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PARADIGM MEDICAL INDUSTRIES INC
Form POS AM
February 03, 2005

As filed with the Securities and Exchange Commission on February 3, 2005
Commission File No. 333-103061

SECURITIES AND EXCHANGE COMMISSION
Washington, D.C. 20549

POST-EFFECTIVE AMENDMENT NO. 2
to
FORM SB-2
REGISTRATION STATEMENT
UNDER
THE SECURITIES ACT OF 1933

PARADIGM MEDICAL INDUSTRIES, INC.
(Name of small business issuer in its charter)

Delaware	3841	87-0459536
(State or jurisdiction of incorporation or organization)	(Primary Standard Classification Code Number)	(I.R.S. Employer Identification Number)

2355 South 1070 West
Salt Lake City, Utah 84119
(801) 977-8970
(Address and telephone number of registrant's principal executive offices
and principal place of business)

John Y. Yoon, President and Chief Executive Officer,
2355 South 1070 West
Salt Lake City, Utah 84119
(801) 977-8970
(Name, address and telephone number of agent for service)

Copies to:

Randall A. Mackey, Esq.
Mackey Price Thompson & Ostler
350 American Plaza II
57 West 200 South
Salt Lake City, Utah 84101-3663
Telephone: (801) 575-5000

Approximate date of proposed sale to the public:
As soon as practicable after this Registration
Statement becomes effective.

If any of the securities being registered on this Form are being
offered on a delayed or continuous basis pursuant to Rule 415 under the
Securities Act of 1933 (the "Securities Act"), check the following box.

If this Form is filed to register additional securities for an offering
pursuant to Rule 462(b) under the Securities Act, please check the following box
and list the Securities Act registration statement for the same offering.

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If this Form is a post-effective amendment filed pursuant to Rule 462(c) under the Securities Act, check the following box and list the Securities Act registration statement number of the earlier effective registration statement for the same offering. []

If delivery of the prospectus is expected to be made pursuant to Rule 434, please check the following box. []

 CALCULATION OF REGISTRATION FEE

Title of each class of securities to be registered	Amount to be registered	Proposed maximum offering price per Share
Resale of Common Stock issuable upon exercise of Class A Warrants	1,000,000	\$ 7.50
Resale of Common Stock issuable upon exercise of Kenneth Jerome Warrants.....	100,000	8.125
Resale of Common Stock issuable upon exercise of Kenneth Jerome Warrants.....	100,000	7.50
Resale of Common Stock issuable upon exercise of Cyndel Warrants	225,000	4.00
Resale of Common Stock issuable upon exercise of Cyndel Warrants	250,000	3.00
Resale of Common Stock issuable upon exercise of Limberg Warrants	200,000	4.00
Resale of Common Stock issuable upon exercise of Limberg Warrants	50,000	4.75
Resale of Common Stock issuable upon exercise of Limberg Warrants	50,000	6.75
Resale of Common Stock issuable upon exercise of Hemmer Warrants	75,000	7.50
Resale of Common Stock issuable upon exercise of Kohn and Sucoff Warrants.....	100,000	4.00
Resale of Common Stock issuable upon exercise of Series E Preferred Warrants.....	241,095	4.00
Resale of Common Stock issuable upon exercise of Series F Preferred Warrants.....	230,589	4.00
Resale of Common Stock issuable upon exercise of Options.....	600,000	4.00
Resale of Common Stock issuable upon exercise of Options.....	73,103	5.00
Resale of Common Stock issuable upon exercise of Options.....	150,000	6.00
Resale of Common Stock issuable upon exercise of Options.....	786,000	2.75
Resale of Common Stock by certain holders of Common Stock.....	425,000	4.00
Resale of Common Stock by certain holders of Common Stock.....	1,307,484	2.125
Resale of Common Stock by certain holders of Common Stock.....	425,580	2.14
Resale of Common Stock by certain holders of Common Stock.....	1,968,509	1.16
Resale of Common Stock issuable upon exercise of Rodman & Renshaw Warrants.....	35,000	2.00
Resale of Common Stock issuable upon exercise of Warrants.....	788,750	.25
Resale of Common Stock by certain holders of common stock.....	365,327	.25
Total.....	9,546,437	

(1) No registration fee is required as securities were previously registered by Form SB-2 Registration Statement, No. 333- 2496,

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effective as of July 10, 1996; Form SB-2 Registration Statement No. 333-57711, effective as of September 14, 1998; Form SB-2 Registration Statement No. 333-68471, effective as of January 4, 1999; Form SB-2 Registration Statement No. 333-77267, effective as of May 7, 1999; Form S-3 Registration Statement No. 333-93725, effective as of January 6, 2000; Form S-3 Registration Statement No. 333-44154, effective as of September 1, 2000; Form S-3 Registration Statement No. 333-50846, effective as of December 8, 2000; Form S-3 Registration Statement No. 333-66742, effective as of August 22, 2001; Form S-3 Registration Statement No. 333-75912, effective as of June 21, 2002; Form S-3 Registration Statement No. 333-97837, effective as of September 26, 2002; and Form S-3 Registration Statement No. 33-103061, effective as of February 14, 2003. Pursuant to Rule 429, this is a combined registration statement which relates to the securities previously registered by the earlier registration statements and the securities being registered by this registration statement. The number of securities being carried forward, which were previously registered by the earlier registration statements, is 14,479,693 shares of common stock, and the total amount of the previously paid registration fees associated with such securities that were previously registered is \$22,703.74. The number of shares being registered by this registration statement is 9,546,437 shares.

