PARADIGM MEDICAL INDUSTRIES INC
Form 10KSB
April 28, 2005

SECURITIES AND EXCHANGE COMMISSION
Washington, D.C. 20549

Form 10-KSB

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

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

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

DELAWARE	87-0459536
(State or other jurisdiction of incorporation or organization)	(I.R.S. Employer Identification Number)
2355 South 1070 West, Salt Lake City, Utah	84119
(Address of principal executive offices)	(Zip Code)

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

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

None

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

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

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

Indicate by check mark whether the registrant (1) has filed all reports required to be filed by Section 13 or 15(d) of the Securities Exchange Act of 1934 during the preceding 12 months (or for such shorter period that the Registrant was required to file such reports), and (2) has been subject to such filing requirements for the past 90 days. Yes [X] No [ ]

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

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

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

As of March 31, 2005, Registrant had outstanding 27,764,868,shares of common stock, 5,627 shares of Series A preferred stock, 8,986 shares of Series B preferred stock, no shares of Series C preferred stock and 5,000 shares of Series D preferred stock, 1,000 shares of Series E preferred stock, 4,598.75 shares of Series F preferred stock, and 1,726,560 shares of Series G preferred stock.

DOCUMENTS INCORPORATED BY REFERENCE:

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

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

PART I

Item 1. Description of Business

General

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

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

additional applications for all of its diagnostic products.

A cataract is a condition that largely affects the elderly population, in which the natural lens of the eye hardens and becomes cloudy, thereby 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 Occular 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 expenses relating to the sale of such shares, the Company would be required to issue additional shares of common stock, or pay additional funds to Humphrey Systems as would be necessary to increase the net proceeds from the sale of the assets to $375,000. Since Humphrey Systems realized only $162,818 from the sale of 78,947 shares of its common stock, the Company issued 80,000 additional shares in January 1999 to enable Humphrey Systems to receive its guaranteed amount. The amount of $21,431 was paid to the Company as excess proceeds from the sale of this additional stock.

The rights to the ophthalmic diagnostic instruments, which have been purchased from Humphrey Systems, complement both the Company's cataract surgical equipment and the Company's ocular Blood Flow Analyzer(TM). The Ultrasonic

Biometer calculates the prescription for the intraocular lens to be implanted during cataract surgery. The P55 pachymetric measures corneal thickness for the new refractive surgical applications that eliminate the need for eyeglasses and for optometric applications including contact lens fitting. The P37 Ultrasonic A/B Scan combines the Ultrasonic Biometer and ultrasound imaging for advanced diagnostic testing throughout the eye and is a viable tool for retinal specialists. The P40 UBM Ultrasound Biomicroscope utilizes microscopic digital ultrasound resolution for detection of tumors and improved glaucoma management. The Company introduced the P45 in the fall of 2000, which combines the P37 Ultrasonic A/B Scan, and the Ultrasonic Biometer in one machine.

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

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

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

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

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

issuance of an aggregate of 94,000 shares of its common stock to the company and its counsel. During 2004, the Company sold all 2,663,254 shares of International Bio-Immune Systems stock for net proceeds of $505,000.

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.

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

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

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

Background

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

Industries, Inc. French Bar had operated a mining and tourist business in Montana. Prior to its merger with Paradigm Medical, Inc. in 1993, French Bar had disposed of its mineral and mining assets in a settlement of outstanding debt and had returned to the status of a dormant entity. Pursuant to the merger, the Company caused a 1-for-7.96 reverse stock split of its shares of common stock. The Company then acquired all of the issued and outstanding shares of common stock of Paradigm Medical, Inc. using shares of its own common stock as consideration. As part of the merger, the Company changed its name from French Bar Industries, Inc. to Paradigm Medical Industries, Inc. and the management of Paradigm Medical, Inc. assumed control of the company. In April 1994, the Company caused a 1-for-5 reverse stock split of its shares of common stock. In February 1996, the Company re-domesticated to Delaware pursuant to a reorganization.

Overview

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

Birth defects, trauma from accidents, disease and age related deterioration of the components of the eye could all contribute to eye disorders. The most common eye disorders are either pathological or refractive. Many pathological disorders of the eye can be corrected by surgery. These include cataracts (clouded lenses), glaucoma (elevated or low pressure in the eye), loss of nerve fibers resulting in loss of vision, corneal disorders such as scars, defects and irregular surfaces and vitro-retinal 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 lazing 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 lazing medium. Differing wavelengths of laser light are produced by the selection of the lazing 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, trabeulorplasty, 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 system provides greater control for the surgeon and allows the safe operation at much higher vacuum settings by sampling changes in aspiration 100 times per second. Greater vacuum in phaco surgery means less use of ultrasound or laser energy to fragment the cataract and less chance for surrounding tissue damage. In addition to the full complement of surgical modalities (e.g., irrigation, aspiration, bipolar coagulation and anterior vitrectomy), system automation includes "dimensional" audio feedback of vacuum levels and voice confirmation for major system functions, providing an intuitive environment in which the advanced phaco surgeon can concentrate on the surgical technique rather than the equipment. Sales of the Precisionist(TM) and related accessories were 0% of total revenues in both the fiscal years 2004 and 2003, respectively.

