

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

PARADIGM MEDICAL INDUSTRIES INC  
Form 10KSB/A  
November 04, 2004

SECURITIES AND EXCHANGE COMMISSION  
Washington, D.C. 20549

Form 10-KSB/A-2

ANNUAL REPORT PURSUANT TO SECTION 13 OR 15(d) OF  
THE SECURITIES EXCHANGE ACT OF 1934  
For the fiscal year ended December 31, 2003, 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  
(State or other jurisdiction  
of incorporation or organization)

87-0459536  
(I.R.S. Employer  
Identification Number)

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

84119  
(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, 2003 were \$3,059,000.

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 second fiscal quarter was \$6,690,000 based on the closing price on that date on the OTC Bulletin Board.

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

As of March 31, 2004, Registrant had outstanding 25,509,868, shares of common stock, 5,627 shares of Series A preferred stock, 8,986 shares of Series B 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 1,981,560 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]

1

### 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.

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

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

2

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

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

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 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 SSTM, 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

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

issuance of an aggregate of 94,000 shares of its common stock to the company and its counsel.

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 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,

3

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).

### 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 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

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

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.

**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 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 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

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

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% and 3% of total revenues in the fiscal years 2003 and 2002, 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

5

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 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



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

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 the 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 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 532mm green laser which is 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.

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

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 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 11% and 4% of the total revenues for fiscal years 2003 and 2002, 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% and 3% of total revenues for 2003 and 2002, 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.

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

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

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 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

7

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) 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

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

accounted for approximately 16% and 12% of total sales for the fiscal years ended December 31, 2003 and 2002, 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% and 20% of the total revenues for 2003 and 2002, 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 9% and 7% of the total revenues for 2003 and 2002, 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 2003 and 2002.

**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 2% of the total revenues for both 2003 and 2002.

**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 4% and 7% of the total revenues for 2003 and 2002, respectively.

**P40 UBM Ultrasound Biomicroscope:** The P40 UBM Ultrasound Biomicroscope was developed by Humphrey Systems in conjunction with the New York Eye and Ear Infirmary in Manhattan and the University of Toronto. The UBM biomicroscope, and its intellectual property were included in the purchase from Humphrey Systems and gives the Company the proprietary rights to this device. The UBM biomicroscope creates a high-resolution computer image of the unseen parts of the eye that is a "map" for the glaucoma surgeon. The UBM 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 UBM biomicroscope at a price-point targeted for the average practitioners seeking to add glaucoma filtering surgical procedures and income to their cataract surgical practice.

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

The P40 UBM Ultrasound Biomicroscope related surgical filtering procedures are fully reimbursable by Medicare and insurance providers. This untapped new market positions the Company with its proprietary UBM 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 UBM Ultrasound Biomicroscope

8

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 UBM Ultrasound Biomicroscope and related accessories sales were approximately 7% and 12% of the total revenues for 2003 and 2002, respectively. The P45 UBM Ultrasound Biomicroscope and related accessories sales contributed approximately 13% and 12% of the total revenues for 2003 and 2002, respectively.

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% and 11% of total revenues in 2003 and 2002, respectively.

Sales of other products represented approximately 1% and 4% of total revenues in 2003 and 2002, respectively.

The following table identifies each product class, status of commercial development, the percentage of sales contributed by that class, reimbursement status, and status of applicable United States and foreign regulatory approvals:

Product (1)	Product Class	Commercial Development	Reimbursement Status	% 2003 Sales
P55 Pachymetric Analyzer	System, Imaging, Pulsed Echo Diagnostic	Complete	Yes	3%
P20 A-Scan Biometric Ultrasound Analyzer	System, Imaging, Pulsed Echo Diagnostic	Discontinued	Yes	2%
P37 A/B Scan Ocular Ultrasound Diagnostic	Transducer, Ultrasound Diagnostic	Complete	Yes	4%
P40 UBM Ultrasound Biomicroscope	System, Imaging, Pulsed Echo Ultrasound Diagnostic	Complete	Yes	7%
P45 UBM Ultrasound Biomicroscope, Workstation Plus	System, Imaging, Pulsed Echo Ultrasound Diagnostic	Complete	Yes	13%

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

BFA Ocular Blood Flow Analyzer (TM) and Disposables	Tonometer, Manual Diagnostic	Complete	Yes****	16%
CT 200 Corneal Topography System	Topographer Corneal AC-Powered Diagnostic	Complete	Yes	9%
LD 400 Autoperimetry System	Perimeter, Automatic AC-Powered Diagnostic	Complete	Yes	24%
TKS 5000 Autoperimetry System	Perimeter, Automatic AC-Powered, Diagnostic	Complete	Yes	3%
Precisionist Thirty Thousand(TM), Ocular Surgery Workstation with Surgical Equipment and Disposables	Phacofragmentation	Complete	Yes	0%
SISem(TM) and Odyssey(TM) (2)	Phacofragmentation	Sold	Yes	11%
Photon(TM) Laser Ocular Surgery Workstation with Surgical Equipment and Disposables(3)	Phacoemulsification BFA tips	Complete	No	0%
Parts and Services	Perimeter, BFA, Tonometer, Topographer, Ultrasound Workstations, Systems, Imaging	Complete	Yes	8%

9

- 
- (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 SISem(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.

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

- \* FDA 510(K) K844299 represents domestic clearance or 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 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

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

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.

**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 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 Ocular 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



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

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.

11

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 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.

### 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.

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

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 \$1,786,000, or 63%, to \$1,033,000 for the twelve months ended December 31, 2003, from \$2,819,000 for the same period in 2002. Pursuant to the asset purchase agreement with Innovative Optics, Inc., the Company issued 477,000 shares of its common stock, which was valued at \$630,000 based upon the current market value of the stock at the time of issue. This amount was recorded in 2002 as in-process research and development costs related to the blade cost reduction project. No such expense was recorded in 2003. Consulting fees related to software development and enhancements increased to \$197,000 during 2003 from \$111,000 for the same period in 2002. None of the costs of research and development activities during 2003 and 2002 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

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.

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

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.

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 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

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

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.

13

### 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 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.

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

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

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 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

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

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.

14

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.

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

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

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, 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.

15

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

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

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.

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 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



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

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.

16

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 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

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

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 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.

17

### Employees

As of December 31, 2003, the Company had 31 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

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

and transferring its manufacturing from its site in San Diego, California to Salt Lake City, resulting in further reductions in operating expenses. As a 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 in 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 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 March 7, 2000 in the Third District Court of Salt Lake County, State of Utah, by the Merrill Corporation that alleges that the Company owes the Merrill Corporation approximately \$20,000 together with interest thereon at the rate of 10% per annum from August 30, 1999, plus costs and attorney's fees. The complaint alleges a breach of contract relative to printing services. The Company filed an answer to the complaint. On August 12, 2003, the court dismissed the action without prejudice.

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. Discovery has taken place and the Company has paid royalties of \$14,736 to bring all payments up to date through June 30, 2001. 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. The 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)

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

laser system has been sold and no systems returned. Thus, the amount of royalties due, according to its calculations, is \$600. The Company intends to make payment of this amount to PhotoMed and Dr. Eichenbaum and, as a result, to have the legal action 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 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.

The Company received a demand letter dated December 9, 2002 from counsel for Dan Blacklock, dba Danlin Corp. The letter demands payment in the amount of \$65,160 for manufacturing and supplying parts for microkeratome blades. The Company's records show that it received approximately \$34,824 in parts from the Danlin Corp., but that the additional amounts that the Danlin Corp contends are owed were from parts that were received but rejected by the Company because they had never been ordered. On August 14, 2003, the Company agreed to make a \$13,650 payment to Danlin Corp. in settlement of the dispute. The Company has since made the \$13,650 payment to Danlin Corp.

18

The Company received a demand letter dated December 30, 2002 from counsel for Thomas F. Motter, its former Chairman and Chief Executive Officer. Mr. Motter claims in the letter that he was entitled to certain stock options that had not been issued to him in a timely manner. By the time the options were actually issued to him, however, they had expired. Mr. Motter contends that if the options had been issued in a timely manner, he would have exercised them in a manner that would have given him a substantial benefit. Mr. Motter requests restitution for the loss of the financial opportunity. Mr. Motter also claims that he was defrauded by the Company not being given an extended employment agreement when he terminated the change of control agreement that he had entered into with us.

Mr. Motter is further claiming payment for accrued vacation time during the 13 years he had been employed by the Company, asserting that he only had a total of four weeks of vacation during that period. Finally, Mr. Motter is threatening a shareholder derivative action against the Company because of the board of directors' alleged failure to conduct an investigation into conversations that took place in a chat room on Yahoo. Mr. Motter asserts that certain individuals participating in the conversations were its officers or directors whose interests were in conflict with the interest of the shareholders. The Company believes that Mr. Motter's claims and assertions are without merit and intends to vigorously defend against any legal action that Mr. Motter may bring.

On January 24, 2003, an action was brought by Dr. John Charles Casebeer against the Company in the Montana Second Judicial District Court, Silver Bow County, State of Montana (Civil No. DU-0326). The complaint alleges that Dr. Casebeer entered into a personal services contract with the Company memorialized by a letter agreement dated April 20, 2002, with it being alleged that Dr. Casebeer fully performed his obligations. Dr. Casebeer asserts that he is entitled to \$43,750 per quarter for consultant time and as an incentive to be granted each quarter \$5,000 in options issued at the fair market value. An additional purported incentive was \$50,000 in shares of stock being issued at the time a formalized contract was to be signed by the parties. In the letter it is provided that at its election, the Company may pay the consideration in the form of stock or cash and that stock would be issued within 30 days of the close of the quarter. Prior to the litigation, the Company issued 43,684 shares to Dr. Casebeer. The referenced letter provides that termination may be made by either party upon giving 90 days written notice. Notice was given by the Company in early November 2002. The Company recently filed its answer in defense of the

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

action. Issues included whether or not Dr. Casebeer fully performed as asserted. The case has been settled through the issuance of 300,000 additional shares of its common stock to Dr. Casebeer.

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 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

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

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 Company has received authorization from the CPT Editorial Research and Development Department of the American Medical Association to use CPT code number 92120 for its Blood Flow Analyzer(TM), for reimbursement purposes for doctors using the device.

19

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 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

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

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. The Company believes the consolidated cases are without merit and intends to vigorously defend and protect its interests in the said cases.

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 not paid any amounts toward satisfaction of any part 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.

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.

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.

20

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

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



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

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 two copy machines that were delivered to its 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 the equipment it returned to the leasing company did not work properly. A responsive pleading has not yet been filed. The Company is currently engaged in settlement discussions with CitiCorp.

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 \$2,300 to Franklin Funding, with the first monthly payment due on August 29, 2003.

21

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. The Company disputes the amounts allegedly owed and intends to vigorously defend and protect its interests in the action.

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

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

pursuant to Utah law. The Company disputes the amount allegedly owed 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, 2003.

## 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.

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 12, 2004, the closing sale prices of the common stock and Class A warrants were \$.16 per share and \$.03 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.