The Registrant hereby amends this Registration Statement on such date or dates as may be necessary to delay its effective date until the Registrant shall file a further amendment which specifically states that this registration statement shall thereafter become effective in accordance with Section 8(a) of the Securities Act or until the Registration Statement shall become effective on such date as the Commission acting pursuant to said Section 8(a) may determine.

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PROSPECTUS

9,546,437 Shares of Common Stock

PARADIGM MEDICAL INDUSTRIES, INC.

Paradigm Medical Industries, Inc. is registering for resale a total of 9,546,437 shares of common stock. Our COMMON STOCK AND Class A warrants are quoted on the Over-the-Counter Bulletin Board under the symbols PMED.OB and PMEDW.OB. On February 1, 2005 the last reported sale price for our common stock was \$.10 per share and the last reported sale price for our Class A warrants was \$.02 per warrant.

We are registering the resale of common stock for certain shareholders and will only receive proceeds to the extent that outstanding warrants or options are exercised. The exercise price for all of the outstanding warrants and options exceeds the current trading price for our common stock and, as a result, the outstanding warrants and options are not likely to be exercised unless the trading price increases substantially. All other shares of our common stock being registered are either outstanding or will be issued upon conversion of outstanding preferred stock, and we will derive no proceeds from the

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conversions or subsequent resales of such shares.

Investing in the common stock involves risks that are described in the "Risk Factors" section beginning on page 6 of this prospectus.

Neither the Securities and Exchange Commission nor any state securities commission has approved or disapproved these securities or determined if this prospectus is truthful or complete. Any representation to the contrary is a criminal offense.

The date of this prospectus is February __, 2005.

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PROSPECTUS SUMMARY

This summary highlights some information from this prospectus. It may not contain all of the information that is important to you. To understand this offering fully, you should read the entire prospectus carefully, including the risk factors and the financial statements.

The Company

We develop, manufacture, source, market and sell ophthalmic surgical and diagnostic instrumentation and related accessories, including disposable products. Our surgical equipment is designed for minimally invasive cataract treatment. A cataract is a condition, which 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.

We sell our equipment and related products in all countries of the world in which we are permitted to do so. The nature of the regulatory approval processes in those countries vary by country but, in general terms, follow the approach of the regulatory approval processes of the United States Food and Drug Administration, or FDA, and the approval processes of the countries in the European Union. The status of specific approvals is detailed in the table in the Business section of this prospectus.

We market two cataract surgery systems with related accessories and disposable products. Our cataract removal system, the Photon(TM) laser system, is a laser cataract surgery system marketed as the next generation of cataract removal. The Photon(TM) product has yet to be approved by the Food and Drug Administration. Except for the Photon(TM) laser system, which can only be sold in countries outside of the United States, our 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

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United Arab Emirates . Both the Photon(TM) and the Precisionist ThirtyThousand (TM) are manufactured as an Ocular Surgery Workstation(TM). At present, because the Photon(TM) has not received FDA approval, it does not provide significant revenue to us. We are in the process of completing the clinical trials in order to file for FDA approval. However, due to the uncertainty surrounding the timetable for obtaining FDA approval and the lack of significant revenue from other surgical products, we have recorded an inventory reserve against the majority of inventory associated with the Photon(TM) and Precisionist Thirty Thousand(TM).

Our diagnostic products include 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, Inc. in 1998. We developed and offered for sale in the fall of 2000 the P45, which combines the A/B scope and the P40 UBM Biomicroscope in one machine. The perimeter and the corneal topographer were added when we acquired the outstanding shares of the stock of Vismed, Inc. d/b/a/ Dicon(TM) in June 2000. We acquired Ocular Blood Flow, Ltd. in June of 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 treatment of glaucoma. We are currently attempting to develop additional applications for all of our diagnostic products.

We rely upon several products for revenues. For the nine months ended September 30, 2004, 32% of our revenues were derived from the Dicon(TM) diagnostic products sales (the perimeter and corneal topographer), 21% of revenues from Blood Flow Analyzer(TM) sales, 29% of revenues from P40 and P45 UBM Ultrasound Biomicroscope sales, 9% of revenues from Humphrey Systems diagnostic product sales (the P55 pachymetric analyzer and the P37 Ultrasonic A/B Scan), and 9% of revenues from services, disposables and other sales. For the fiscal year ended December 31, 2003, 36% of our revenues were derived from the Dicon (TM) diagnostic products sales (the perimeter and corneal topographer), 16% of revenues from Blood Flow Analyzer(TM) sales, 20% of revenues from P40 and P45 UBM Ultrasound Biomicroscope sales, 9% of revenues from Humphrey Systems diagnostic product sales (the P55 pachymetric analyzer, the P20 A-Scan and the P37 A/B Scan), 11% of revenues from cataract removal surgery sales, including the sale of our SIStem(TM) and Odyssey(TM) product lines, and 8% of revenues from services, disposables and other sales.