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

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

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

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

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

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

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

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

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

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

blood flow activity in order to diagnose and treat glaucoma at an earlier stage.

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

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

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

The manufacturing activities for the Blood Flow Analyzer(TM) have been moved to the Salt Lake City facility from the outsourced plant located in

England. On October 21, 2002, the Company received FDA approval on its 510(k) application for additional indications of use for the Blood Flow Analyzer(TM). The additional indications include pulsatile ocular blood flow and pulsatile ocular blood volume. These are diagnostic measurements that assess the hemodynamic and vascular health of the eye. Also, the Company is continuing its aggressive campaign to educate the insurance payers about the Blood Flow Analyzer(TM), its purposes and the significance of its performance in patient care in order to achieve reimbursements to the doctors using its Blood Flow Analyzer(TM). Sales of the Blood Flow Analyzer(TM) and related accessories accounted for approximately 19% and 16% of total sales for the fiscal years ended December 31, 2004 and 2003, respectively.

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

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

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

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

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

P40 and P45 UBM Ultrasound Biomicroscopes: Humphrey Systems developed the P40 UBM Ultrasound Biomicroscope in conjunction with the New York Eye and Ear Infirmary in Manhattan and the University of Toronto. The P40 biomicroscope and its intellectual property were included in the purchase from Humphrey

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

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

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

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

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

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

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

The following table identifies each product class, status of commercial

development, the percentage of sales contributed by that class, reimbursement 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%
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%
SIStem(TM) and Odyssey(TM)(2)	Phacofragmentation	Sold	Yes	11%

Photon(TM) Laser, Ocular Surgery Workstation with Surgical Equipment and Disposables(3)	Phacoemulsification BFA tips	In-Process (4)	No	0%
Parts and Services	Perimeter, BFA, Tonometer, Topographer, Ultrasound Workstations, Systems, Imaging	Complete	Yes	8%

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(1) Except for the Photon(TM) Ocular Surgery Workstation, which can only be sold in countries outside the United States, these products can be sold in the United States and in foreign countries including but not limited to Argentina, Australia, Bangladesh, Borneo, Brazil, Canada, China, Czechoslovakia, Egypt, France, Germany, Greece, Hong Kong, India, Israel, Italy, Japan, Jordan, Korea, Malaysia, Mexico, New Zealand, Pakistan, Peru, Poland, Puerto Rico, Russia, Saudi Arabia, Spain, Sri Lanka, Taiwan, Thailand, Turkey, United Kingdom, and United Arab Emirates

(2) Due to the lack of recent sales volume, the inventory associated with the Precisionist Thirty Thousand (TM), the SIStem(TM) and the Odyssey(TM) has been deemed obsolete and a reserve has been recorded to offset such inventory.

(3) Due to the lack of recent evidence to support the recoverability of inventory associated with the Photon(TM), the Company has recorded a reserve to offset the majority of such inventory on hand.

(4) The Photon(TM) is in-process and not complete because the Company has not completed the clinical trials in order to obtain FDA regulatory approval.

* FDA 510(K) K844299 represents domestic approval by U.S. Food and Drug Administration

** ISO 9001: 1994, EN ISO 9001 represents international approval

*** IDE G940151 represents approval for international distribution only

**** Represents full reimbursement in 22 states and partial reimbursement in four other states.

As detailed in the table above, except for the Photon(TM) Laser Ocular Surgery Workstation, which requires additional development and regulatory approvals, the Company's current products are developed and available for sale in the footnote (1) of the table. The Company's possible future efforts to finalize development of the Photon(TM) and obtain the necessary regulatory approvals would depend on its economic evaluations and adequate funding. If these efforts were undertaken but proved to be unsuccessful, the impact would include the costs associated with these efforts and the anticipated future revenues which the Company would not receive as expected. The Company

anticipates that a majority of the estimated costs for Research and Development will be used for the enhancement and upgrading of its current products approved for sale. The Company is unable to provide an estimate of the details of possible liquidity needs and expected source of funds for possible future efforts to finalize development of the Photon(TM) and obtain the necessary regulatory approvals since this estimate would depend on a possible

comprehensive economic evaluation.

Any possible future efforts to complete development of the Photon(TM) and obtain the necessary regulatory approvals would depend on the Company's economic evaluations and adequate funding. If these efforts were undertaken but proved to be unsuccessful, the impact would include the costs associated with these efforts and the anticipated future revenues that the Company would not receive as expected. The Company anticipates that a majority of the estimated costs for research and development will be used for the enhancement and upgrading of its current products being offered for sale. The Company is unable to provide a detailed estimate of possible liquidity needs and expected sources of funds for possible future efforts to complete development of the Photon(TM) and obtain the necessary regulatory approvals since this estimate would depend on a comprehensive economic evaluation.

