares; Douglas A. MacLeod, M.D. Profit Sharing

Edgar Filing: PARADIGM MEDICAL INDUSTRIES INC - Form 10KSB/A

Trust; 100,000 shares; St. Mark's Eye Institute, 50,000 shares; and Milan Holdings, Ltd., 180,000 shares.

- (3) The amounts shown include shares that may be acquired currently, or within 60 days after March 31, 2005 through the exercise of stock options are follows: Dr. Silver, 725,000 shares; Mr. Mackey, 725,000 shares; Mr. Ignatz, 453,851 shares; Mr. Yoon, 222,224; Mr. Pingree, 125,000 shares; and Mr. Mohabbat, 44,448 shares.

Item 12. Certain Relationships and Related Transactions

The information set forth herein describes certain transactions between the Company and certain affiliated parties. Future transactions, if any, will be approved by a majority of the disinterested members and will be on terms no less favorable to the Company than those that could be obtained from unaffiliated parties.

Thomas F. Motter, the Company's former Chairman of the Board and Chief Executive Officer, leased his former residence to the Company for \$2,500 per month. The primary use of the residential property was for housing accommodations for its employees living outside of Utah while they were working at its corporate headquarters in Salt Lake City. The Company paid \$2,500 and \$14,000 in rent during 2003 and 2002, respectively. This agreement was terminated on January 31, 2003.

The Company entered into a consulting agreement with Mark R. Miehle, the its former president and chief operating officer for a period of six months commencing on September 3, 2002. The agreement was renewable for additional six month terms. The Company did not renew the contract upon its expiration. The Company paid \$1,000 and \$15,000 under this agreement during 2003 and 2002, respectively, and had an accrual of \$5,000 as of December 31, 2002.

Randall A. Mackey, a director since January 21, 2000, and from September 1995 to September 3, 1998 and chairman of the board since August 30, 2002, is President and a shareholder of the law firm of Mackey Price & Thompson, which rendered legal services in connection with various corporate matters.

44

Legal fees and expenses paid to Mackey Price & Thompson for the fiscal years ended December 31, 2004 and 2003, totaled \$100,000 and \$97,000, respectively. As of December 31, 2004, the Company owed this firm \$197,727, which is included in accounts payable.

PART IV

Item 13. Exhibits and Reports on Form 8-K

(a) Exhibits

The following Exhibits are filed herewith pursuant to Rule 601 of Regulation S-B or are incorporated by reference to previous filings.

Exhibit

No.	Document Description
-----	-----
2.1	Amended Agreement and Plan of Merger between Paradigm Medical Industries, Inc., a California corporation and Paradigm Medical

Edgar Filing: PARADIGM MEDICAL INDUSTRIES INC - Form 10KSB/A

	Industries, Inc., a Delaware corporation(1)
3.1	Certificate of Incorporation(1)
3.2	Amended Certificate of Incorporation(10)
3.3	Bylaws(1)
4.1	Warrant Agency Agreement with Continental Stock Transfer & Trust Company(3)
4.2	Specimen Common Stock Certificate (2)
4.3	Specimen Class A Warrant Certificate(2)
4.4	Form of Class A Warrant Agreement(2)
4.5	Underwriter's Warrant with Kenneth Jerome & Co., Inc.(3)
4.6	Warrant to Purchase Common Stock with Note Holders re bridge financing (1)
4.7	Specimen Series C Convertible Preferred Stock Certificate(4)
4.8	Certificate of the Designations, Powers, Preferences and Rights of the Series C Convertible Preferred Stock(4)
4.9	Specimen Series D Convertible Preferred Stock Certificate (6)
4.10	Certificate of the Designations, Powers, Preferences and Rights of the Series D Convertible Preferred Stock (7)
4.11	Warrant to Purchase Common Stock with Cyndel & Co. (6)
4.12	Warrant to Purchase Common Stock with R.F. Lafferty & Co., Inc. (6)
4.13	Warrant to Purchase Common Stock with Dr. Michael B. Limberg (7)
4.14	Warrant to Purchase Common Stock with John W. Hemmer (7)
4.15	Stock Purchase Warrant with Triton West Group, Inc.(9)
4.16	Warrant to Purchase Common Stock with KSH Investment Group, Inc.(9)
4.17	Warrant to Purchase Common Stock with Consulting for Strategic Growth, Ltd.(9)
4.18	Certificate of Designations, Powers, Preferences and Rights of the Series G Convertible Preferred Stock (14)

45

10.1	Exclusive Patent License Agreement with PhotoMed(1)
10.2	Consulting Agreement with Dr. Daniel M. Eichenbaum(1)
10.3	1995 Stock Option Plan (1)
10.4	Employment Agreement with Thomas F. Motter (5)
10.5	Stock Purchase Agreement with Ocular Blood Flow, Ltd. and Malcolm Redman (7)
10.6	Consulting Agreement with Malcolm Redman (7)
10.7	Royalty Agreement with Malcolm Redman (7)
10.8	Registration Rights with Malcolm Redman (7)
10.9	Employment Agreement with Mark R. Miehle (8)
10.10	Agreements with Steven J. Bayern and Patrick M. Kolenik (8)
10.11	Private Equity Line of Credit Agreement with Triton West Group, Inc. (9)
10.12	Asset Purchase Agreement with Innovative Optics, Inc. and Barton Dietrich Investments, L.P.(10)
10.13	Escrow Agreement with Innovative Optics, Inc., Barton Dietrich Investments, L.P. (10)
10.14	Assignment and Assumption Agreement with Innovative Optics, Inc.(10)
10.15	General Assignment and Bill of Sale with Innovative Optics, Inc.(10)
10.16	Non-Competition and Confidentiality Agreement with Mario F. Barton(10)
10.17	Termination of Employment Agreement with Mark R. Miehle(12)
10.18	Consulting Agreement with Mark R. Miehle(12)
10.19	Employment Agreement with Jeffrey F. Poore (13)
10.20	License Agreement with Sunnybrook Health Science Center(15)
10.21	Major Account Facilitator Contract(15)
10.22	Mutual Release with Douglas A. MacLeod, M.D. and Others(15)
10.23	Purchase Agreement with American Optisurgical, Inc.(15)
10.24	Purchase Order with Westland Financial Corporation(16)
10.25	Non-Waiver Agreement with United States Fire Insurance Company(16)