For the fiscal year ended December 31, 2002, 28% of our revenues were derived from the Dicon(TM) diagnostic products sales (the perimeter and the corneal topographer), 9% of revenues from Blood Flow Analyzer(TM) sales, 24% of revenues from the P40 and P45 UBM Ultrasound Biomicroscope sales, 11% of revenues from Humphrey systems diagnostic products sales (the P55 pachymetric analyzer, the P20 A-Scan and the P37 A/B Scan), 5% of revenues from cataract removal surgery sales, and 23% of revenues from services, disposables and other sales. Our principal executive offices are located at 2355 South 1070 West, Salt Lake City, Utah 84119 and our telephone number is (801) 977-8970.

Audited revenues for the fiscal year ended December 31, 2003 were \$3,059,000 as compared to \$5,368,000 for the comparable period for fiscal 2002. Unaudited revenues for the nine months ended September 30, 2004 were \$2,288,000 as compared to \$2,225,000 for the comparable period of 2003.

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On March 18, 2004, our board of directors appointed John Y. Yoon as President and Chief Executive Officer of the company, replacing Jeffrey F. Poore, who served in those positions from March 19, 2003 to March 18, 2004. Our board of directors terminated Mr. Poore's employment for cause as defined in the employment agreement. On March 22, 2004, our board of directors appointed Aziz A. Mohabbat as Vice President of Operations and Chief Operating Officer of the company, replacing David I. Cullumber who resigned as Chief Operating Officer and Chief Technical Officer on March 22, 2004 to pursue other business opportunities. Mr. Mohabbat had previously served as Chief Operating Officer of the Company from August 2002 to March 2003, and as Vice President of Operations from 2001 to March 2003.

On June 23, 2003, our board of directors appointed Gregory Hill as Vice President of Finance, Treasurer and Chief Financial Officer of the Company, replacing Heber C. Maughan, who resigned as Vice President of Finance, Treasurer and Chief Financial Officer on May 31, 2003 to pursue other business opportunities. Mr. Hill resigned from his positions on December 5, 2003 to pursue other business opportunities.

The board of directors has not yet appointed a new Chief Financial Officer since Gregory Hill resigned in an effort to conserve our financial resources. Moreover, since Mr. Hill's resignation, we have endeavored to reduce our operating expenditures, which has resulted in a reduction in the number of our employees. Luis A. Mostacero, our Controller, is currently handling the responsibilities previously assumed by Mr. Hill when he served as our Chief Financial Officer. It is our intention to appoint a new Chief Financial Officer in the future when we have adequate funds to do so.

On January 14, 2005, we issued 2,000,000 restricted shares of common stock to Dr. Endre Bodnar, an accredited investor, through a private offering at a price of \$.075 per share. We received a total of \$150,000 in cash from the private offering and, as a commission, issued warrants to purchase 200,000 shares of our common stock at an exercise price of \$.15 per share, exercisable through January 14, 2008.

The Offering

Securities Offered The resale of 9,546,437 shares of common stock, consisting of the following:

- o The resale of 1,000,000 shares issuable upon exercise of Class A warrants with an exercise price of \$7.50 per share.
- o The resale of 200,000 shares issuable upon exercise of warrants by Kenneth Jerome & Co. with exercise prices ranging from \$7.50 to \$8.125 per share.
- o The resale of 475,000 shares issuable upon exercise of warrants by Cyndel & Co., Inc. with exercise prices ranging from \$3.00 to \$4.00 per share.
- o The resale of 300,000 shares issuable upon exercise of warrants by Dr. Michael B. Limberg with exercise prices

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ranging from \$4.00 to \$6.75 per share.

- o The resale of 75,000 shares issuable upon the exercise of warrants by John W. Hemmer with exercise price of \$7.50 per share.
- o The resale of 50,000 shares issuable upon exercise of warrants by Helen Cohn with an exercise price of \$4.00 per share.
- o The resale of 50,000 shares issuable upon the exercise of warrants by Ronit Sucoff with an exercise price of \$4.00 per share.
- o The resale of 35,000 shares issuable upon the exercise of warrants by Rodman & Renshaw, Inc. with an exercise price of \$2.00 per share.
- o The resale of 241,095 shares issuable upon the exercise of warrants by Series E preferred holders with an exercise price of \$4.00 per share.
- o The resale of 230,589 shares issuable upon exercise of warrants by Series F preferred holders with an exercise price of \$4.00 per share.

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- o The resale of 788,750 shares issuable upon exercise of warrants by Paul L. Archambeau, M.D., John H. Banzhaf, Daniel S. Lipson, Douglas A. MacLeod, M.D., Douglas A. MacLeod, M.D. Profit Sharing Trust, St. Mark's Eye Institute, Milan Holdings, Ltd., Frank G. Mauro and Delbert D. Reichardt with an exercise price of \$.25 per share.
- o The resale of 150,000 shares issuable upon exercise of options by executive officers, employees and directors with an exercise price of \$6.00 per share.

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- o The resale of 73,103 shares issuable upon exercise of options by executive officers, employees and directors with an exercise price of \$5.00 per share.
- o The resale of 600,000 shares issuable upon exercise of options by executive officers, employees and directors with an exercise price of \$4.00 per share.
- o The resale of 786,000 shares issuable upon exercise of options by executive officers, employees and directors with an exercise price of \$2.75 per share.
- o The resale of 4,491,900 shares held by certain stockholders with registration rights.