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

Marketing and Sales

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

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

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.

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Manufacturing and Raw Materials: Currently, the Company maintains a 23,238 square foot facility in Salt Lake City. The Company transferred the manufacturing activities for the Blood Flow Analyzer(TM) to San Diego from Occular Blood Flow, Ltd. in England during 2001. During the second quarter of 2002, the Company consolidated and closed the San Diego operations into the Salt Lake City facility. The facility accommodates its manufacturing, marketing and engineering capabilities. The Company manufactures under systems of quality control and testing, which complies with the Quality System Requirements established by the FDA, as well as similar guidelines established by foreign governments, including the CE Mark and IS0-9001.

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

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

On July 11, 2002, the Company entered into a Major Account Facilitator

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

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 $265,000, or 26%, to $768,000 for the twelve months ended December 31, 2004, from $1,033,000 for the same period in 2003. None of the costs of research and development activities during 2004 and 2003 was borne directly by customers.

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

During the period in which Thomas F. Motter served as the Company's Chairman and Chief Executive Officer, he formed a clinical advisory board and met from time to time with the board. Jeffrey F. Poore, who served as the

Company's President and Chief Executive Officer from March 2003 to March 2004, decided not to utilize the clinical advisory board. Instead, he consulted with former members of the advisory board on an informal basis. The Company currently has no agreements with any former members of the clinical advisory board and none of these former members hold or own any rights to its products or technologies.

Competition

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

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

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

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

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

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

Intellectual Property Protection

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

The Company acquired proprietary intellectual property in the 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 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 partes are unable to agree on a method for calculating royalties, there is a risk that PhotoMed and Dr. Eichenbaum might amend the complaint to request termination of the license agreement and, if successful, the Company would lose its rights to manufacture or sell the Photon(TM) laser system.

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

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

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

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

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

Regulation

The FDA under the Food, Drug and Cosmetics Act regulates the Company's surgical and diagnostic systems as medical devices. As such, these devices require premarket clearance or approval by the FDA prior to their marketing and sale. Such clearance or approval is premised on the production of evidence sufficient for the Company to show reasonable assurance of safety and effectiveness regarding its products. Pursuant to the Food, Drug and Cosmetics Act, the FDA regulates the manufacture, distribution and production of medical devices in the United States and the export of medical devices from the United States. Noncompliance with applicable requirements can result in fines, injunctions, civil penalties, recall or seizure of products, total or partial

suspension of production, denial of premarket clearance or approval for devices. Recommendations by the FDA that the Company not be allowed to enter into government contracts and criminal prosecution may also be made.

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

There are two principal methods by which FDA approval may be obtained. One method is to seek FDA approval through a pre-marketing notification filing under Section 510(k) of the Food, Drug and Cosmetics Act. If a manufacturer or distributor of a medical device can establish that a proposed device is "substantially equivalent" to a legally marketed Class I or Class II medical device or to a pre-1976 Class III medical device for which the FDA has not

called for a pre- marketing approval, the manufacturer or distributor may seek FDA Section 510(k) pre-marketing clearance for the device by filing a Section 510(k) pre-marketing notification. The Section 510(k) notification and the claim of substantial equivalence will likely have to be supported by various types of data and materials, possibly including clinical testing results, obtained under an Investigational Device Exemption granted by the FDA. The manufacturer or distributor may not place the device into interstate commerce until an order is issued by the FDA granting pre-marketing clearance for the device. There can be no assurance that the Company will obtain Section 510(k) pre-marketing clearance for any of the future devices for which the Company seeks such clearance including the Photon(TM) laser system.

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

The alternate method to seek approval is to obtain pre-marketing approval from the FDA. If a manufacturer or distributor of a medical device cannot establish that a proposed device is substantially equivalent to another legally marketed device, whether or not the FDA has made a determination in response to a Section 510(k) notification, the manufacturer or distributor will have to seek pre-marketing approval for the proposed device. A pre-marketing

approval application would have to be submitted and be supported by extensive data, including preclinical and clinical trial data to prove the safety and efficacy of the device. If human clinical trials of a proposed device are required and the device presents a significant risk, the manufacturer or the distributor of the device will have to file an Investigational Device Exemption application with the FDA prior to commencing human clinical trials. The Investigational Device Exemption application must be supported by data, typically including the results of animal and mechanical testing. If the Investigational Device Exemption application is approved, human clinical trials may begin at a specific number of investigational sites, and the approval letter could include the number of patients approved by the FDA.

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

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.

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

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

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

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

medical procedures. The Company's two ultrasound systems, the Photon(TM) laser cataract system it is developing and the ocular blood flow analyzer are all devices, which require FDA approval. Therefore, a significant aspect of the acceptance of the devices in the market is the Company's effectiveness in obtaining the necessary approvals. Having an approved Investigational Device Exemption allows the Company to export a product to qualified investigational sites.