22

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.....	1.91	.60	.32	.05
Third Quarter.....	1.50	.16	.20	.08
Fourth Quarter.....	.30	.13	.10	.01
2003				
First Quarter.....	.42	.14	.12	.01

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

Second Quarter.....	.74	.14	.44	.01
Third Quarter.....	.42	.18	.18	.01
Fourth Quarter .....	.24	.15	.10	.02
2004				
First Quarter .....	.21	.11	.04	.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.

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 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

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

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.

23

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 do 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 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

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

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, 2003, 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 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 and Odyssey 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 intangibles of \$150,000, and increases in accruals to settle outstanding disputes in the amount of \$446,000. Although management believes these adjustments are sufficient, it will continue to monitor and evaluate its financial position and the recoverability of its assets.

24

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 \$0 cost of sales because a reserve for obsolete inventory had been recorded on all

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

SIStem and Odyssey 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, 2003, diagnostic products are currently its 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 other certain 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.

Activities for the twelve months ended December 31, 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. The Company named a new Vice President of Sales and Marketing, Raymond P.C. 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. John Y. Yoon was appointed as President and Chief Executive Officer on March 18, 2004, to replace Mr. Poore. 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. 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 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

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

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

25

organization and sales channels by decreasing its direct sales force who are full-time employees from 10 direct sales employees on January 1, 2003, to five direct sales employees on December 31, 2003. 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 2004 will be the judicious reconstruction of the sales force in anticipation of increased sales. The Company is projecting an increase in revenues in 2004, however there can be no assurance that this will occur.

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, 2003, 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 its diagnostic products. Due to concerns over the budget and the effectiveness of trade shows, the Company exhibited at only three trade shows during 2003. The Company monitors trade show attendance to determine the extent to which it will exhibit at future trade shows.

In April 2002, the Company announced the closure of its San Diego facility in anticipation of the termination of the lease for that location. The operations were transferred to the Salt Lake City facility. The Company incurred a reduction of force of 28 San Diego personnel. The consolidation was intended to save costs and to eliminate duplicities in functions and facilities that occurred with the acquisition of Dicon. The cost of the consolidation was approximately \$80,000.

In January 2002, the Company purchased certain assets and lease obligations of Innovative Optics, Inc. by issuing an aggregate of 1,272,825 shares of its common stock (636,412 shares are held in escrow pending the result of a project to reduce the cost of the disposable razor blades utilized by the microkeratome, which was acquired in the transaction), 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 the raw materials, work-in-process and finished goods inventories. Additionally, it acquired the patents and trade name associated with the product, the furniture and equipment of Innovative Optics used in the manufacturing process of the microkeratome console and the inspection and packaging of the disposable blades. The Company

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

subsequently issued 477,039 shares of common stock that were held in escrow at a value of \$630,000, based on the market price of such shares on the date of issuance. This amount was charged to in-process research and development because the issuance of such shares related to the continuing research and development of the microkeratome blades.

The Company was unsuccessful in reducing the costs of the blade production process and was unable to supply blades to the user base. The Company terminated its marketing and sales efforts for the microkeratome, but the Company continues to search for an alternative source of blades. Because the Company determined that it could not manufacture the blades to support its customer base at an economical cost, in accordance with Statement of Financial Accounting Standards No. 142, due to the lack of projected future cash flows, during 2002 the Company recorded an impairment expense of \$2,082,000 for the remaining book value of property and equipment and intangible assets purchased from Innovative Optics. In addition, the Company recorded an inventory reserve for the remaining inventory purchased from Innovative Optics of approximately \$160,000.

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, or 19.9%, of its outstanding shares and warrants to purchase 1,200,000 shares of its common stock at \$2.50 per share for a period of two years, in exchange for the issuance of 736,945 shares of the Company's common stock to International Bio-Immune Systems, the lending of 300,000 shares of the Company's common stock to International Bio-Immune Systems, and the payment of certain expenses through the issuance of an aggregate of 94,000 shares of the Company's common stock to International Bio-Immune Systems and its counsel. The issuance of 736,945 shares was valued based on the market price of the Company's common stock on the date of the transaction and resulted in an investment in International Bio-Immune Systems, when combined with a cash investment of \$65,000 made in 2000, of \$879,000. The 300,000 shares were also valued at the market price on the date of issuance and were recorded as a stock subscription receivable of \$294,000 because such shares will either be paid for or returned in the future.

International Bio-Immune Systems is a privately held biotechnology based, cancer diagnostic and immunotherapy company, located in Great Neck, New York, with potential clinically effective products for the diagnosis, treatment and imaging of patients with major tumor types (e.g. colon, lung, cervix, pancreas and breast). International Bio-Immune Systems does not produce significant revenues as its products have not received FDA approval. Due to the uncertainty of future cash flows and the fact that the FDA has not approved such products, the Company was unable to support the value of the investment by substantiated methods and determined that the likelihood of recovery of its investment was remote. Therefore, in accordance with generally accepted accounting principles, the investment of \$879,000 was charged to impairment expense in 2002.

26

The tragic events of September 11, 2001, the Afghanistan conflict and the Iraq war combined with a recessionary trend in the economy have had a negative effect on its sales. International attendance at the trade shows following September 11, 2001, and through 2003 were down markedly. The absence of these professionals eliminates many opportunities for the Company to demonstrate and sell its products to this sector. It is difficult to quantify how much an effect that these events have had on us, but the Company believes that the Company has suffered some negative impact due to September 11, 2001, the Afghanistan conflict, the Iraq war and the downturn in the economy in general, which may continue for an indefinite period of time.



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

### Results of Operations

Fiscal Year Ended December 31, 2003, Compared to Fiscal Year Ended December 31, 2002

Net sales decreased by \$2,309,000, or 43%, to \$3,059,000 for the twelve months ended December 31, 2003, from \$5,368,000 for the comparable period in 2002. Sales of the Company's diagnostic products and related accessories were \$2,484,000, or 81% of total revenues, during the twelve months of 2003 compared with \$4,015,000, or 75% of total revenues, for the comparable period of 2002. Sales of surgical products and related accessories totaled \$324,000, or 11% of total revenues, for the twelve months of the current year in comparison with \$556,000, or 10%, of total revenues in the comparable period of 2002. Surgical product sales for 2003 include the sale of the SISTEM and Odyssey product lines for \$125,000. In 2003, sales of the P40 and P45 UBM Ultrasound Biomicroscope and related accessories were \$615,000, or 20% of total revenues, compared to \$1,303,000, or 24% of total revenues, in the same period of 2002. Sales from the Blood Flow Analyzer(TM) and related accessories decreased by \$121,000 to \$499,000, or 16% of total revenues, during the year ended December 31, 2003 compared with \$620,000, or 12% of total revenues, in the same period of last year. During the twelve months of 2003, sales from other ultrasonic products and related accessories totaled \$191,000, or 6% of total revenues, compared with \$464,000, or 9% of total revenues, in the same period last year. Sales of the perimeter and corneal topographer and related accessories generated \$1,100,000, or 36% of total revenues, in 2003 compared with \$1,487,000, or 28% of total revenues, during the same period of 2002.

There were a number of material reasons that contributed to the decrease in sales during the twelve months ended December 31, 2003, compared to the same period of 2002. Along with generally weak economic conditions in the United States, the Company initiated the restructuring of its management structure, its sales organization and the development of new sales channels during the twelve months ended December 31, 2003. During the first three months of 2003, the Company reduced its direct sales force from 10 representatives to five representatives, and during the remainder of 2003, there were only five direct sales representatives compared to 10 direct sales representatives during the comparable period of 2002. International sales were impacted by weakness in the economies of the large industrial countries and by the residual impact of the Afghanistan situation, which had a negative impact on sales to the Middle East, Pakistan, India and other countries in that region.

The decrease in sales of the P40 and P45 Plus Ultrasound Biomicroscope as well as other products were the direct result of the restructuring of the sales and marketing organization. With respect to the decrease in sales of the Biomicroscope, there has not been an increase in price, competition remains similar to what it has been previously, and there are no other particular factors of which the Company is aware. This restructuring has significantly reduced the sales expenses and funds dedicated to marketing. In addition, the sales channels have been altered to include distributor and independent sale representatives instead of relying more on a direct sales force. Domestic and international sales have also decreased as a result of the global financial markets declines beginning in 2000 and the adverse impact of the events of September 11, 2001.

Other reasons for the decrease in sales were the uncertainties resulting from its efforts to reduce costs and constraints on availability of funds that reduced the Company's ability to upgrade and enhance its products and pursue further regulatory approvals for its products. Additionally, changes in the exchange rate between these periods have generally made its products more expensive to some customers outside of the United States. The Company's objective is to focus its sales efforts on the products with the highest

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

potential for sales and strong margins.

Gross profit for the year ended December 31, 2003 was 32% of total revenues, compared to 22% for the same period in 2002. Cost of goods sold for the year ended December 31, 2003 was \$2,086,000 as compared to \$4,210,000 for the same period in 2002, a reduction of \$2,124,000. Cost of goods sold for the year ended December 31, 2003 included an increase in the reserve for obsolete or estimated non-recoverable inventory of \$403,000. Cost of goods sold for 2002 included an increase in the reserve for obsolete or estimated non-recoverable inventory of \$1,755,000. Since its inception, the Company has purchased several complete lines of inventory. While its initial intention was to utilize the substantial majority of inventory acquired in the manufacture of its products, in some circumstances the Company has been unable to utilize certain items acquired.

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

27

enhancements, a reserve is established for such products. Such analysis resulted in material increases in the reserve for obsolete or estimated non-recoverable inventory in 2003 and 2002. There can be no assurance that the Company will not identify further obsolete inventory due to significant declines in sales of certain products or technological advances of products in the future. 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. The Company does not expect the sales of these items to be significant in the future. During 2003, the Company 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, the Company 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 \$1,875,000, or 67%, to \$920,000 in 2003, from \$2,795,000 in 2002 due primarily to the lower headcounts of sales persons and travel related and associated sales expenses.

General and administrative expenses decreased by \$1,256,000, or 34%, to \$2,446,000 in 2003, from \$3,702,000 in 2002, reflecting the results of the Company's efforts to reduce costs, specifically costs associated with maintaining two manufacturing facilities and consulting costs. As noted above, in April 2002, the Company announced the closure of its San Diego facility in anticipation of the termination of the lease for that location. All operations associated with the San Diego facility were transferred to the Salt Lake City facility. The Company incurred a reduction of force of 28 San Diego personnel. The consolidation was intended to save costs and to eliminate duplicities in functions and facilities that occurred with the acquisition of Dicon. The cost of the consolidation was approximately \$80,000. The Company believes that the annual cost savings of the closure of the San Diego facility are approximately \$2 million. Administrative salaries and wages decreased from approximately \$786,000 in 2002 to approximately \$321,000 in 2003. Depreciation and amortization expense, which includes amortization of leasehold improvements, decreased by approximately \$305,000, or 49%, to \$319,000 in 2003 compared to the

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

same period of last year. General and administrative expenses for 2003, included \$123,000 for additions to the allowance for doubtful accounts and increases in accruals of \$443,000 to settle outstanding disputes.