Common stock outstanding prior to the offering(1) 27,764,868 shares.

Common stock outstanding after the offering(1)..... 37,311,305 shares.

Use of proceeds..... All funds received by us upon the exercise of the warrants and options will be used for general corporate purposes. We will not receive any proceeds from the conversion of the shares of Series E preferred stock or Series F preferred stock.

Risk Factors/Dilution..... The offering involves a high degree of risk.

OTC Bulletin Board symbols
 Common stock..... PMED.OB
 Class warrants..... PMEDW.OB

(1) Does not include 6,753 shares of common stock issuable upon conversion of 5,627 shares of Series A preferred stock, 10,783 shares of common stock issuable upon conversion of 8,986 shares of Series B preferred stock, 8,750 shares of common stock issuable upon conversion of 5,000 shares of Series D preferred stock, 53,333 shares of common stock issuable upon conversion of 1,000 shares of Series E preferred stock, 245,217 shares of common stock issuable upon conversion of 4,598.75 shares of Series F preferred stock, 1,726,560 shares of stock issuable upon conversion of 1,726,560 shares of Series G preferred stock, options to purchase a total of 3,781,262 shares of common stock issuable upon the exercise of stock options at prices ranging from \$.16 to \$6.00 per share, and warrants to purchase 4,584,182 shares of common stock issuable upon the exercise of warrants at prices ranging from \$.15 to \$8.125 per share. Also does not include 515,206 shares of common stock issuable to the holders of Series G preferred stock. Under the terms of the private offering of Series G preferred shares, we are required to file a registration statement with the Securities and Exchange Commission to register the common shares issuable to the Series G preferred stockholders upon conversion of their Series G

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preferred shares and exercise of their warrants. If the registration statement has not been declared effective within 120 days of the initial closing of such offering on August 29, 2003, there is a penalty of 2% per month payable to the Series G preferred stockholders in common shares (or 39,631 common shares per month) until the registration statement is declared effective.

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Summary Financial Information

Statement of Operations Data: -----	For the year ended December 31,		For the nine months September 30,	
	2002 ----	2003 ----	2003 ----	
Net Sales.....	\$5,368,000	\$3,059,000	\$2,225,000	\$2
Net cost of sales.....	4,210,000	2,086,000	1,237,000	
Operating expenses.....	12,277,000	4,549,000	3,526,000	1
Operating loss.....	(11,119,000)	(3,576,000)	(2,538,000)	
Other income (expense).....	(36,000)	415,000	(233,000)	
Net income (loss).....	(11,155,000)	(3,161,000)	(2,305,000)	
Net income (loss) applicable to common shareholders.....	(11,155,000)	(3,431,000)	(2,305,000)	
Net income (loss) per common share.....	\$(.63)	\$(.14)	\$(.10)	
Shares used in computing net loss per share	17,736,000	24,058,000	22,795,000	25

Balance Sheet Data: -----	As of December 31, 2002 -----	As of December 31, 2003 -----	Se ---
Current assets.....	\$3,868,000	\$1,984,000	
Current liabilities.....	2,362,000	2,181,000	
Working capital (deficit).....	1,506,000	(197,000)	
Total assets.....	5,289,000	2,922,000	
Accumulated deficit.....	(53,656,000)	(56,817,000)	
Stockholder's equity	2,847,000	680,000	

RISK FACTORS

Before you invest in our common stock, you should be aware of the risks described below which constitute material risks to potential investors. You should consider carefully these risk factors together with all of the other information included in this prospectus before you decide to invest in our common stock. If any of the following risks actually occurs, our business, financial condition and results of operations could suffer, in which case the trading price of our common stock could decline. No investment should be made by any person who is not in a position to lose the entire amount of his investment.

Special Note Regarding Forward-Looking Statements

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Some of the information in this prospectus may contain forward-looking statements. Such statements can be identified by the use of forward-looking terminology such as "may," "will," "expect," "anticipate," "estimate," "continue" or other similar words. These statements discuss future expectations, contain projections of results of operations or of financial condition or state other "forward-looking" information. When considering such forward-looking statements, you should keep in mind the risk factors and other cautionary statements in this Prospectus. The risk factors noted in this section and other factors noted throughout this prospectus, including certain risks and uncertainties, could cause our actual results to differ materially from those contained in any forward-looking statement.

Our auditors have expressed substantial doubt about our ability to continue as a going concern.

Due to our significant recurring losses and our inability to generate sufficient cash flows from operations to satisfy our liabilities and sustain operations, our auditors have expressed substantial doubt about our ability to continue as a going concern. Although we have had success in raising working capital from the sale of our common stock in the past, the going concern language in our auditors' report could negatively affect our ability to raise such funds in the future. Some investors are unwilling to invest with companies that have going concern language in the auditors' report and others demand substantial discounts from the market price. Unless we are able to raise additional working capital through the sale of our common stock, we will not be able to continue the development of our products nor will we be able to pay our existing current liabilities, which could result in protection under bankruptcy laws. Under certain conditions, including but not limited to having judgments rendered against us in a court of law, a group of creditors could force us into bankruptcy due to our inability to pay the liabilities arising out of such judgments. At this time, we are unable to assess the likelihood that we would seek bankruptcy protection in the near future. There can be no assurance that we will be successful in raising working capital from the sale of our common stock.