Regulatory Status of Products

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

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

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

The Company received a warning letter dated August 30, 2000, from the Office of Compliance, Center for Devices and Radiological Health of the Food and Drug Administration relating to certain deficiencies in the human clinical trials for its Photon(TM) Laser Cataract System. The warning letter concerns the

conditions found by the FDA during several audits at its clinical sites. The FDA's comments were isolated to the administrative procedures of compiling data from the clinical sites. The Company responded to the warning letter in a submission dated September 27, 2000. In the submission the Company took corrective action that included submitting a revised clinical protocol and case report forms and procedures for the collection and control of data. In a subsequent letter dated November 2, 2000 to us, the FDA granted conditional approval provided that the Company correct certain deficiencies. After providing several additional submissions to the FDA, the Company received a letter dated February 13, 2001 from the FDA stating that the deficiencies had been corrected and the clinical trials could continue.

Subsequent to the warning letter, the Company received approval to continue its clinical trials, the results of which were included in its supplemental submission to the FDA in October 2001 for the existing (510)(k) predicate device application for the Photon(TM) laser system. In December 2001,

the Company received a preliminary review from the FDA regarding the supplemental submission. As a result of that preliminary review, the Company submitted additional clinical information to the FDA on February 6, 2002. The application is receiving ongoing review by the FDA. On May 7, 2002, the Company received a letter from the FDA requesting further clinical information. The Company has generated additional clinical information in response to the letter and are uncertain if the Company will make a submission to the FDA with the additional clinical information. Because of the "going concern" status of the Company, management has focused efforts on those products and activities that will, in its opinion, achieve the most resource efficient short-term cash flow to the Company. Its diagnostic products are currently its major focus and the Photon(TM) and other extensive research and development prospects have been put on hold pending future evaluation when the Company's financial position improves. Its focus is not on any specific diagnostic product or products, but rather on its entire group of diagnostic products.

Employees

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

In December 2001, the Company initiated the first phase of a corporate downsizing program to reduce its operating expenses. The Company implemented the second phase of its downsizing program in the second quarter of 2002, by closing and transferring its manufacturing from its site in San Diego, California to Salt Lake City, resulting in further reductions in operating expenses. As a result of the downsizing program and some resignations, the number of its employees has been reduced by 72% from 112 to 31 employees. The estimated cost savings from the downsizing program will be in excess of $2,000,000 annually. The costs of downsizing have included one-time expenses of approximately $43,000 for moving and travel. In addition, the Company incurred additional one-time expenses of approximately $18,000 for housing accommodations for key employees working in Salt Lake City. The Company realized a net cost savings from downsizing of approximately $2,394,000 during the twelve months ended December 31, 2002.

Item 2. Description of Property

The Company's executive offices are currently located at 2355 South 1070 West, Salt Lake City, Utah. This facility consists of approximately 23,238 square feet of leased office space under a three-year lease that was to expire on March 1, 2003 with an additional three-year renewal option. These facilities are leased from Eden Roc, a California partnership, at a base monthly rate of $21,163 plus a $3,342 monthly common area maintenance fee. In January 2003, the Company renegotiated a three-year lease with Eden Roc at a monthly rate of $9,295 plus a $1,859 common area maintenance fee for the year 2003, with rate increases to $9,574 for 2004 and to $9,861for 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 September 11, 2000 by PhotoMed International, Inc. and Daniel M. Eichenbaum, M.D. in the Third District Court of Salt Lake County, State of Utah. The action involves an amount of royalties that are allegedly due and owing to PhotoMed International, Inc. and Dr. Eichenbaum under a license agreement dated July 7, 1993, with respect to the sale of certain equipment, plus costs and attorneys' fees. Certain discovery has taken place and the Company has paid royalties of $15,717, which the Company

believes brings all payments current as of the date of last payment on January 7, 2005. The Company has been working with PhotoMed and Dr. Eichenbaum to ensure that the calculations have been correctly made on the royalties paid as well as the proper method of calculation for the future.

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

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

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

The complaint also alleges that on July 11, 2002, the Company issued a press release falsely announcing that it had received a purchase order from

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

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

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

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

by the second order of $35 million in equipment to be completed in the third year. The press release further stated that delivery would be made in traunches 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 suffered millions of dollars in damages from the Company's alleged misstatements.