In addition, general and administrative expense for the twelve months ended December 31, 2003, included \$259,000 for 1,562,000 shares of common stock issued to settle potential litigation. 1,262,000 common shares were issued to six investors due to a dispute arising from a private offering that was completed on January 22, 2003. The Company 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 and service expenses decreased by \$1,786,000, or 63%, to \$1,033,000 in 2003, from \$2,819,000 in 2002. This decrease was mainly due to the issuance of common stock to Innovative Optics in the fourth quarter of 2002, which was valued at \$630,000 and expensed as in-process research and development costs. Expenses associated with the development of new products during the twelve months of 2003 decreased compared to the same period in 2002 as a consequence of the Company's efforts to reduce costs and focus on products that are fully developed and have the highest potential for sales and strong margins.

Impairment of assets was \$150,000 in 2003, compared to \$2,961,000 in 2002. The impairment expense for 2003 was due to a reduction in the value of certain intangible assets based on their currently estimated fair value. The impairment expense for 2002 was due to an evaluation by the Company of its intangible assets, namely goodwill and patents, rights, and trade name acquired from Innovative Optics, resulting in a charge of \$1,949,000 as a write down of the goodwill and other intangibles. The remaining impairment charge of \$1,012,000 was a result of the write-off of the investment in IBS of \$879,000 and other assets of \$133,000.

Other income and (expense) increased by \$451,000 to income of \$415,000 in 2003, from expense of \$(36,000) for the same period in 2002. During 2003, interest income was \$3,000 compared with \$10,000 during 2002. During 2003, the Company recorded a gain of \$436,000 on discounted settlements of accounts payable and obligations. The Company had a \$22,000 reduction in interest expense to \$(24,000) in 2003, from \$(46,000) in 2002 due to a decrease in interest expense related to capital leases.

### Liquidity and Capital Resources

The Company used \$707,000 cash in operating activities for the twelve months ended December 31, 2003, compared to \$2,782,000 for the twelve months ended December 31, 2002. The reduction in cash used by operating activities for the twelve months of 2003 was primarily attributable to reduced operating costs, including the closure of the San Diego facility, as well as other savings resulting from its ongoing efforts to substantially reduce costs and management of its current assets and current liabilities. The Company used \$2,000 from investing activities for the twelve months ended December 31, 2003, compared to cash used of \$229,000 in the same period in 2002. Cash used in investing

activities in the twelve months of 2002 was primarily due to the cash paid in the acquisition of certain assets of Innovative Optics and capital equipment. Net cash provided by financing activities was \$647,000 for the twelve months

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

ended December 31, 2003 versus \$503,000 in the same period in 2002. During the twelve months ended December 31, 2003, the Company raised approximately \$84,000 through a \$20,000,000 equity line of credit and \$700,000 through private placements from the sale of the Company's common stock and Series G preferred stock and warrants. However, the equity line of credit is not currently available as a source of equity because a registration statement is not currently effective registering the shares issuable under the equity line of credit. 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 its securities, and bank borrowings. The Company is uncertain whether or not the combination of existing working capital and benefits from sales of its products will be sufficient to assure continued operations through December 31, 2004. As of December 31, 2003, the Company had accounts payable of \$706,000, a significant portion of which is over 90 days past due. The Company has contacted many of the vendors or companies that have significant amounts of 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 it 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 noncancellable capital lease obligations and operating lease obligations that require the payment of approximately \$187,000 in 2004, \$172,000 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.

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

At December 31, 2003, the Company had net operating loss carryforwards of approximately \$44,000,000 and research and development tax credit carryforwards of approximately \$34,000. These loss carryforwards 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 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 loss carryforwards can be utilized. The Tax Reform Act of 1986 significantly limits the annual amount that can be utilized for certain of these loss carryforwards as a result of change of ownership.

As of December 31, 2003, the Company had raised approximately \$1,584,000 through a \$20,000,000 equity line of credit under an investment

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

banking arrangement. As of December 31, 2003, approximately \$18,416,000 was available under the equity line of credit. However, the equity line of credit expired by its terms on December 8, 2003, but the Company is currently in the process of renewing the agreement. Moreover, the equity line of credit is currently unavailable as a source of equity because there is currently no registration statement that is effective registering the shares of its common stock that may be sold under the equity line of credit. 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/or private placements of its securities or bank borrowings. The Company is uncertain whether or not the combination of existing working capital and benefits from sales of its products will be sufficient to assure its operations through December 31, 2003.

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 27% of total outstanding receivables as of December 31, 2002 and 40% as of December 31, 2003. Much of the increase in the allowance relates to outstanding receivable balances pertaining to international dealers. 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

29

require more payments at the time of sale via letters of credit and not on a credit term basis. The Company intends to continue its efforts to reduce the allowance as a percentage of accounts receivable. While the allowance as a percentage of accounts receivable has grown, it is mainly a result of the significant decline in sales. The total amount of the allowance has increased from \$347,000 at December 31, 2002, to \$470,000 at December 31, 2003. The majority of the receivables included in the allowance for doubtful accounts are a result of sales before the Company implemented the various changes to improve the collectibility of its receivables. During 2002, the Company had a net recovery of receivables previously allowed for of \$23,000 and during the twelve months ended December 31, 2003, the Company added a net of \$123,000 to the allowance for doubtful accounts. 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 \$1,642,000 at December 31, 2003, and \$2,126,000 as of December 31, 2002, or approximately 62% and 45% of total inventory, respectively. This inventory reserve was increased by \$403,000 in the twelve months of 2003 and \$1,755,000 during 2002 mainly due to the decline in sales and the discontinuance of the microkeratome purchased from Innovative Optics in 2002, however the increase in 2003 was offset by a decrease of \$887,000 due to the sale of inventory that was fully reserved. 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 SIsTem(TM) and Odyssey(TM) for \$125,000. Because the full amount of inventory related to the SIsTem(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 additional development and regulatory approvals. Any possible future efforts to complete development of the Photon(TM) and obtain the necessary regulatory approvals would depend on the Company obtaining adequate funding. The Company estimates that the liquidity needed to complete development of the Photon(TM) and obtain the necessary regulatory approvals to be approximately \$225,000.

#### 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 November 2002, the EITF reached a consensus on Issue No.00-21, Revenue Arrangements with Multiple Deliverables. EITF Issue No. 00-21 provides guidance on how to account for certain arrangements that involve the delivery or performance of multiple products, services and/or rights to use assets. The provisions of EITF Issue No. 00-21 will apply to revenue arrangements entered into in fiscal periods beginning after June 15, 2003. The adoption of EITF Issue No. 00-21 did not have a material impact on operating results or financial condition of the Company as the Company followed the provisions of Statement of Position ("SOP") 97-2, Software Revenue Recognition, as modified by SOP 98-9, Modification of SOP 97-2 with Respect to Certain Transactions, which provide guidance for revenue recognition of arrangements with multiple deliverables.

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 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.

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

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.

30

In April 2003, FASB issued SFAS No. 149, Amendment of Statement 133 on Derivative Instruments and Hedging Activities. SFAS 149 amends and clarifies accounting for derivative instruments, including certain derivative instruments embedded in other contracts and for hedging activities under SFAS 133, Accounting for Derivatives and Hedging Activities. SFAS 149 is generally effective for derivative instruments, including derivative instruments embedded in certain contracts, entered into or modified after June 30, 2003. The adoption of SFAS 149 did not have a material impact on the operating results or financial condition of the Company.

In May 2003, the FASB issued SFAS 150, Accounting for Certain Financial Instruments with Characteristics of Both Liabilities and Equity. SFAS 150 clarifies the accounting for certain financial instruments with characteristics of both liabilities and equity and requires that those instruments be classified as liabilities in statements of financial position. Previously, many of those financial instruments were classified as equity. SFAS 150 is effective for financial instruments entered into or modified after May 31, 2003 and otherwise is effective at the beginning of the first interim period beginning after June 15, 2003. On November 7, 2003, FASB Staff Position 150-3 was issued, which indefinitely deferred the effective date of SFAS 150 for certain mandatory redeemable non-controlling interests. As the Company does not have any of these financial instruments, the adoption of SFAS 150 did not have any impact on the Company's consolidated financial statements. In December 2003, the Securities and Exchange Commission (SEC) issued Staff Accounting Bulletin (SAB) No. 104, Revenue Recognition. SAB 104 revises or rescinds portions of the interpretive guidance included in Topic 13 of the codification of staff accounting bulletins in order to make this interpretive guidance consistent with current authoritative accounting and auditing guidance and SEC rules and regulations. The adoption of SAB 104 did not have a material effect on the Company's results of operations or financial position.

### 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.

31

### Item 8. Financial Statements and Supplementary Data

PARADIGM MEDICAL INDUSTRIES, INC.  
Financial Statements  
December 31, 2003 and 2002

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

## PARADIGM MEDICAL INDUSTRIES, INC. Index to Financial Statements

---

	Page
Report of Tanner + Co.	F-2
Balance Sheet	F-3
Statement of Operations	F-4
Statement of Stockholders' Equity	F-5
Statement of Cash Flows	F-6
Notes to Financial Statements	F-7

---

F-1

### INDEPENDENT AUDITORS' REPORT

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

We have audited the balance sheet of Paradigm Medical Industries, Inc. (the Company) as of December 31, 2003, and the related statements of operations, stockholders' equity, and cash flows for the years ended December 31, 2003 and 2002. These financial statements are the responsibility of the Company's management. Our responsibility is to express an opinion on these financial statements based on our audits.

We conducted our audits in accordance with auditing standards generally accepted in the United States of America. 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 audits provide a reasonable basis for our opinion.

In our opinion, the financial statements referred to above present fairly, in



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

all material respects, the financial position of Paradigm Medical Industries, Inc. as of December 31, 2003, and the results of its operations and its cash flows for the years ended December 31, 2003 and 2002, in conformity with accounting principles generally accepted in the United States of America.

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.

/s/TANNER + CO.

Salt Lake City, Utah  
March 5, 2004

F-2

### PARADIGM MEDICAL INDUSTRIES, INC. Balance Sheet

December 31, 2003

---

Assets	
-----	
Current assets:	
Cash	\$ 132,000
Receivables, net	708,000
Inventories, net	1,003,000
Prepaid and other current assets	141,000
	-----
Total current assets	1,984,000
Intangibles, net	682,000
Property and equipment, net	256,000
	-----
Total	\$ 2,922,000
	-----

---

### Liabilities and Stockholders' Equity

---

Current liabilities:	
Accounts payable	\$ 706,000
Accrued liabilities	1,419,000
Current portion of capital lease obligations	56,000
	-----

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

Total current liabilities	2,181,000
	-----
Capital lease obligations, net of current portion	61,000
	-----
Commitments and contingencies	
Stockholders' equity:	
Preferred stock \$.001 par value, 5,000,000 shares authorized, 2,006,770 shares issued and outstanding (aggregate liquidation preference of \$1,106,000)	2,000
Common stock, \$.001 par value, 80,000,000 shares authorized, 25,372,794, shares issued and outstanding	25,000
Additional paid-in capital	57,470,000
Accumulated deficit	(56,817,000)
	-----
Total stockholders' equity	680,000
	-----
Total liabilities and stockholders' equity	\$ 2,922,000
	-----

See accompanying notes to financial statements.