We have limited working capital, have accumulated significant losses, and expect our losses to continue.

As of December 31, 2003, we had a deficit working capital of \$(197,000). As of September 30, 2004, our working capital was \$33,000. Our accumulated deficit was \$56,817,000 as of December 31, 2003, and \$56,629,000 as of September 30, 2004. We had a net loss of \$11,155,000 for the fiscal year ended December 31, 2002 and \$3,161,000 for the fiscal year ended December 31, 2003, but a net profit of \$188,000 for the nine months ended September 30, 2004. Our losses have resulted principally from costs incurred in connection with research and development, including clinical trials, of the laser surgery

system. We did not sell medical products until late 1992. Our ability to become profitable largely depends on successfully developing clinical applications and obtain regulatory approvals for our laser surgery products, including the Photon(TM) laser system, and to effectively market such products. The problems and expenses frequently encountered in developing new products and the competitive industry in which we operate will impact whether we are successful. We may never achieve profitability. Furthermore, we may encounter substantial delays and unexpected expenses related to research, development, production, marketing, regulatory matters or other unforeseen difficulties.

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Because our securities trade on the OTC Bulletin Board, your ability to sell your shares in the secondary market may be limited.

Since June 26, 2003, our shares have traded on the OTC Bulletin Board. As a result, it may be more difficult for an investor to dispose of our securities, or to obtain accurate quotations on their market value. Furthermore, the prices for our securities may be lower than might otherwise be obtained. On October 8, 2002, we received a notice from Nasdaq's Listing Qualifications staff that for the previous 30 consecutive trading days, the price of our common stock closed below the minimum \$1.00 per share requirement for continued inclusion on Nasdaq. The notice further provided that if at anytime before April 7, 2003, the bid price of our common stock closed at \$1.00 or more for a minimum of 10 consecutive trading days, we would be notified by the staff that we comply with such rule.

On April 15, 2003, we received notice of a determination by Nasdaq's Listing Qualifications staff that we failed to comply with the minimum bid price rules for continued listing set forth in Nasdaq's rules. Specifically, the notice stated that we have not regained compliance with the minimum \$1.00 closing bid price per share requirement (noting that pursuant to the October 8, 2002, notice from the Nasdaq Listing Qualifications staff, we were provided 180 calendar days, or until April 7, 2003, to regain compliance with this requirement) and we do not qualify with the \$5,000,000 shareholders equity, \$50,000,000 market value of listed securities or \$750,000 net income from continuing operations requirement for an additional 180 calendar day compliance period to comply with Nasdaq's rules. The April 15, 2003, notice further stated that as of December 31, 2002, we reported stockholders' equity of \$2,847,000 and net losses from continuing operations of approximately \$11,155,000, and as of April 14, 2003, the market value of our listed securities was \$4,208,108. Accordingly, our common stock would be delisted from the Nasdaq SmallCap Market at the opening of business on April 24, 2003. Separately, Nasdaq informed us that listing fees of \$22,500 and \$18,000 under Rule 4310(c)(13) are owed to the Nasdaq SmallCap Market.

We requested an oral hearing before a Nasdaq Listing Qualifications Panel to review the staff's determination. The request automatically stayed the delisting of our common stock. On April 23, 2003, we received formal notice from Nasdaq that a hearing to consider our appeal would be held on May 29, 2003. On May 29, 2003, Dr. Jeffrey F. Poore, our former President and Chief Executive Officer; Randall A. Mackey, our Chairman of the Board; and Dr. David M. Silver, a director of the company, attended an oral hearing before a Nasdaq Listing Qualifications Panel in Washington, D.C. At the hearing Dr. Poore presented to the panel a definitive plan both for regaining compliance with the particular deficiencies cited in the April 15, 2003, letter from the Nasdaq Listing Qualifications staff and sustaining long-term compliance with the Nasdaq Marketplace Rules, including all applicable maintenance criteria. On June 24, 2003 we received notification from the Nasdaq Listing Qualifications Panel that we were to be delisted from the Nasdaq Stock Market effective June 26, 2003. Our securities trade on the OTC Bulletin Board effective June 26, 2003. Because our securities are delisted from the Nasdaq SmallCap Market and now trade on the OTC Bulletin Board, additional sales requirements on broker-dealers will adversely affect the ability of purchasers to sell our securities and the trading price of our securities could decline.

Moreover, because our securities currently trade on the OTC Bulletin Board, they are subject to the rules promulgated under the Securities Exchange Act of 1934, as amended, which impose additional sales practice requirements on broker-dealers that sell securities governed by these rules to persons other than established customers and "accredited investors" (generally, individuals with a net worth in excess of \$1,000,000 or annual individual income exceeding \$200,000 or \$300,000 jointly with their spouses). For such transactions, the broker-dealer must determine whether persons that are not established customers

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or accredited investors qualify under the rule for purchasing such securities and must receive that person's written consent to the transaction prior to sale. Consequently, these rules may adversely affect the ability of purchasers to sell our securities and otherwise affect the trading market in our securities.

Because our shares may be deemed "penny stocks," you may have difficulty selling them in the secondary trading market.