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

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

The Company has paid $30,000 to U.S. Fire toward satisfaction of the

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

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

The Company will be in default under the non-waiver agreement if it fails to make any payment due to U.S. Fire thereunder when such payment is due, or institute proceedings to be adjudicated as bankrupt or insolvent. U.S. Fire's obligation to advance defense costs under the agreement .99pt;padding-top:2pt;text-align:right;

Shares	Description (1)	Value
	Electrical Equipment – 0.4%	
11,800	Ametek Inc	$779,272
4,200	Eaton PLC	322,518
	Total Electrical Equipment	1,101,790
	Electronic Equipment, Instruments & Components – 1.2%	
34,800	Amphenol Corporation, Class A	2,945,472
	Equity Real Estate Investment Trust – 8.7%	
3,400	Alexandria Real Estate Equities Inc	404,498
19,900	American Tower Corporation, REIT	2,719,932
14,300	AvalonBay Communities, Inc.	2,551,406
10,300	Crown Castle International Corporation	1,029,794
16,300	Digital Realty Trust Inc.	1,928,779
8,400	Duke Realty Corporation	242,088
1,543	Equinix Inc.	688,641
1,900	Equity Residential	125,267
9,300	Essex Property Trust Inc.	2,362,479
4,500	Extra Space Storage Inc.	359,640
23,000	Health Care Property Investors Inc	640,090
5,900	Host Hotels & Resorts Inc	109,091
15,100	Mid-America Apartment Communities	1,613,888
46,600	Prologis Inc	2,957,236
3,600	SBA Communications Corporation, (3)	518,580
18,600	UDR Inc.	707,358
19,700	Ventas Inc	1,283,061
23,300	Welltower Inc	1,637,524
	Total Equity Real Estate Investment Trust	21,879,352
	Food Products – 1.0%	
12,200	Hershey Foods Corporation	1,331,874
16,800	Tyson Foods, Inc., Class A	1,183,560
	Total Food Products	2,515,434
	Health Care Equipment & Supplies – 8.0%	
18,800	Abbott Laboratories	1,003,168
8,700	Align Technology, Inc, (3)	1,620,549
53,100	Baxter International, Inc., (2)	3,332,025
800	Becton, Dickinson and Company	156,760
20,800	Boston Scientific Corporation, (3)	606,736
5,100	C. R. Bard, Inc	1,634,550
10,500	Cooper Companies, Inc	2,489,655
3,200	Edwards Lifesciences Corporation, (3)	349,792
29,300	Hologic Inc., (3)	1,075,017
4,100	Idexx Labs Inc, (3)	637,509
2,600	Intuitive Surgical, Inc., (3)	2,719,288
9,900	Medtronic, PLC	769,923

Shares	Description (1)	Value
	Health Care Equipment & Supplies (continued)	
13,500	ResMed Inc	$1,038,960
7,600	Stryker Corporation	1,079,352
10,300	Varian Medical Systems, Inc, (3)	1,030,618
4,500	Zimmer Biomet Holdings, Inc.	526,905
	Total Health Care Equipment & Supplies	20,070,807
	Health Care Providers & Services – 5.0%	
7,200	Aetna Inc.	1,144,872
10,300	Anthem Inc.	1,955,764
9,600	Cardinal Health, Inc.	642,432
25,600	Centene Corporation, (3)	2,477,312
3,700	CIGNA Corporation	691,678
9,800	Henry Schein Inc, (3)	803,502
7,700	Humana Inc.	1,875,951
3,500	Laboratory Corporation of America Holdings, (3)	528,395
24,700	Quest Diagnostics Incorporated	2,312,908
1,200	UnitedHealth Group Incorporated	235,020
	Total Health Care Providers & Services	12,667,834
	Health Care Technology – 0.6%	
21,400	Cerner Corporation, (3)	1,526,248
	Hotels, Restaurants & Leisure – 5.3%	
36,500	Carnival Corporation	2,356,805
3,300	Chipotle Mexican Grill, (3)	1,015,839
10,500	Darden Restaurants, Inc.	827,190
33,700	Marriott International, Inc., Class A	3,715,762
12,200	McDonald's Corporation	1,911,496
16,000	Wyndham Worldwide Corporation	1,686,560
12,800	Wynn Resorts Ltd	1,906,176
	Total Hotels, Restaurants & Leisure	13,419,828
	Household Durables – 2.2%	
70,500	D.R. Horton, Inc., (2)	2,815,065
1,500	Leggett and Platt Inc	71,595
22,900	Lennar Corporation, Class A	1,209,120
2,400	Mohawk Industries Inc., (3)	594,024
35,100	PulteGroup Inc	959,283
	Total Household Durables	5,649,087
	Household Products – 0.7%	
10,200	Clorox Company	1,345,482
3,200	Kimberly-Clark Corporation	376,576
	Total Household Products	1,722,058
	Independent Power & Renewable Electricity Producers – 0.1%	
7,700	NRG Energy Inc.	197,043