F-3

PARADIGM MEDICAL INDUSTRIES, INC.  
Statement of Operations

Years Ended December 31,

	2003	2002
	-----	-----
Sales	\$ 3,059,000	\$ 5,368,000
Cost of sales	2,086,000	4,210,000
	-----	-----
Gross profit	973,000	1,158,000
	-----	-----
Operating expenses:		
General and administrative	2,446,000	3,702,000
Marketing and selling	920,000	2,795,000
Research, development and service	1,033,000	2,819,000
Impairment of assets	150,000	2,961,000
	-----	-----
Operating loss	(3,576,000)	(11,119,000)

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

Other income (expense):		
Interest income	3,000	10,000
Interest expense	(24,000)	(46,000)
Gain on settlement of liabilities	436,000	-
	-----	-----
Total other income (expense)	415,000	(36,000)
	-----	-----
Loss before provision for income taxes	(3,161,000)	(11,155,000)
Provision for income taxes	-	-
	-----	-----
Net loss	\$ (3,161,000)	\$ (11,155,000)
Beneficial conversion feature on Series G preferred stock	(217,000)	-
Deemed dividend from Series G preferred detachable warrants	(53,000)	-
	-----	-----
Net loss applicable to common shareholders	\$ (3,431,000)	\$ (11,155,000)
	-----	-----
Loss per common share - basic and diluted	\$ (0.14)	\$ (0.63)
	-----	-----
Weighted average common shares - basic and diluted	24,058,000	17,736,000
	-----	-----

See accompanying notes to financial statements.

F-4

				PARADIGM MEDICAL INDUSTRIES INC
				State of Delaware
				Years Ended
				-----
	Preferred Stock	Common Stock	Additional	
	(see note 9)	Shares	Paid-in	
			Capital	
				-----
Balance, January 1, 2002	\$ -	15,072,531	\$ 15,000	\$ 52,156,000
Conversion of preferred stock	-	3,132,356	3,000	(3,000)
Issuance of common stock for:				
Cash	-	1,262,000	2,000	560,000
Settlement of litigation	-	75,000	-	34,000
Services	-	167,684	-	183,000
Assets	-	1,467,358	2,000	2,626,000
In process research and development	-	477,309	-	630,000
Subscription receivable	-	300,000	-	294,000

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

Issuance of stock warrants in acquisition	-	-	-	295,000
Net loss	-	-	-	-
-----				
Balance, December 31, 2002	-	21,954,238	22,000	56,775,000
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 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)
Net loss	-	-	-	-
-----				
Balance, December 31, 2003	\$ 2,000	25,372,794	\$ 25,000	\$ 57,470,000
-----				

See accompanying notes to financial statements.

PARADIGM MEDICAL INDU  
Statement o  
Years Ended

-----		
		2003
-----		
Cash flows from operating activities:		
Net loss	\$	(3,161,000) \$
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation and amortization		319,000
Issuance of common stock for services		-
Issuance of common stock for in process research and development		-
Issuance of stock option/warrant for services		35,000
Issuance of Series G preferred stock for services		-
Common stock issued for settlement of litigation		259,000
Allowance for (recovery of) bad debt expense		123,000
Provision for losses on inventory		403,000
Impairment of intangibles and investment		150,000
(Gain) on settlement of liabilities		(436,000)
(Increase) decrease in:		
Receivables		113,000
Inventories		1,243,000

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

Prepaid and other assets	(44,000)	
Increase (decrease) in:		
Accounts payable	53,000	
Accrued liabilities	236,000	
	-----	
Net cash used in operating activities	(707,000)	
	-----	
Cash flows from investing activities:		
Purchase of property and equipment	(2,000)	
Increase in intangibles	-	
Proceeds from the disposal of assets	-	
Net cash paid in acquisition	-	
	-----	
Net cash used in investing activities	(2,000)	
	-----	
Cash flows from financing activities:		
Proceeds from issuance of Series G preferred stock	270,000	
Principal payments on capital lease obligations	(53,000)	
Proceeds from the issuance of common stock, including exercise of common stock warrants and options	430,000	
	-----	
Net cash provided by financing activities	647,000	
	-----	
Net change in cash	(62,000)	
Cash, beginning of year	194,000	
	-----	
Cash, end of year	\$ 132,000	\$
	-----	

See accompanying notes to financial statements.

PARADIGM MEDICAL INDUSTRIES, INC.  
Notes to Financial Statements

December 31, 2003 and 2002

- |   |   |
|---|---|
| 1. Organization and Significant Accounting Policies | Organization<br>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.

Inventories

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

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.

-----  
F-7

PARADIGM MEDICAL INDUSTRIES, INC.  
Notes to Financial Statements  
Continued  
-----

1. Organization and Significant Accounting Policies Continued

Intangible Assets

As of December 31, 2003, 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.

Effective January 1, 2002, the Company adopted SFAS No. 142, "Goodwill and Other Intangible Assets." The adoption of SFAS No. 142 required an initial impairment assessment involving a comparison of the fair value of goodwill and other intangible assets to current carrying values. The Company performed such impairment test on its intangible assets as of January 1, 2002. At that date, the Company's intangible assets consisted of product and technology rights with a net book value of approximately \$297,000, engineering and design costs with a net book value of approximately \$86,000, patents with a net book value of approximately \$98,000, and purchase price in excess of net assets acquired (or goodwill) with a net book value of approximately \$679,000. The Company's initial impairment test performed on January 1, 2002 consisted of a cash flow analysis based on estimated future revenues and directly

related costs of products directly associated with the intangible assets. Based on such cash flow projections, the initial impairment test did not result in any impairment of the intangibles. As disclosed in Note 3, during 2002 the Company acquired the asset of Innovative Optics, Inc. The acquisition originally resulted in goodwill and identifiable intangible assets of \$1,949,000. However, due to the Company's inability to cost effectively develop and manufacture the products acquired, an estimate of future cash flows shows that all of the assets acquired, including goodwill and identifiable intangible assets, were impaired as of December 31, 2002. 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 are being amortized over five years, capitalized engineering and design costs are fully amortized as of December 31, 2002, and patents are being amortized over the life of the patents which is ten years. 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.

-----  
F-8

PARADIGM MEDICAL INDUSTRIES, INC.  
Notes to Financial Statements  
Continued

-----  
1. Organization and Significant Accounting Policies Continued

Intangible Assets - Continued

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, estimates of sales proceeds and independent appraisals. Where applicable, an appropriate discount rate is used, based on the Company's cost of capital rate or location-specific economic factors.

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.

-----  
F-9

PARADIGM MEDICAL INDUSTRIES, INC.  
Notes to Financial Statements  
Continued  
-----

1. Organization and Significant Accounting Policies Continued

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 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. 123, "Accounting for Stock-Based Compensation," to stock-based employee compensation.



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

	Years Ended December 31,	
	2003	2002
Net loss applicable to common shareholders- as reported	\$ (3,431,000)	\$ (11,155,000)
Deduct: total stock-based employee compen-sation determined under fair value based method for all awards, net of related tax effects	(595,000)	(618,000)
Net loss applicable to common shareholders- pro forma	\$ (4,026,000)	\$ (11,773,000)
Earnings per share:		
Basic and diluted - as reported	\$ (.14)	\$ (.63)
Basic and diluted - pro forma	\$ (.17)	\$ (.66)

F-10

PARADIGM MEDICAL INDUSTRIES, INC.  
Notes to Financial Statements  
Continued

1. Organization and Significant Accounting Policies Continued
- Stock - Based Compensation - Continued  
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,	
	2003	2002
Expected dividend yield	\$ -	\$ -
Expected stock price volatility	110% - 117%	102%-103%
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 2003 and 2002 are \$0.16 and \$1.25, 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.

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 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 6,036,439 and 5,151,557 shares of common stock at prices ranging from \$0.16 to \$12.98 per share were outstanding at December 31, 2003 and 2002, respectively, but were not included in the diluted earnings per share calculation because the effect would have been antidilutive.

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).

---

F-11

PARADIGM MEDICAL INDUSTRIES, INC.  
Notes to Financial Statements  
Continued

---

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, 2003 and 2002, no single customer represented more than 10 percent of total net sales.

-----  
F-12

PARADIGM MEDICAL INDUSTRIES, INC.  
Notes to Financial Statements  
Continued  
-----

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 2002 financial statements have been reclassified to conform to the presentation of the current year financial statements.

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. These factors raise substantial doubt about the Company's ability to continue as a going concern.

-----  
F-13

PARADIGM MEDICAL INDUSTRIES, INC.  
Notes to Financial Statements  
Continued

2. Going Concern Continued

-----  
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 options to obtain additional capital and financing.

In addition, the Company has taken significant steps to reduce costs and increase operating efficiencies. Specifically, during the second quarter of 2002, 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. 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 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.

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

3. Acquisitions Innovative Optics, Inc.  
 On January 31, 2002, the Company completed the purchase of certain assets of Innovative Optics, Inc. ("Innovative Optics"), pursuant to the terms of the Asset Purchase Agreement (the "Agreement") which the Company entered into on January 31, 2002 with Innovative Optics and Barton Dietrich Investments, L.P., the majority shareholder of Innovative Optics. Innovative Optics is a Georgia domiciled corporation which manufactures and sells the Innovatome(TM), a software driven microkeratome that provides ophthalmic surgeons a means of cutting a corneal flap in refractive surgery, and microkeratome blades.

-----  
 F-14

PARADIGM MEDICAL INDUSTRIES, INC.  
 Notes to Financial Statements  
 Continued

3. Acquisitions Innovative Optics, Inc. - Continued  
 Continued  
 As consideration for the purchase of certain assets of Innovative Optics, the Company paid \$100,000 and issued an aggregate of 1,272,825 shares of its common stock, and warrants to purchase 250,000 shares of the Company's common stock at \$5.00 per share, exercisable over a period of three years from the closing date. The Company filed a registration statement with the Securities and Exchange Commission to register the shares of common stock for resale that Innovative Optics received as purchase consideration and the shares that Innovative Optics will receive upon the exercise of the warrants. The assets purchased included but were not limited to patents, inventory, work in process and finished goods relating to the Innovatome(TM), a microkeratome, and microkeratome blades. Of the 1,272,825 shares of the Company's common stock issued to Innovative Optics at closing, one-half the number of these shares, or 636,412 shares, were placed in an escrow account maintained at the law firm of Mackey Price & Thompson (the "Disbursing Agent") pursuant to the terms of an Escrow Agreement.