The Commission has adopted regulations which generally define a "penny stock" to be any non-Nasdaq equity security that has a market price (as therein defined) less than \$5.00 per share or with an exercise price of less than \$5.00 per share, subject to certain exceptions. For any transactions by broker-dealers involving a penny stock (unless exempt), rules promulgated under the Securities Exchange Act of 1934 require delivery, prior to a transaction in a penny stock, of a risk disclosure document relating to the penny stock market. Disclosure is also required to be made about compensation payable to both the broker-dealer and the registered representative and current quotations for the securities. Furthermore, monthly statements are required to be sent disclosing recent price information for the penny stocks.

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If the litigants in the class action lawsuits succeed on any of their claims and we are denied coverage for the lawsuits under our Directors and Officers Liability and Company Insurance Policy, we would be unable to pay such liability, and we would be forced to seek bankruptcy protection.

On May 14, 2003, a complaint was filed in the United States District Court, District of Utah, captioned Richard Meyer, individually and on behalf of all others similarly suited v. Paradigm Medical Industries, Inc., Thomas Motter, Mark Miehle and John Hemmer, Case No. 2:03 CV00448TC. The complaint also indicates that it is a "Class Action Complaint for Violations of Federal Securities Law and Plaintiffs Demand a Trial by Jury." We have retained legal counsel to review the complaint, which appears to be focused on alleged false and misleading statements pertaining to the Blood Flow Analyzer(TM) and concerning a purchase order from Valdespino Associates Enterprises and Westland Financial Corporation. More specifically, the complaint alleges that we falsely stated in our Securities and Exchange Commission filings and press releases that we had received authorization to use an insurance reimbursement CPT code from the CPT Code Research and Development Division of the American Medical Association 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 we never received the CPT code from the American Medical Association at any time. Nevertheless, it is alleged that we continued to misrepresent in our SEC filings and press releases that we had received the CPT code. It is also alleged that we have never made a full, corrective disclosure with respect to this alleged misstatement.

The complaint also alleges that on July 11, 2002, we issued a press release falsely announcing that we had received a purchase order from Valdespino Associates Enterprises and Westland Financial Corporation for 200 sets of our entire portfolio of products, with \$70 million in systems to be delivered over a two-year period, then another \$35 million of orders to be completed in the third year. The complaint further alleges that we had never received a true purchase order for our products. As a result of these alleged misstatements, the

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complaint contends that the price of our shares of common stock was artificially inflated during the period from April 25, 2001 through May 14, 2003, and the persons who purchased or retained our common shares during that period suffered substantial damages. The complaint requests judgment for unspecified damages, together with interest and attorney's fees.

We dispute 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, we issued a press release that stated we had received authorization to use common procedure terminology or CPT code number 92120 for our Blood Flow Analyzer(TM). This press release was based on a letter we received from the CPT Editorial Research and Development Department of the American Medical Association 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 our 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. We are endeavoring to obtain reimbursement by insurance payors in other states where there is currently no reimbursement being made. We believe we have continued to correctly represent in our Securities and Exchange Commission filings that the CPT Editorial Research and Development Department of the American Medical Association has advised us that CPT code number 92120 is the appropriate CPT code for our Blood Flow Analyzer(TM), for reimbursement purposes for doctors using the device.

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

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

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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 our common stock was artificially inflated and the persons who purchased our 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 our securities in the class action suit filed on July 11, 2003, stated that our 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 our 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 our securities in the consolidated class action. On June 28, 2004, a consolidated amended class action complaint was filed on behalf of purchasers of our securities. The consolidated complaint is similar to the three class action complaints and alleges that we made false representations regarding the CPT code for the Blood Flow Analyzer(TM), but it includes additional allegations that we 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 we made false statements regarding the purchase order from Westland Financial Corporation and Valdespino Associates Enterprises. We believe the consolidated complaint is without merit and intend to vigorously defend and protect our interests in the case.

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

We have paid \$30,000 to U.S. Fire toward satisfaction of the \$250,000 retention that is applicable to the consolidated cases. We have advised U.S. Fire that we cannot pay the \$250,000 retention due to our current financial circumstances. As a consequence, on January 8, 2004, we entered into a non-waiver agreement with U.S. Fire in which U.S. Fire agreed to fund and advance our retention obligation in consideration for which we have agreed to reimburse U.S. Fire the sum of \$5,000 a month for a period of six months, with the first of such payments due on February 15, 2004. Thereafter, commencing on August 15, 2004, we are required to reimburse U.S. Fire the sum of \$10,000 per month until the entire amount of \$250,000 has been paid to U.S. Fire. We have made payments to U.S. Fire in the aggregate amount of \$30,000, of which our last

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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 we or our former officers and directors named in the consolidated cases are not entitled to coverage under the policy, or that it is entitled to rescind the policy, or should we be declared in default under the non-waiver agreement, for not making the monthly payments in a timely manner that are owed to U.S. Fire, then we agree to pay U.S. Fire, on demand, the full amount of all costs advanced by U.S. Fire, except for those amounts that we may have reimbursed to U.S. Fire pursuant to the monthly payments due under the non-waiver agreement. Moreover, if U.S. Fire denies coverage for the consolidated cases under the policy, we would owe our 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.