Shares	Description (1)	Value
	Industrial Conglomerates – 1.0%	
7,900	3M Co.	$1,658,210
3,800	Roper Technologies, Inc	924,920
	Total Industrial Conglomerates	2,583,130
	Insurance – 5.2%	
4,200	Ace Limited	598,710
8,500	AFLAC Incorporated	691,815
28,700	Allstate Corporation	2,637,817
6,100	AON PLC	891,210
27,600	Arthur J. Gallagher & Co.	1,698,780
32,900	Hartford Financial Services Group, Inc.	1,823,647
16,000	Principal Financial Group, Inc	1,029,440
37,800	Progressive Corporation	1,830,276
400	Prudential Financial, Inc.	42,528
1,100	Travelers Companies, Inc	134,772
2,400	Willis Towers Watson PLC	370,152
33,200	XL Group Limited	1,309,740
	Total Insurance	13,058,887
	Internet & Direct Marketing Retail – 1.2%	
15,200	Expedia, Inc.	2,187,888
3,300	NetFlix.com Inc, (3)	598,455
100	Priceline Group Incorporated, (3)	183,082
	Total Internet & Direct Marketing Retail	2,969,425
	Internet Software & Services – 0.1%	
3,300	VeriSign, Inc, (3)	351,087
	IT Services – 2.7%	
28,300	Automatic Data Processing, Inc.	3,093,756
9,328	DXC Technology Company	801,089
5,900	Fiserv, Inc., (3)	760,864
8,200	Gartner Inc, (3)	1,020,162
900	Global Payments Inc.	85,527
14,300	PayPal Holdings, Inc., (3)	915,629
	Total IT Services	6,677,027
	Leisure Products – 0.1%	
3,600	Hasbro, Inc	351,612
	Life Sciences Tools & Services – 2.1%	
5,600	Agilent Technologies, Inc.	359,520
3,400	Illumina Inc, (3)	677,280
3,000	Mettler-Toledo International Inc, (3)	1,878,480
12,900	Perkinelmer Inc	889,713
8,900	Waters Corporation, (3)	1,597,728
	Total Life Sciences Tools & Services	5,402,721

Shares	Description (1)	Value
	Machinery – 2.8%	
16,300	Deere & Company	$2,047,117
15,700	Fortive Corporation	1,111,403
2,700	Illinois Tool Works, Inc.	399,492
20,000	Ingersoll Rand Company Limited, Class A	1,783,400
12,900	Pentair Limited	876,684
4,900	Stanley Black & Decker Inc.	739,753
	Total Machinery	6,957,849
	Media – 1.5%	
23,400	CBS Corporation, Class B	1,357,200
22,400	Time Warner Inc.	2,294,880
	Total Media	3,652,080
	Multi-Utilities – 4.9%	
21,600	Ameren Corporation	1,249,344
57,900	CenterPoint Energy, Inc., (2)	1,691,259
14,400	CMS Energy Corporation	667,008
15,000	Consolidated Edison, Inc	1,210,200
38,900	Dominion Resources, Inc.	2,992,577
16,900	DTE Energy Company	1,814,384
17,100	NiSource Inc	437,589
12,000	Sempra Energy	1,369,560
15,600	WEC Energy Group, Inc.	979,368
	Total Multi-Utilities	12,411,289
	Oil, Gas & Consumable Fuels – 0.4%	
3,900	Andeavor	402,285
4,600	Cabot Oil & Gas Corporation	123,050
12,000	Williams Companies Inc, (2)	360,120
	Total Oil, Gas & Consumable Fuels	885,455
	Personal Products – 0.2%	
4,100	Estee Lauder Companies Inc., Class A	442,144
	Pharmaceuticals – 0.5%	
6,200	Eli Lilly and Company	530,348
12,500	Zoetis Incorporated	797,000
	Total Pharmaceuticals	1,327,348
	Professional Services – 0.3%	
2,800	Equifax Inc	296,772
10,900	IHS Markit Limited, (3)	480,472
	Total Professional Services	777,244
	Road & Rail – 1.9%	
62,600	CSX Corporation, (2)	3,396,676
11,900	Kansas City Southern Industries	1,293,292
	Total Road & Rail	4,689,968

Shares	Description (1)	Value
	Semiconductors & Semiconductor Equipment – 9.7%	
12,325	Analog Devices, Inc.	$1,062,045
114,200	Applied Materials, Inc., (2)	5,948,678
10,444	Broadcom Limited	2,533,088
25,700	KLA-Tencor Corporation	2,724,200
12,300	Lam Research Corporation	2,275,992
7,600	Microchip Technology Incorporated	682,328
128,200	Micron Technology, Inc., (2), (3)	5,042,106
22,900	NVIDIA Corporation, (2)	4,093,833
	Total Semiconductors & Semiconductor Equipment	24,362,270
	Software – 1.8%	
33,400	Activision Blizzard Inc	2,154,634
15,200	Adobe Systems Incorporated, (2), (3)	2,267,536
600	Ansys Inc, (3)	73,638
	Total Software	4,495,808
	Specialty Retail – 0.7%	
9,500	Best Buy Co., Inc.	541,120
12,700	Tiffany & Co.	1,165,606
	Total Specialty Retail	1,706,726
	Technology Hardware, Storage & Peripherals – 1.4%	
3,100	Apple, Inc., (2)	477,772
18,100	HP Inc	361,276
30,800	Western Digital Corporation	2,661,120
	Total Technology Hardware, Storage & Peripherals	3,500,168
	Textiles, Apparel & Luxury Goods – 0.8%	
15,300	Coach, Inc.	616,284
20,400	Hanesbrands Inc	502,656
2,800	PVH Corporation	352,968
8,100	VF Corporation	514,917
	Total Textiles, Apparel & Luxury Goods	1,986,825
	Tobacco – 2.5%	
46,600	Altria Group, Inc.	2,955,372
29,600	Philip Morris International	3,285,896
	Total Tobacco	6,241,268
	Water Utilities – 0.0%	
1,400	American Water Works Company	113,274
	Total Long-Term Investments (cost $216,038,787)	247,160,793