In connection with this acquisition, the Company recorded the following:

Inventory	\$	225,000
Property, plant and equipment		35,000
Intangibles:		
Patents, rights, trade name		530,000
Goodwill		1,419,000
Equity:		
Common stock issued		(1,814,000)
Warrants issued		(295,000)

Net cash paid \$ 100,000  
-----

The Company was required to use its best efforts to implement, within 90 days of the closing, Phase I of a Blade Price Reduction Program as prepared by a consultant. Immediately after such 90 day period, the Disbursing Agent was to distribute three-fourths of the shares held in escrow, or 477,309 shares, to Innovative Optics, unless the Company had certified that it had implemented Phase I of the Blade Price Reduction Program.

-----  
F-15

PARADIGM MEDICAL INDUSTRIES, INC.  
Notes to Financial Statements  
Continued

-----  
3. Acquisitions  
Continued

Innovative Optics, Inc. - Continued

Despite best efforts, the Company was unable to manufacture microkeratome blades at a targeted materials cost per blade. If the Company certified that implementation of Phase I of the Blade Price Reduction Program resulted in materials cost that exceeded the target cost per blade and such certification was not disputed by Innovative Optics, the number of escrow shares disbursed to Innovative Optics was to be reduced by 300 shares for every cent that the materials cost per blade exceeded the target cost. The Company was not successful in achieving the blade price reduction. Innovative Optics requested that the total number of shares associated with Phase I be issued to them stating that the Company did not use its best efforts to achieve the target cost and that proper notification was not delivered to them. In August 2002, the Company issued 477,309 shares of common stock, which were held in escrow to Innovative Optics.

The shares were valued at \$630,000, based upon the market price per share at the date of issue. The transaction amount was recorded as in-process research and development costs and charged to expense in 2002.

The Company was also required to use its best efforts to implement, within six months after closing, Phase II of the Blade Price Reduction Program. Immediately after such six month period, the Disbursing Agent was to disburse the remaining shares in escrow to Innovative Optics unless the Company certified that it had implemented Phase II of the Blade Price Reduction Program and, despite best efforts, was unable to manufacture the microkeratome blades at a second targeted materials cost or less per blade. If Paradigm certified that implementation of Phase II of the Blade

Price Reduction Program resulted in a materials cost that exceeded the second target cost per blade and such certification was not disputed by Innovative Optics, the number of escrow shares disbursed to Innovative Optics was to be reduced by 300 shares for every cent that the materials cost per blade exceeded the second target cost. If Innovative Optics disputes the Company's certification, the dispute will be resolved by arbitration by submitting the matter for resolution to the accounting firm of KPMG LLP. The Company did not implement Phase II of the Blade Price Reduction Project due to the lack of success experienced in Phase I. Also, the Company has not issued the remaining shares, which remain in escrow.

-----  
F-16

PARADIGM MEDICAL INDUSTRIES, INC.  
Notes to Financial Statements  
Continued  
-----

3. Acquisitions  
Continued

Innovative Optics, Inc. - Continued

The Company determined that it could not manufacture the blades to support its customer base at an economical cost. There are no blades in inventory at this time. The Company has attempted to sell the product and related intangibles, but has not been successful in such efforts. Accordingly, due to the lack of projected future cash flows, during 2002 the Company recorded an impairment expense of \$2,082,000 for the remaining book value of property and equipment and intangible assets purchased from Innovative Optics.

International Bioimmune Systems, Inc.

During 2002, the Company acquired 2,663,254, or 19.9%, of the outstanding shares of International Bioimmune Systems, Inc. (IBS) and warrants to purchase 1,200,000 shares of common stock of IBS at \$2.50 per share for a period of two years, through the exchange and issuance of 736,945 shares of Paradigm common stock, the lending of 300,000 shares of Paradigm common stock to IBS, and the payment of certain expenses of IBS through the issuance of an aggregate of 94,000 shares of Paradigm common stock to IBS and its counsel.

The issuance of 736,945 and 94,000 shares were valued based on the market price of Paradigm's common stock on the date of the transaction and resulted in an investment in IBS of \$814,000, which combined with a cash investment of \$65,000 made in 2000, resulted in a total investment of \$879,000. The 300,000 shares were also valued at the market price on the date of issuance and were recorded as a stock subscription receivable of \$294,000 because it was anticipated that such shares will either be paid for or returned in the future.

Due to the uncertainty of future cash flows and the fact that the products have not been approved by the FDA, the Company determined that the likelihood of recovery of its investment was remote and recorded an impairment expense for the investment of \$879,000 in 2002. In 2003, due to the decline in value of the Company's common stock and the Company's inability to collect the subscription receivable, the Company wrote-off the subscription receivable of \$294,000 against additional paid-in capital.

-----  
F-17

PARADIGM MEDICAL INDUSTRIES, INC.  
Notes to Financial Statements  
Continued  
-----

4. Detail of  
Certain  
Balance  
Sheet  
Accounts

Receivables:

Trade receivables	\$ 1,178,000
Allowance for Doubtful accounts	(470,000)
	-----

	\$ 708,000
	-----

Inventories:

Finished goods	\$ 703,000
Raw materials	1,942,000
Reserve for obsolescence	(1,642,000)
	-----

	\$ 1,003,000
	-----

Accrued liabilities:

Payroll and employee benefits	\$ 540,000
Warranty and return allowance	413,000
Customer deposits	207,000
Consulting and other	108,000
Deferred revenue	90,000
Royalties	61,000
	-----

	\$ 1,419,000
	-----

5. Intangible Assets Intangible assets consist of the following at December 31, 2003:



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

Goodwill	\$	799,000
Product and technology rights		700,000
Engineering and design costs		482,000
Patents		92,000
		-----
		2,073,000
Accumulated amortization		(1,391,000)
		-----
Net intangible assets	\$	682,000
		-----

Amortization expense for the years ended December 31, 2003 and 2002 was \$79,000 and \$248,000, respectively.

-----  
F-18

PARADIGM MEDICAL INDUSTRIES, INC.  
Notes to Financial Statements  
Continued

- 
5. Intangible Assets Continued      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 and \$69,000 related to patents and product and technology rights, respectively.
6. Property and Equipment      Property and equipment consists of the following:
- |   |    |             |
|---|----|-------------|
| Office equipment                          | \$ | 750,000     |
| Computer equipment                        |    | 658,000     |
| Automobile                                |    | 53,000      |
| Furniture and fixtures                    |    | 264,000     |
| Leasehold improvements                    |    | 166,000     |
|   |    | -----       |
|   |    | 1,891,000   |
| Accumulated depreciation and amortization |    | (1,635,000) |
|   |    | -----       |
|   | \$ | 256,000     |
|   |    | -----       |
7. Lease Obligations      During the years ended December 31, 2003 and 2002, the Company leased certain equipment under noncancellable capital leases. These leases provide the Company the

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

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		(177,000)
		-----
	\$	114,000
		-----

Amortization expense on assets under capital leases during the years ended December 31, 2003 and 2002 was \$56,000 and \$46,000, respectively.

-----  
F-19

PARADIGM MEDICAL INDUSTRIES, INC.  
Notes to Financial Statements  
Continued

7. 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:

2004	\$	72,000
2005		54,000
2006		14,000
		-----
		140,000
Less amount representing interest		(33,000)
		-----
Present value of future minimum lease payments		117,000
Less current portion		(56,000)
		-----
Long-term portion	\$	61,000
		-----

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, 2003 are approximately as follows:

Year Ending December 31,	Amount
	-----
2004	\$ 115,000

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

2005	118,000
	-----
Total future minimum rental payments	\$ 233,000
	-----

Rent expense related to noncancelable operating leases was approximately \$159,000 and \$437,000 for the years ended December 31, 2003 and 2002, respectively.

F-20

PARADIGM MEDICAL INDUSTRIES, INC.  
Notes to Financial Statements  
Continued

8. Income Taxes                      The provision for income taxes is different than amounts which would be provided by applying the statutory federal income tax rate to loss before provision for income taxes for the following reasons:

	Years Ended December 31,	
	2003	2002
	-----	-----
Income tax benefit at statutory rate	\$ 1,170,000	\$ 4,127,000
Expiration of research and development tax credit carryforwards	-	(25,000)
Meals and entertainment	(7,000)	(33,000)
Other	2,000	1,000
Change in valuation allowance	(1,165,000)	(4,070,000)
	-----	-----
	\$ -	\$ -
	-----	-----

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

Net operating loss carryforward	\$ 16,384,000
Depreciation, amortization, and impairment	883,000
Allowance and reserves	1,122,000
Impairment of investment in IBS	325,000
Research and development tax credit carryforwards	34,000
	-----
	18,748,000

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

Valuation allowance	(18,748,000)
	-----
	\$ -
	-----

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-21

PARADIGM MEDICAL INDUSTRIES, INC.  
Notes to Financial Statements  
Continued  
-----

8. Income Taxes Continued  
At December 31, 2003, the Company had net operating loss carryforwards of approximately \$44 million and research and development tax credit carryforwards of approximately \$34,000. These carryforwards are available to offset future taxable income and expire in 2004 through 2020. The utilization of the net operating loss 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.

9. 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 40,000,000 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, 2003 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-22

PARADIGM MEDICAL INDUSTRIES, INC.  
Notes to Financial Statements  
Continued

---

9. Capital  
Stock  
Continued

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

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, 2003

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-23

PARADIGM MEDICAL INDUSTRIES, INC.  
Notes to Financial Statements  
Continued

---

9. Capital  
Stock  
Continued

Series C Preferred Stock

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, 2003 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.

PARADIGM MEDICAL INDUSTRIES, INC.  
Notes to Financial Statements  
Continued

9. Capital  
Stock  
Continued

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 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, 2003 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.

PARADIGM MEDICAL INDUSTRIES, INC.  
Notes to Financial Statements  
Continued

9. Capital  
Stock  
Continued

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 dividends; or (b) the stated value, subject to adjustment. Total liquidation preference at December 31, 2003 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.



PARADIGM MEDICAL INDUSTRIES, INC.  
Notes to Financial Statements  
Continued

9. Capital  
Stock  
Continued

Series E Preferred Stock - Continued

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.
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, 2003 was \$460,000.

F-27

PARADIGM MEDICAL INDUSTRIES, INC.  
Notes to Financial Statements  
Continued

9. Capital  
Stock  
Continued

Series F Preferred Stock - Continued

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-28

PARADIGM MEDICAL INDUSTRIES, INC.  
Notes to Financial Statements  
Continued  
-----

9. Capital  
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, 2003 was \$495,000.

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.