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

On July 10, 2003, a complaint was filed in the United States District Court, District of Utah captioned Innovative Optics, Inc. and Barton Dietrich Investments, L.P. v. Paradigm Medical Industries, Inc., Thomas Motter, Mark Miehle and John Hemmer, Case No. 2:03 CV 00582DB. The complaint claims that Innovative and Barton entered into an asset purchase agreement with us on January 31, 2002, in which we agreed to purchase all the assets of Innovative in consideration for the issuance of 1,310,000 shares of the Company's common stock to Innovative. The complaint claims we breached the asset purchase agreement. The complaint also claims that we allegedly made false and misleading statements pertaining to the Blood Flow Analyzer(TM) and concerning a purchase order from Valdespino Associates Enterprises and Westland Financial Corporation. The purpose of these statements, according to the complaint, was to induce

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

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

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Innovative and Barton suffered damages in an unspecified amount to be proven at trial. We filed an answer to the complaint and also filed counterclaims against Innovative and Barton for breach of contract. We believe the complaint is without merit and intend to vigorously defend and protect our interests in the action. If we are not successful in defending and protecting our interests in this action, and a judgment for substantial damages is entered against us, and U.S. Fire denies coverage in the litigation under the Directors and Officers Liability and Company Reimbursement Policy, we would be unable to pay such liability and, as a result, would be forced to seek bankruptcy protection.

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

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

On December 8, 2004, we announced that verbal agreements have been made to settle certain lawsuits brought against us and our former executive officers, Thomas F. Motter, Mark R. Miehle and John W. Hemmer. The following are the lawsuits that have been verbally settled:

- o The class action lawsuit filed on May 14, 2003 by Richard Meyer, individually and on behalf of all others similarly situated, against us and certain former executive officers in the United States District Court for the District of Utah, which was consolidated into a single action on June 28, 2004 with two other class action lawsuits -- the class action lawsuit filed by Michael Marone on June 2, 2003 and the class action lawsuit filed by Lidia Milian on July 21, 2003 against us and our former executive officers in the same court. The consolidated action is captioned In re Paradigm Medical Industries Securities Litigation, with lead plaintiffs Rock Solid Investments of Miami, Inc., Brito & Brito Accounting, Inc. and Joseph Savanjo.
- o The class action lawsuit filed on October 14, 2003 by Albert

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Kinzinger, Jr., individually and on behalf of all others similarly situated, in the Third District Court for the State of Utah against us and certain former executive officers.

- o The lawsuit filed on July 10, 2003 by Innovative Optics, Inc. against us and certain former executive officers.

Under the terms of the settlement agreements, U.S. Fire Insurance Company, which issued a Directors and Officers Liability and Company Reimbursement Policy to us for the period from July 10, 2002 to July 10, 2003, has agreed to pay \$2,500,000 in cash to the classes in the class action lawsuits and to Innovative Optics, Inc. in settlement of these lawsuits. Under the terms of settlement, we are to pay U.S. Fire the sum of \$220,000, representing the remaining amount owing under a \$250,000 retention obligation in the insurance policy, and to execute a policy release in favor of U.S. Fire as to coverage under the insurance policy. The remaining retention obligation of \$220,000 is payable in monthly installments of \$10,000 until the entire amount owing is paid.

The parties to the settlement and their respective legal counsel are in the process of completing written settlement agreements to memorialize the terms of the verbal agreements. Settlement of the lawsuits is subject to certain conditions, which include but are not limited to the following:

- o Each of the settlement classes shall, in their respective actions and at their own expense, obtain preliminary approval of the terms of settlement by both the court in the federal action and the court in the state action.

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- o After obtaining a court order granting preliminary approval of the terms of settlement in the respective actions, each of the classes are required, in their respective actions and at their own expense, to provide notice to all persons that are potential members of the federal settlement class and the state settlement class, respectively.
- o The federal settlement class members and the state settlement class members shall have a period of time from the date of the mailing of such notice in which to "opt-out" of the federal settlement class and state settlement class, respectively.

Under the terms of the settlement, U.S. Fire has the option to terminate the settlement agreements if the cumulative dollar value of the claims held by individuals or entities that "opt-out" of the federal settlement class or the state settlement class exceeds \$250,000. However, if such "opt-outs" exceed \$250,000, the parties in the class have a period of time to cure by reducing the amount of "opt-outs" to less than \$250,000.

If U.S. Fire exercises its option to terminate the settlement agreements in the event the "opt-outs" exceed \$250,000 and the parties are unable to reduce the amount of "opt-outs" within an allowable time period, the terms and conditions of the settlement agreements will have no further force and effect, and all parties will be restored to their respective positions in the various legal actions prior to such settlement.

On January 26, 2005, we entered into a written settlement agreement to settle the lawsuit that Innovative Optics, Inc. and Barton Dietrich Investments,

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L.P. brought against us and our former executive officers, Thomas F. Motter, Mark R. Miehle and John W. Hemmer. Under the terms of the settlement, U.S. Fire has agreed to pay Innovative Optics, Inc. and Barton Dietrich Investments, L.P. the sum of \$367,500. Payment of this amount by U.S. Fire is contingent, however, upon the settlement of a federal court class action lawsuit and a state court class action lawsuit against us and our former executive officers.