Principal Amount (000)	Description (1)	Coupon	Maturity	Ratings (4)	Value
	SHORT-TERM INVESTMENTS – 2.6%				
	REPURCHASE AGREEMENTS – 1.6%				
$ 4,024	Repurchase Agreement with Fixed Income Clearing Corporation, dated 9/29/17, repurchase price $4,023,823, collateralized by $4,115,000 U.S. Treasury Notes, 2.250%, due 2/15/27, value $4,107,877	0.120%	10/02/17	N/A	$ 4,023,783
	U.S. GOVERNMENT AND AGENCY OBLIGATIONS – 1.0%				
2,500	U.S. Treasury Bills, (2)	0.000%	1/18/18	Aaa	2,492,409
	Total Short-Term Investments (cost $6,515,529)				6,516,192
	Total Investments (cost $222,554,316) – 100.9%				253,676,985
	Other Assets Less Liabilities – (0.9)% (5)				(2,298,799)
	Net Assets – 100%				$ 251,378,186

Investments in Derivatives as of September 30, 2017

Futures Contracts

Description	Contract Position	Number of Contracts	Expiration Date	Notional Amount	Value	Unrealized Appreciation (Depreciation)	Variation Margin Receivable/ (Payable)
S&P 500 E-Mini	Long	45	12/17	$5,611,936	$5,661,225	$49,289	$18,900

Options Written

Description	Number of Contracts	Notional Amount (6)	Exercise Price	Expiration Date	Value
RUSSELL 2000® Index	(151)	$(21,744,000)	$1,440	10/20/17	$(853,150)
RUSSELL 2000® Index	(475)	(68,875,000)	1,450	10/20/17	(2,272,875)
Total Options Written (premiums received $422,700)	(626)	$(90,619,000)			$(3,126,025)

Fair Value Measurements

Fair value is defined as the price that would be received upon selling an investment or transferring a liability in an orderly transaction to an independent buyer in the principal or most advantageous market for the investment. A three-tier hierarchy is used to maximize the use of observable market data and minimize the use of unobservable inputs and to establish classification of fair value measurements for disclosure purposes. Observable inputs reflect the assumptions market participants would use in pricing the asset or liability. Observable inputs are based on market data obtained from sources independent of the reporting entity. Unobservable inputs reflect the reporting entity's own assumptions about the assumptions market participants would use in pricing the asset or liability. Unobservable inputs are based on the best information available in the circumstances. The following is a summary of the three-tiered hierarchy of valuation input levels.

Level 1 – Inputs are unadjusted and prices are determined using quoted prices in active markets for identical securities.

Level 2 – Prices are determined using other significant observable inputs (including quoted prices for similar securities, interest rates, prepayment speeds, credit risk, etc.).

Level 3 – Prices are determined using significant unobservable inputs (including management's assumptions in determining the fair value of investments).

The inputs or methodologies used for valuing securities are not an indication of the risks associated with investing in those securities. The following is a summary of the Fund's fair value measurements as of the end of the reporting period:

	Level 1	Level 2	Level 3	Total
Long-Term Investments:				
Common Stocks	$247,160,793	$ —	$ —	$247,160,793
Short-Term Investments:				
Repurchase Agreements	—	4,023,783	—	4,023,783
U.S. Government and Agency Obligations	—	2,492,409	—	2,492,409
Investments in Derivatives:				
Futures Contracts*	49,289	—	—	49,289
Options Written	(3,126,025)	—	—	(3,126,025)
Total	$244,084,057	$6,516,192	$ —	$250,600,249

*Represents net unrealized appreciation (depreciation).

Income Tax Information

The following information is presented on an income tax basis. Differences between amounts for financial statement and federal income tax purposes areprimarily due to timing differences in recognizing certain gains and losses on investment transactions and the recognition of unrealized gain or loss for tax(mark-to-market) on futures contracts and certain options contracts. To the extent that differences arise that are permanent in nature, such amounts are reclassified within the capital accounts on the Statement of Assets and Liabilities presented in the annual report, based on their federal tax basis treatment; temporary differences do not require reclassification. Temporary and permanent differences do not impact the net asset value of the Fund.