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

-----  
F-29

PARADIGM MEDICAL INDUSTRIES, INC.  
Notes to Financial Statements  
Continued

9. Capital Stock Continued
- The following table summarizes preferred stock activity during the years ended December 31, 2003 and 2002:

	Series A		Series B		Series C		Series D		Series E
	Shares	Amount	Shares	Amount	Shares	Amount	Shares	Amount	
Balance at January 1, 2002	5,747	\$ -	8,986	\$ -	-	\$ -	10,000	\$ -	19,3
Conversion of preferred stock	(120)	-	-	-	-	-	(5,000)	-	(17,8
Balance at December 31, 2002	5,627	-	8,986	-	-	-	5,000	-	1,5
Issuance of Series G preferred stock for cash	-	-	-	-	-	-	-	-	-
Issuance of Series G preferred stock									

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

for commissions	-	-	-	-	-	-	-	-	-
Conversion of preferred stock	-	-	-	-	-	-	-	-	(5)
-----									
Balance at December 31, 2003	5,627	\$ -	8,986	\$ -	-	\$ -	5,000	\$ -	1,0
-----									
Authorized	500,000	-	500,000	-	30,000	-	1,140,000	-	50,0
-----									
Liquidation preference	-	\$ 6,000	\$36,000			\$ -		\$9,000	
-----									

	Series G	
	Shares	Amount
-----		
Balance at January 1, 2002	-	\$ -
Conversion of preferred stock	-	-
-----		
Balance at December 31, 2002	-	-
Issuance of Series G preferred stock for cash	1,764,706	2,000
Issuance of Series G preferred stock for commissions	216,854	-
Conversion of preferred stock	-	-
-----		
Balance at December 31, 2003	1,981,560	\$ 2,000
-----		
Authorized	2,000,000	-
-----		
Liquidation preference		\$ 495,000
-----		

PARADIGM MEDICAL INDUSTRIES, INC.  
Notes to Financial Statements  
Continued

10. 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.

Options were issued to employees and directors of the Company during 2003 for 2,145,000 shares of common stock with vesting periods ranging from 3 to 7 years. The exercise price of the options ranges from \$0.16 to \$0.25

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.

10. Stock Option  
Plan and  
Warrants  
Continued

During 2002, in connection with the Innovative Optics acquisition (see note 3), Plan and the Company granted warrants to purchase 250,000 shares of common stock at an Warrants exercise price of \$5.00 per share. These warrants were nonforfeitable, vested Continued and fully exercisable at the time of grant. The exercise prices of these options were not issued at a discount to the then market price of the common stock. The options and warrants were valued according to the Black-Scholes pricing model. As a result of these warrants, the Company included approximately \$295,000 in the purchase price relating to the acquisition of the assets from Innovative Optics, Inc.

A schedule of the options and warrants is as follows:

	Number of		Exercise Price Per Share
	Options	Warrants	
Outstanding at January 1, 2002	3,906,776	2,315,022	\$ 2.00 - 12.98
Granted	70,000	250,000	2.00 - 5.00
Exercised	-	-	-
Expired	(115,479)	-	5.00
Forfeited	(1,374,762)	-	2.31 - 5.00
Outstanding at December 31, 2002	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	\$ 0.16 - 12.98

F-32

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

10. Stock Option Plan and Warrants Continued
- The following table summarizes information about stock options and warrants outstanding at December 31, 2003:

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	3,474,986	4.23	\$ 0.25	2,661,653	\$ 0.32	
2.00 - 5.00	2,660,570	2.89	3.32	2,599,154	3.75	
6.00 - 8.13	275,000	1.46	3.27	275,000	6.55	
12.98	25,883	N/A	12.98	25,883	12.98	
\$ 0.16 - 12.98	6,436,439	3.5	\$ 1.71	5,561,689	\$ 2.29	

11. Related Party Transactions

Thomas F. Motter, former Chairman of the Board and Chief Executive Officer of the Company, leased his former residence to the Company for \$2,500 per month. The primary use of the residential property was for housing accommodations for the Company's employees living outside of Utah while they were working at the Company's corporate headquarters in Salt Lake City. The Company obtained an appraisal from an independent appraiser, which had concluded that the monthly rate of \$2,500 represents the fair market rate for leasing the residential property. The Company paid \$2,500 and \$14,000 in rent during 2003 and 2002. This agreement was terminated on January 31, 2003.

The Company entered into a consulting agreement with a former executive officer of the Company commencing in September 2002 and ending February 2003. The Company paid approximately \$1,000 and \$15,000 under this agreement during 2003 and 2002, respectively, and had an accrual of approximately \$14,000 and \$5,000 as of December 31, 2003 and 2002, respectively.

F-33

PARADIGM MEDICAL INDUSTRIES, INC.  
Notes to Financial Statements  
Continued

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

11. Related Party Transactions Continued  
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 \$97,000 and \$167,000, for the years ended December 31, 2003 and 2002, respectively. As of December 31, 2003, the Company owed this firm \$136,000, which is included in accounts payable.

12. 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.
- 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.

-----  
F-34

PARADIGM MEDICAL INDUSTRIES, INC.  
Notes to Financial Statements  
Continued

-----  
12. Supplemental Cash Flow Information Continued  
During the year ended December 31, 2002, the Company:

- o Acquired certain assets of Innovative Optics, Inc. in a purchase transaction (see note 3). The transaction required the payment of \$100,000 and a potential issuance of 1,272,000 shares of common stock. In connection with this acquisition, the Company recorded the following:

Inventory	\$	225,000
Property, and equipment		35,000
Intangibles:		



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

Patents, rights, trade name	530,000
Goodwill	1,419,000
Equity:	
Common stock issued	(1,814,000)
Warrants issued	(295,000)
	-----
Net cash paid	\$ 100,000
	-----

- o Acquired 2,663,254, or 19.9%, of the outstanding shares of International Bioimmune Systems, Inc. (IBS) and warrants to purchase 1,200,000 shares of common stock of IBS at \$2.50 per share for a period of two years, through the exchange and issuance of 736,945 shares of Paradigm common stock, the lending of 300,000 shares of Paradigm common stock to IBS, and the payment of certain expenses of IBS through the issuance of an aggregate of 94,000 shares of Paradigm common stock to IBS and its counsel.

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

	Years Ended December 31,	
	2003	2002
	-----	-----
Interest	\$ 24,000	\$ 46,000
	-----	-----
Income taxes	\$ -	\$ -
	-----	-----

-----  
F-35

PARADIGM MEDICAL INDUSTRIES, INC.  
Notes to Financial Statements  
Continued

13. Export  
Sales

Total sales include export sales by major geographic area as follows:

	Years Ended	
	December 31,	
Geographic Area	2003	2002
	-----	-----

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

Far East	\$	272,000	\$	1,171,000
South America		9,000		308,000
Middle East		228,000		337,000
Europe		363,000		505,000
Canada		62,000		121,000
Mexico		9,000		61,000

-----  
 \$ 943,000 \$ 2,503,000  
 -----

14. Savings Plan

In November 1996, the Company established a 401(k) 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, 2003 and 2002, the Company contributed approximately \$1,000 and \$64,000 to the Plan, respectively.

15. Commitments and Contingencies

Consulting Agreements During the year ended December 31, 1999 the Company entered a consulting agreement with a former officer of the Company, which expires 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 15).

-----  
 F-36

PARADIGM MEDICAL INDUSTRIES, INC.  
 Notes to Financial Statements  
 Continued

15. 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 common stock plus costs, attorney's fees and a wage penalty (equal to 1,960 additional shares of our common stock) pursuant to Utah law. The action is based upon an extension of a written employment agreement. We dispute the amount allegedly owed and intend to

vigorously defend against the action.

An action was brought against us on March 7, 2000 in the Third District Court of Salt Lake County, State of Utah, by the Merrill Corporation that alleges that we owe the Merrill Corporation approximately \$20,000 together with interest thereon at the rate of 10% per annum from August 30, 1999, plus costs and attorney's fees. The complaint alleges a breach of contract relative to printing services. We filed an answer to the complaint. On August 12, 2003, the court dismissed the action without prejudice.

An action was brought against us 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. Discovery has taken place and we have paid royalties of \$14,736 to bring all payments up to date through June 30, 2001. We have 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.

-----  
F-37

PARADIGM MEDICAL INDUSTRIES, INC.  
Notes to Financial Statements  
Continued  
-----

15. Commitments  
and  
Contingencies  
Continued

Litigation - Continued It is anticipated that once the parties can agree on the correct calculations on the royalties, the legal action will be dismissed. The 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. Thus, the amount of royalties due, according to our calculations, is \$600. We intend to make payment of this amount to PhotoMed and Dr. Eichenbaum and, as a result, to have the legal action 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 their complaint to request termination of the license agreement and, if successful, we would lose our right to manufacture and sell the Photon(TM) laser system.

We received a demand letter dated December 9, 2002 from counsel for Dan Blacklock, dba Danlin Corp. The letter demands payment in the amount of \$65,160 for manufacturing and supplying parts for microkeratome blades. Our records show that we received approximately \$34,824 in parts from the Danlin Corp., but that the additional amounts that the Danlin Corp contends are owed were from parts that were received but rejected by us because they had never been ordered. On August 14, 2003, we agreed to make a \$13,650 payment to Danlin Corp. in settlement of the dispute. We have since made the \$13,650 payment to Danlin Corp.

We received a demand letter dated December 30, 2002 from counsel for Thomas F. Motter, our former Chairman and Chief Executive Officer. Mr. Motter claims in the letter that he was entitled to certain stock options that had not been issued to him in a timely manner. By the time the options were actually issued to him, however, they had expired. Mr. Motter contends that if the options had been issued in a timely manner, he would have exercised them in a manner that would have given him a substantial benefit. Mr. Motter requests restitution for the loss of the financial opportunity. Mr. Motter also claims that he was defrauded by us by not being given an extended employment agreement when he terminated the change of control agreement that he had entered into with us.

---

F-38

PARADIGM MEDICAL INDUSTRIES, INC.  
Notes to Financial Statements  
Continued

---

15. Commitments  
and  
Contingencies  
Continued

Litigation - Continued Mr. Motter is further claiming payment for accrued vacation time during the 13 years he had been employed by the Company, asserting that he only had a total of four weeks of vacation during that period. Finally, Mr. Motter is threatening a shareholder derivative action against us because of the board of directors' alleged failure to conduct an investigation into conversations that took place in a chat room on Yahoo. Mr. Motter asserts that certain individuals participating in the conversations were our officers or directors whose interests were in conflict with the interest of the shareholders. We believe that Mr. Motter's claims and assertions are without merit and intend to vigorously defend against any legal action that Mr. Motter may bring.

On January 24, 2003, an action was brought by Dr. John Charles Casebeer against us in the Montana Second Judicial District Court, Silver Bow County, State of Montana (Civil No. DU-0326). The complaint alleges that Dr. Casebeer entered into a personal services contract with us memorialized by a letter dated April 20, 2002, with it being alleged that Dr. Casebeer fully performed his obligations. Dr. Casebeer asserts that he is entitled to \$43,750 per quarter for consultant time and as an incentive to be granted each quarter \$5,000 in options issued at the fair market value. An additional purported incentive was \$50,000 in shares of stock being issued at the time a formalized contract was to be signed by the parties. In the letter it is provided that at its election, we may pay the consideration in the form of stock or cash and that stock would be issued within 30 days of the close of the quarter. Prior to the litigation, we issued 43,684 shares to Dr. Casebeer. The referenced letter provides that termination may be made by either party upon giving 90 days written notice. Notice was given by us in early November 2002. We recently filed its answer in defense of the action. Issues include whether or not Dr. Casebeer fully performed as asserted. The case has been settled through the issuance of 300,000 additional shares of our common stock to Dr. Casebeer.