Edgar Filing: PARADIGM MEDICAL INDUSTRIES INC - Form 10KSB/A

- 10.26 Employment Agreement with John Y. Yoon(17)
- 10.27 Consulting Agreement with Dr. John Charles Casebeer(18)
- 10.28 Consulting Agreement with Kinexsys Corporation(18)
- 10.29 Stock Purchase and Sale Agreement with William Ungar (19)
- 10.30 Employment Agreement with Aziz A. Mohabbat (20)
- 10.31 Investment Banking Agreement with Alpha Advisory Services, Inc. (21)
- 10.32 Manufacturing and Distribution Agreement with E-Technologies, Inc. (21)
- 10.33 Settlement Agreement with Innovative Optics, Inc., Barton Dietrich Investments, L.P. and United States Fire Insurance Company (22)
- 31.1 Certification pursuant to 18 U.S.C. Section 1350, as enacted by Section 302 of the Sarbanes-Oxley Act of 2002
- 31.2 Certification pursuant to 18 U.S.C. Section 1350, as enacted by Section 302 of the Sarbanes-Oxley Act of 2002
- 32.1 Certification pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002
- 32.2 Certification pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002

- (1) Incorporated by reference from Registration Statement on Form SB-2, as filed on March 19, 1996.
- (2) Incorporated by reference from Amendment No. 1 to Registration Statement on Form SB-2, as filed on May 14, 1996.
- (3) Incorporated by reference from Amendment No. 2 to Registration Statement on Form SB-2, as filed on June 13, 1996.
- (4) Incorporated by reference from Annual Report on Form 10-KSB, as filed on April 16, 1998.
- (5) Incorporated by reference from Report on Form 10-QSB, as filed on November 12, 1998.
- (6) Incorporated by reference from Registration Statement on Form SB-2, as filed on April 29, 1999.
- (7) Incorporated by reference from Report on Form 10-QSB, as filed on August 16, 2000.
- (8) Incorporated by reference from Report on Form 10-QSB, as filed on November 1, 2000.
- (9) Incorporated by reference from Report on Form 10-KSB, as filed on April 16, 2001.
- (10) Incorporated by reference from Current Report on Form 8-K, as filed on March 5, 2002.
- (11) Incorporated by reference from Amendment No. 1 to Registration Statement on Form S-3, as filed on March 20, 2002.
- (12) Incorporated by reference from Report on Form 10-QSB, as filed on November 18, 2002.
- (13) Incorporated by reference from Registration Statement on Form SB-2, as filed on July 7, 2003.
- (14) Incorporated by reference from Report on Form 10-QSB, as filed on November 14, 2003.

- (15) Incorporated by reference from Amendment No. 2 to Registration Statement on Form SB-2, as filed on December 15, 2003.
- (16) Incorporated by reference from Amendment No. 3 to Registration Statement on Form SB-2, as filed on February 27, 2004.
- (17) Incorporated by reference from Current Report on Form 8-K, as filed on March 23, 2004.
- (18) Incorporated by reference from Report in Form 10-KSB, as filed on April 14, 2004.

Edgar Filing: PARADIGM MEDICAL INDUSTRIES INC - Form 10KSB/A

- (19) Incorporated by reference from Quarterly Report on Form 10-QSB, as filed on August 16, 2004.
- (20) Incorporated by reference from Amendment No. 6 to Registration Statement on Form SB-2, as filed on October 20, 2004.
- (21) Incorporated by reference from Report on Form 10-QSB, as filed on November 15, 2004.
- (22) Incorporated by reference from Current Report on Form 8-K, as filed on January 26, 2005.

(b) Reports on Form 8-K

No reports on Form 8-K were filed by the Company during the quarter ended December 31, 2004.

Item 14. Principal Accountant- Fees and Services

Fees for the 2004 annual audit of the financial statements and related quarterly review services were approximately \$35,000. Fees in 2004 related to the review of registration statements and assistance in responding to SEC comments were approximately \$16,000. Fees in 2004 for edgarization of filings were approximately \$10,000. Fees in 2004 for tax return preparation were approximately \$7,000. Other fees in 2004 for meetings and other consultation were approximately \$1,000.

Fees for the 2003 annual audit of the financial statements and related quarterly review services were approximately \$51,000. Fees in 2003 related to the review of registration statements and assistance in responding to SEC comments were approximately \$14,000. Fees in 2003 for edgarization of filings were approximately \$8,000. Fees in 2003 for tax return preparation were approximately \$10,000. Other fees in 2003 for meetings and other consultation were approximately \$3,000.

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, there unto duly authorized.

PARADIGM MEDICAL INDUSTRIES, INC.

Dated: May 12, 2005

By: /s/ John Y. Yoon

John Y. Yoon,
President and Chief Executive Officer

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

Signature	Title	Date
-----	-----	----