The tables below present the cost and unrealized appreciation (depreciation) of the Fund's investment portfolio, as determined on a federal income tax basis, as of September 30, 2017.

For purposes of this disclosure, derivative tax cost is generally the sum of any upfront fees or premiums exchanged and any amounts unrealized for income statement reporting but realized in income and/or capital gains for tax reporting. If a particular derivative category does not disclose any tax unrealized appreciation or depreciation, the change in value of those derivatives have generally been fully realized for tax purposes.

Tax cost of investments	$222,560,572
Gross unrealized:	
Appreciation	$ 33,167,571
Depreciation	(2,045,002)
Net unrealized appreciation (depreciation) of investments	$ 31,122,569

Tax cost of futures contracts	$49,289
Net unrealized appreciation (depreciation) on futures contracts	-

Tax cost of options written contracts	$(3,126,025)
Net unrealized appreciation (depreciation) on option contracts written	-

For Fund portfolio compliance purposes, the Fund's industry classifications refer to any one or more of the industry sub-classifications used by one or more widely recognized market indexes or ratings group indexes, and/or as defined by Fund management. This definition may not apply for purposes of this report, which may combine industry sub-classifications into sectors for reporting ease.

(1) All percentages shown in the Portfolio of Investments are based on net assets .

(2) Investment, or portion of investment, has been pledged to collateralize the net payment obligations for investments in derivatives.

(3) Non-income producing; issuer has not declared a dividend within the past twelve months.

(4) For financial reporting purposes, the ratings disclosed are the highest of Standard & Poor's Group ("Standard & Poor's"), Moody's Investors Service, Inc. ("Moody's") or Fitch, Inc. ("Fitch") rating. This treatment of split-rated

securities may differ from that used for other purposes, such as for Fund investment policies. Ratings below BBB by Standard & Poor's, Baa by Moody's or BBB by Fitch are considered to be below investment grade. Holdings designated N/R are not rated by any of these national rating agencies.

(5) Other assets less liabilities includes the unrealized appreciation (depreciation) of certain over-the-counter ("OTC") derivatives as presented on the Statement of Assets and Liabilities, when applicable. The unrealized appreciation (depreciation) of OTC-cleared and exchange-traded derivatives is recognized as part of the cash collateral at brokers and/or the receivable or payable for variation margin as presented on the Statement of Assets and Liabilities, when applicable. Other assets less liabilities also includes the value of options as presented on Statement of Assets and Liabilities.

(6) For disclosure purposes, Notional Amount is calculated by multiplying the Number of Contracts by the Strike Price by 100.

N/A Not Applicable

REIT Real Estate Investment Trust

Item 2. Controls and Procedures.

a. The registrant s principal executive and principal financial officers, or persons performing similar functions, have concluded that the registrant s disclosure controls and procedures (as defined in Rule 30a-3(c) under the Investment Company Act of 1940, as amended (the 1940 Act) (17 CFR 270.30a-3(c))) are effective, as of a date within 90 days of the filing date of this report that includes the disclosure required by this paragraph, based on their evaluation of the controls and procedures required by Rule 30a-3(b) under the 1940 Act (17 CFR 270.30a-3(b)) and Rule 13a-15(b) or 15d-15(b) under the Securities Exchange Act of 1934 (17 CFR 240.13a-15(b) or 240.15d-15(b)).

b. There were no changes in the registrant s internal control over financial reporting (as defined in Rule 30a-3(d) under the 1940 Act (17 CFR 270.30a-3(d)) that occurred during the registrant s last fiscal quarter that have materially affected, or are reasonably likely to materially affect, the registrant s internal control over financial reporting.

Item 3. Exhibits.

File as exhibits as part of this Form a separate certification for each principal executive officer and principal financial officer of the registrant as required by Rule 30a-2(a) under the 1940 Act (17 CFR 270.30a-2(a)), exactly as set forth below: EX-99 CERT Attached hereto.

SIGNATURES

Pursuant to the requirements of the Securities Exchange Act of 1934 and the Investment Company Act of 1940, the registrant has duly caused this report to be signed on its behalf by the undersigned, thereunto duly authorized.

(Registrant) Nuveen Core Equity Alpha Fund

By (Signature and Title) /s/ Gifford R. Zimmerman

Gifford R. Zimmerman
Vice President and Secretary

Date: November 29, 2017

Pursuant to the requirements of the Securities Exchange Act of 1934 and the Investment Company Act of 1940, this report has been signed below by the following persons on behalf of the registrant and in the capacities and on the dates indicated.

By (Signature and Title) /s/ Cedric H. Antosiewicz

Cedric H. Antosiewicz
Chief Administrative Officer (principal executive officer)

Date: November 29, 2017

By (Signature and Title) /s/ Stephen D. Foy

Stephen D. Foy
Vice President and Controller (principal financial officer)

Date: November 29, 2017