-----  
F-39

PARADIGM MEDICAL INDUSTRIES, INC.  
Notes to Financial Statements  
Continued

-----  
15. Commitments  
and  
Contingencies  
Continued

Litigation - Continued 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." We have 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 we falsely stated in our Securities and Exchange Commission filings and press releases that we 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 use of the Blood Flow Analyzer(TM). The complaint also alleges that on July 11, 2002, we issued a press release falsely announcing that we had received a purchase order from Valdespino Associates Enterprises and Westland Financial Corporation for 200 sets of our 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. As a result of these statements, the complaint contends that the price of our shares of common stock was artificially inflated during the period from April 25, 2001 through May 14, 2003, and the persons who purchased our common shares during that period suffered substantial damages. The complaint requests judgment for unspecified damages, together with interest and attorney's fees.

-----  
F-40

PARADIGM MEDICAL INDUSTRIES, INC.  
Notes to Financial Statements  
Continued  
-----

15. Commitments  
and  
Contingencies  
Continued

Litigation - Continued We dispute having issued false and misleading statements concerning the Blood Analyzer(TM) and a purchase order from Valdespino Associates Enterprises and Westland Financial Corporation. On April 25, 2001, we issued a press release that stated we had received authorization to use common procedure terminology or CPT code number 92120 for our Blood Flow Analyzer(TM). This press release was based on a letter we received from the CPT Editorial Research and Development Department of the American Medical Association authorizing use of common procedure terminology or CPT code number 92120 for our Blood Flow Analyzer(TM), for reimbursement purposes for doctors using the device.

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. We are endeavoring to obtain reimbursement by insurance payors in other states where there is currently no reimbursement being made. We believe we have continued to correctly represent in our Securities and Exchange Commission filings that we have received authorization from the CPT Editorial Research and Development Department of the American Medical Association to use CPT code number 92120 for our Blood Flow Analyzer(TM), for reimbursement purposes for doctors using the device.

---

F-41

PARADIGM MEDICAL INDUSTRIES, INC.  
Notes to Financial Statements  
Continued

---

15. Commitments  
and  
Contingencies  
Continued

Litigation - Continued On July 11, 2002, we issued a press release that stated we received a purchase order from Valdespino Associates Enterprises and Westland Financial Corporation for 200 complete sets of our 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 we entered into with Westland Financial Corporation for the sale of 200 complete sets of our surgical and diagnostic equipment to Mexican ophthalmic practitioners. The press release also stated that the initial order was for \$70 million of our 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 our 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 our product sales to the Mexican ophthalmic practitioners. In that press release the board stated that we had been in discussions for the prior nine months with Westland Financial Corporation, aimed at supplying our medical device products to the Mexican market. In the past, we have 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, we 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 our medical device products in Mexico, but we could not, at the time, predict or provide any assurance that any transactions would result.

-----  
F-42

PARADIGM MEDICAL INDUSTRIES, INC.  
Notes to Financial Statements  
Continued  
-----

15. Commitments  
and  
Contingencies  
Continued

Litigation - Continued 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 or about June 11, 2003, a complaint was filed in the same United States District Court captioned 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 Valdespino Associates Enterprises and Westland Financial Corporation, the price of our common stock was artificially inflated and the persons who purchased our common shares during the class period suffered substantial damages. The cases request judgment for unspecified damages, together with interest and attorneys' fees. These cases have now been consolidated with the Meyer case into a single action. We believe the consolidated cases are without merit and intend to vigorously defend and protect our interests in the said cases.

We were 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 our



application for insurance.

---

F-43

PARADIGM MEDICAL INDUSTRIES, INC.  
Notes to Financial Statements  
Continued

---

15. Commitments  
and  
Contingencies  
Continued

Litigation - Continued We have not paid any amounts toward satisfaction of any part of the \$250,000 retention that is applicable to the consolidated cases. We have advised U.S. Fire that we cannot pay the \$250,000 retention due to our current financial circumstances. As a consequence, on January 8, 2004, we entered into a non-waiver agreement with U.S. Fire in which U.S. Fire agreed to fund and advance our retention obligation in consideration for which we have 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, we are 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.

In the event U.S. Fire determines that we 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 we be declared in default under the non-waiver agreement, then we agree to pay U.S. Fire, on demand, the full amount of all costs advanced by U.S. Fire, except for those amounts that we may have reimbursed to U.S. Fire pursuant to the monthly payments due under the non-waiver agreement.

We will be in default under the non-waiver agreement if we fail 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 we are not successful in defending and protecting our interests in the cases, resulting in a judgment against us for substantial damages, we would not be able to pay such liability and, as a result, would be forced to seek bankruptcy protection.

---

F-44

15. Commitments  
and  
Contingencies  
Continued

Litigation - Continued 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 us on January 31, 2002, in which we 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 we breached the asset purchase agreement. The complaint also claims that we 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 our 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. Had Innovative and Barton known the truth, the complaint contends, they would not have sold Innovative to us, would not have purchased our 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 these 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 we 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 our common stock issued to Innovative in the transaction declined, and Innovative and Barton suffered damages in an amount to be proven at trial. We filed an answer to the complaint and also filed counterclaims against Innovative and Barton for breach of contract. We believe the complaint is without merit and intend to vigorously defend and protect our interests in the action.

PARADIGM MEDICAL INDUSTRIES, INC.  
Notes to Financial Statements  
Continued

15. Commitments  
and  
Contingencies  
Continued

Litigation - Continued If we are not successful in defending and protecting our interests in this action, resulting in a judgment against us for substantial damages, and U.S. Fire denies coverage in the litigation under the Directors and Officers Liability and Company Reimbursement Policy, we 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." We have 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 we falsely stated in Securities and Exchange Commission filings and press releases that we 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).

PARADIGM MEDICAL INDUSTRIES, INC.  
Notes to Financial Statements  
Continued

15. Commitments  
and  
Contingencies  
Continued

Litigation - Continued The purpose of these statements, according to the complaint, was to induce investors to purchase shares of our 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 our Series E preferred stock in the private offering suffered substantial damages to be proven at trial. The complaint also alleges that we 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. We filed an answer to the complaint. We believe the complaint is without merit and intend to vigorously defend our interests in the action. If we are not successful in defending and protecting our interests in the action, resulting in a judgment against us for substantial damages, and U.S. Fire denies coverage in the litigation under the Directors and Officers Liability and Company Reimbursement Policy, we would not be able to pay such liability and, as a result, would be forced to seek bankruptcy protection.

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 two copy machines that were delivered to our 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. We dispute the amounts allegedly owed, asserting that the equipment we returned to the leasing company did not work properly. A responsive pleading has not yet been filed. We are currently engaged in settlement discussions with CitiCorp.

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 we 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, we 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.

---

F-47

PARADIGM MEDICAL INDUSTRIES, INC.  
Notes to Financial Statements  
Continued

---

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

15. Commitments  
and  
Contingencies  
Continued

Litigation - Continued We 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 our common stock and warrants to purchase 1,192,500 shares of our 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. We believe 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 our common stock or any additional warrants under the terms of the mutual release. We intend to vigorously defend against any legal action that Dr. MacLeod may bring.

On August 3, 2003, a complaint was filed against us 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 we 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. We dispute the amounts allegedly owed and intend to vigorously defend and protect our interests in the action.

-----  
F-48

PARADIGM MEDICAL INDUSTRIES, INC.  
Notes to Financial Statements  
Continued  
-----

15. Commitments  
and  
Contingencies  
Continued

and Litigation - Continued On September 10, 2003, an action was filed against us 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 we have paid Mr. Hicks prior to such termination, plus costs, attorney's fees and a wage penalty pursuant to Utah law. We dispute the amount allegedly owed and intend to vigorously defend against such action.

We are 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 our financial condition or results of operations.

The Company may become or is subject to other investigations, claims or lawsuits ensuing out of conduct of its business, including those related to environmental safety and health, product liability, commercial transactions etc. The Company is currently not aware of any other such items, which it believes could have a material adverse effect on the financial statements.

#### 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.

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.

---

F-49

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

15. Commitments and Contingencies Continued
- Royalty Agreements - Continued 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 Autoperimiter 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.
16. 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.
17. Recent Accounting Pronouncements
- In November 2002, the EITF reached a consensus on Issue No.00-21, Revenue Arrangements with Multiple Deliverables. EITF Issue No. 00-21 provides guidance on how to account for certain arrangements that involve the delivery or performance of multiple products, services and/or rights to use assets. The provisions of EITF Issue No. 00-21 will apply to revenue arrangements entered into in fiscal periods beginning after June 15, 2003. The adoption of EITF Issue No. 00-21 did not have a material impact on operating results or financial condition of the Company as the Company followed the provisions of Statement of Position ("SOP") 97-2, Software Revenue Recognition, as modified by SOP 98-9, Modification of SOP 97-2 with Respect to Certain Transactions, which provide guidance for revenue recognition of arrangements with multiple deliverables.

---

F-50

PARADIGM MEDICAL INDUSTRIES, INC.  
Notes to Financial Statements  
Continued

---

17. Recent Accounting Pronouncements
- In December 2003, the FASB issued Interpretation No. 46 ("FIN 46R") (revised December 2003), Consolidation of Variable Interest Entities, an

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

Continued

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 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 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 April 2003, FASB issued SFAS No. 149, Amendment of Statement 133 on Derivative Instruments and Hedging Activities. SFAS 149 amends and clarifies accounting for derivative instruments, including certain derivative instruments embedded in other contracts and for hedging activities under SFAS 133, Accounting for Derivatives and Hedging Activities. SFAS 149 is generally effective for derivative instruments, including derivative instruments embedded in certain contracts, entered into or modified after June 30, 2003. The adoption of SFAS 149 did not have a material impact on the operating results or financial condition of the Company.

-----  
F-51

PARADIGM MEDICAL INDUSTRIES, INC.  
Notes to Financial Statements  
Continued  
-----

17. Recent  
Accounting  
Pronouncements  
Continued

In May 2003, the FASB issued SFAS 150, Accounting for Certain Financial Instruments with Characteristics of Both Liabilities and Equity. SFAS 150 clarifies the accounting for certain financial instruments with characteristics of both liabilities and equity and requires that those instruments be classified as liabilities in statements of financial position. Previously, many of those financial instruments were classified as equity. SFAS 150 is



effective for financial instruments entered into or modified after May 31, 2003 and otherwise is effective at the beginning of the first interim period beginning after June 15, 2003. On November 7, 2003, FASB Staff Position 150-3 was issued, which indefinitely deferred the effective date of SFAS 150 for certain mandatory redeemable non-controlling interests. As the Company does not have any of these financial instruments, the adoption of SFAS 150 did not have any impact on the Company's consolidated financial statements.

In December 2003, the Securities and Exchange Commission (SEC) issued Staff Accounting Bulletin (SAB) No. 104, Revenue Recognition. SAB 104 revises or rescinds portions of the interpretive guidance included in Topic 13 of the codification of staff accounting bulletins in order to make this interpretive guidance consistent with current authoritative accounting and auditing guidance and SEC rules and regulations. The adoption of SAB 104 did not have a material effect on the Company's results of operations or financial position.

-----  
F-52

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

None.

Item 9A. Controls and Procedures

Under the supervision and with the participation of our management, including our principal executive officer and principal financial officer, we evaluated the effectiveness of the design and operation of our 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, our disclosure controls and procedures were effective and adequately designed to ensure that information required to be disclosed by us in the reports we file or submit under the Exchange Act is recorded, processed, summarized and reported within the time periods specified in applicable rules and forms; provided, however, our principal executive officer and principal financial officer have determined that review of our SEC filings by our outside advisors will need to occur earlier in the process of preparing such filings so such advisors can assist us in better understanding and satisfying rapidly developing regulatory and disclosure requirements. We believe the only consequence of the disclosed deficiency was the delay in filing our Form 10-KSB/A and the need to file Form 12b-25.

During the fourth fiscal quarter, there has been no change in our 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, our internal control over financial reporting.

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

## PART III

Item 10. Directors, Executive Officers, Promoters and Control Persons; Compliance with Section 16(a) of the Exchange Act.

As of March 31, 2004, the Company's executive officers and directors, their ages and their positions are set forth below:

Name	Age	Position
John Y. Yoon	40	President and Chief Executive Officer
Aziz A. Mohabbat	44	Vice President of Operations and Chief Operating Officer
Randall A. Mackey, Esq.	58	Chairman of the Board, Secretary and Director
David M. Silver, PhD.	62	Director
Keith D. Igotz	56	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.

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.

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.

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

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.

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.

### 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.

### 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, 2003. No director attended fewer than 75% of all meetings of the Board of Directors during the 2003 fiscal year. The Audit Committee of the Board of Directors consists of directors Dr. David M. Silver,

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

Randall A. Mackey and Keith D. Igotz. 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 and Keith D. Igotz. 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.

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. Igotz, who currently serves as a director of the Company as well as a member of the Company's audit committee, is an independent audit committee financial expert.

Item 11. 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, 2003, 2002 and 2001.

Summary Compensation Table

Name and Principal Position -----	Year ----	Salary\$ -----	Annual Compensation			Awards Stock Awards (\$) -----	Lon Securi Underl Optio SARS -----
			Bonus (\$) -----	Other Annual Compen- sation (\$) -----	Restricted Stock Awards (\$) -----		
Jeffrey F. Poore Former President and Chief Executive Officer	2003(1)	\$136,015	0	0	0	1,000,000	
David I. Cullumber, Former Chief Operating Officer and Chief Technical Officer	2003(1)	\$ 22,312	0	\$16,616(7)	0	150,000	
Gregory C. Hill Former Vice President of Finance and Chief Financial Officer	2003(1)	\$ 34,000	0	0	0	0	

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

Thomas F. Motter	2002(2)	\$187,483(9)	0	0	0	0
Former Chairman of the Board and Chief Executive Officer	2001(3)	\$200,000	\$ 22,380(10)	0	0	925,000
			0			
Mark R. Miehle	2002(2)	\$134,202	0	0	0	55,000
Former President and Chief Operating Officer	2001(3)	\$150,000	0	0	0	110,000
Aziz A. Mohabbat	2003(1)	\$ 24,219	0	0	0	0
Vice President of Operations(15)	2002(2)	\$126,878	0	0	0	0
Heber C. Maughan	2003(1)	\$ 36,855	0	0	0	150,000
Former Chief Financial Officer(16)	2002(2)	\$114,416	0	0	0	0
	2001(3)	\$ 27,500	0	0	0	30,000

- 
- (1) For the fiscal year ended December 31, 2003
  - (2) For the fiscal year ended December 31, 2002
  - (3) For the fiscal year ended December 31, 2001
  - (4) The amounts under "All Other Compensation" for 2003, 2002 and 2001 include payments related to the operation of automobiles and/or automobiles and insurance by the named executives.

34

- (5) The amounts under "All Other Compensation" for 2002 include payments related to the residential housing accommodations for its 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.
- (6) On March 19, 2003, its 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.
- (7) The Company paid A-Mech Engineering, Inc. a total of \$16,616 for consulting services during 2003. From 1982 to August 2003, Mr. Cullumber served as President of A-Mech Engineering, Inc.
- (8) On November 6, 2003, its board of directors granted Mr. Cullumber options to purchase 150,000 shares of its common stock at an exercise price of \$.21 per share.
- (9) 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.
- (10) The Company awarded Mr. Motter a cash bonus in June 2001.
- (11) On September 11, 2001, the Company granted Mr. Motter options to purchase 925,000 shares of its common stock at an exercise price of \$2.75 per share.
- (12) On January 29, 2002, the Company's Board of Directors granted Mr. Miehle options to purchase the 55,000 shares of its common stock at an exercise price of \$2.75 per share.
- (13) On September 11, 2001, the Company's Board of Directors granted Mr. Miehle options to purchase 110,000 shares of its common stock at an exercise price of \$2.75 per share.

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

- (14) 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.
- (15) Mr. Mohabbat was named as Interim Chief Operating Officer on August 30, 2002. He was not an officer in prior years.
- (16) Mr. Maughan was named as Interim Chief Executive Officer on August 30, 2002. He was appointed Vice President of Finance, Treasurer and Chief Financial Officer on October 1, 2001.
- (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.
- (18) On October 1, 2001, the Company's Board of Directors granted options Mr. Maughan options to purchase 30,000 shares of its common stock at an exercise price of \$2.75 per share.

Options

The following table sets forth information regarding stock options granted during the fiscal year ended December 31, 2003, to each named executive officer.

Option Grants in Last Fiscal Year

Name	Number of Securities Underlying Options Granted (#)	Percentage of Total Options Granted to Employees in Fiscal Year(%)	Individual Grants	
			Exercise Price Per Share (\$/Sh)	Expiration Date
Jeffrey F. Poore.....	1,000,000 (1)	56.3%	\$.16	3/19/08
David I. Cullumber.....	150,000 (2)	8.5%	\$.21	11/6/08
Gregory C. Hill.....	0	--	--	--
Heber C. Maughan.....	150,000 (3)	8.5%	\$.16	5/13/08
Aziz A. Mohabbat.....	0	--	--	-

- (1) Options for 800,000 shares vested on March 19, 2003, options for an additional 100,000 shares vest on March 19, 2004, and options for the remaining 100,000 shares vest on March 19, 2005.
- (2) Options vest in three equal annual installments, beginning on November 6, 2003. (3) Options vest in three equal annual installments, beginning on May 13, 2003.

The following table sets forth information regarding unexercised options to acquire shares of the Company's common stock held as of December 31, 2003, by each named executive officer.

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

Number of Securities

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

Name	Shares Acquired on Exercise	Value Realized(\$)	Underlying Unexercised Options at December 31, 2003(##)	
			Exercisable	Unexercisable
Jeffrey F. Poore.....	0	0	800,000	200,000
David I. Cullumber.....	0	0	50,000	100,000
Gregory C. Hill.....	0	0	0	
Heber C. Maughan.....	0	0	50,000	100,000
Aziz A. Mohabbat.....	0	0	0	

Director Compensation

On July 11, 2003, 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 its common stock at an exercise price of \$.25 per share. In addition, outside directors are also reimbursed for their expenses in attending board and committee meetings. Directors are not precluded from serving the Company 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 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.

36

#### 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 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



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

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.

### Severance Agreement

On August 30, 2002, the Board of Directors terminated the employment

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

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, 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.

37

### 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.

### Item 12. 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 December 31, 2003 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	2,538,451	10.0%
John Y. Yoon	-	*
Jeffrey F. Poore(3)	800,000	3.1%
Dr. David M. Silver(4)	741,166	2.9%

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

Randall A. Mackey(4)	725,000	2.8%
Keith D. Ignatz(5)	454,560	1.8%
David I. Cullumber	50,000	*
Gregory C. Hill	-	*
Heber C. Maughan(6)	50,000	*
Aziz A. Mohabbat	-	*
Executive officers and directors as a group (eight persons)	2,820,726	11.1%

-----  
\*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) Includes the stock held by Douglas A. MacLeod, M.D. Profit Sharing Trust, St. Mark's Eye Institute and Milan Holdings, Ltd.
- (3) Includes options to purchase 800,000 shares of common stock granted to Dr. Poore that are currently exercisable or will become exercisable within 60 days of December 31, 2003.
- (4) Includes options to purchase 725,000 shares of common stock granted to each of Dr. Silver and Mr. Mackey that are currently exercisable or will become exercisable within 60 days of December 31, 2003.
- (5) Includes options to purchase 453,851 shares of common stock granted to Mr. Ignatz that are currently exercisable or will become exercisable within 60 days of December 31, 2003.
- (6) Includes options to purchase 50,000 shares of common stock granted to Mr. Maughan that are currently exercisable or will become exercisable within 60 days of December 31, 2003.

### Item 13. 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. Legal fees and expenses paid to Mackey Price & Thompson for the fiscal years ended December 31, 2003 and 2002, totaled \$97,000 and \$167,000, respectively. As of December 31, 2003, the Company owed this firm \$136,000, which is included in

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

accounts payable.

### PART IV

#### Item 14. Principal Accountant Fees and Services

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.

Fees for the 2002 annual audit of the financial statements and related quarterly review services were approximately \$43,000. Fees in 2002 related to the review of registration statements, private placement memorandums, proxy statements, other SEC filings, and assistance in responding to SEC comments were approximately \$20,000. Fees in 2002 for edgarization of filings were approximately \$9,000. Other fees in 2002 for meetings and other consultation were approximately \$2,000.

#### Item 15. 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

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

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

- 5.1 Opinion of Mackey Price & Thompson
- 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)

39

- 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)
- 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)
- 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.

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

- (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 on Form 10-KSB, as filed on April 14, 2004.

(b) Reports on Form 8-K

No reports on Form 8-K were filed by the Company during the quarter ended December 31, 2003.

40

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: November 4, 2004

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
-----	-----	----
/s/Randall A. Mackey ----- Randall A. Mackey	Chairman of the Board and Secretary	November 4, 2004
/s/David M. Silver	Director	November 4, 2004

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

-----  
David M. Silver, Ph.D.

/s/Keith D. Igotz                      Director                      November 4, 2004  
-----  
Keith D. Igotz

/s/John Y. Yoon                      President and Chief Executive                      November 4, 2004  
-----  
John Y. Yoon                      Officer (Principal Executive  
Officer)

/s/Luis A. Mostacero                      Controller (Principal Financial                      November 4, 2004  
-----  
Luis A. Mostacero                      and Accounting Officer)