As a condition to the settlement agreement with Innovative Optics, Inc. and Barton Dietrich Investments, L.P., the courts in the federal court class action lawsuit and the state court class action lawsuit must have entered orders granting final approval of the settlements reached in those respective actions, and such orders must have become final and non-appealable. In addition, we and our former executive officers agree to execute a policy release in favor of U.S. Fire. The policy release is to be in a form agreed to by the parties.

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

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

If the litigants in other lawsuits succeed on any of their claims, we may be unable to pay such liability and we would be forced to seek bankruptcy protection.

We have been involved in other lawsuits besides the class action lawsuits. If the litigants in these other lawsuits succeed on any of their claims, we may be unable to pay such liability and, as a result, we could be forced to seek bankruptcy protection. These other lawsuits include (i) the complaint filed against us on June 20, 2003 by Citicorp Vendor Finance, Inc., formerly known as Copelco Capital, Inc., alleging that \$49,626 plus interest is due for the leasing of two copy machines; (ii) the complaint filed against us on August 3, 2003, by Corinne Powell, a former employee, alleging that at the time we laid her off, she was owed \$2,030 for business expenses, \$11,063 for accrued vacation days, \$12,818 for unpaid commissions, the fair market value of 50,000 stock options exercisable at \$5.00 per share that she claims she was prevented from exercising, plus attorney's fees and a wage penalty under Utah law; (iii) the complaint filed against us on September 10, 2003 by Larry Hicks for payments due under a consulting agreement in the aggregate amount of \$110,000 minus whatever we have paid to him prior to such termination, plus attorney's fees and a wage penalty under Utah law; and (iv) the complaint brought against us on or about May 25, 2004 by Jeffrey F. Poore, former President and Chief Executive Officer of the company, alleging that we unlawfully terminated his employment with us and, as a result, he demands judgment against us for \$350,000, representing his annual salary for the two remaining years under the employment agreement, for money judgment based on the value of his benefits for the two remaining years under the employment agreement, and for money judgment equal to the value of the stock options granted to him under the employment agreement.

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If we are unable to obtain additional capital, we would be required to eliminate certain activities that would adversely effect our operations.

We may require substantial funds for various purposes, including continuing research and development, expanding clinical trials, completing the FDA approval process for our products (including the Photon(TM) laser system), and manufacturing and marketing our existing products. We will need to seek additional capital, possibly through public or private sales of our securities, in order to fund our activities on a long-term basis. Adequate funds may not be available when needed or on terms acceptable to us. Insufficient funds may require us to delay, scale back or eliminate certain or all of our research and development programs or to license third parties to commercialize products or technologies that we would otherwise seek to develop ourselves, which may materially adversely affect our continued operations.

Our research activities may not result in any commercially profitable products.

The science and technology of medical products, including lasers, is rapidly evolving. Our medical systems may require significant further research, development, testing and regulatory clearances. They are also subject to the risks of failure inherent in the development of products based on innovative technologies. These risks include the possibility that any or all of the proposed products will prove to be ineffective or unsafe; that they fail to receive necessary regulatory clearances; that the proposed products are uneconomical; that others hold proprietary rights which preclude us from marketing such products; or that others market better products. Accordingly, we are unable to predict whether our research and development activities will result in any commercially profitable products. Further, due to the extended testing and regulatory review process required, we may be unable to sell our

current and proposed products. There is also no guarantee that we will be able to develop and sell a glaucoma surgery system.

We are uncertain of obtaining FDA approval for our Photon(TM) laser system and further development of the Photon(TM) is on hold until our financial situation improves, and we may lose our rights to manufacture or sell the Photon(TM) laser system if we are unable to agree on the correct method of calculating royalty payments under a license agreement.

We are subject to substantial regulation by the Food and Drug Administration or FDA and other federal and state regulatory agencies. FDA regulations require us to obtain either 510(k) clearance or pre-marketing approval prior to marketing a product in the United States. We are also subject to foreign regulation and must receive various types of approvals from foreign government agencies prior to selling our products in some countries. The clearance and approval processes for both the FDA and foreign regulatory authorities are costly, time consuming and uncertain. In addition, we are required to obtain FDA approval before exporting a device that has not received FDA marketing clearance or approval. We may never be able to obtain these required government approvals. Delays or failure to obtain such approvals would materially and adversely effect us, as would changes in existing requirements. We have received 510(k) clearance from the FDA for our ultrasonic surgery systems allowing us to sell both devices in the United States. We have also received 510(k) clearance to market our Blood Flow Analyzer(TM).

In May 1995, we were granted an investigational device exemption for our Photon(TM) laser system allowing us to conduct clinical studies in support of our application with the FDA to obtain approval to market the system. During the clinical trials, we discovered that the Photon(TM) laser system may not

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effectively remove hard (dense or impacted) cataracts. In May 1998, we received FDA clearance to conduct clinical tests on soft cataracts. We believe the FDA will approve our 510(k) predicate device application for the Photon(TM) laser system because in the United States most cataracts are removed before tissue hardens. We received an FDA warning letter in August 2000 concerning deficiencies in the Phase I clinical trials and, after making several submissions to the FDA, we received a letter from the FDA in February 2001 stating that the deficiencies had been corrected and the clinical trials could continue.

We have completed the authorized clinical studies and, in October 2001, made a supplemental submission to the FDA regarding the 510(k) application. We received a preliminary review from the FDA of our supplemental submission in December 2001 and submitted additional clinical information to the FDA on February 6, 2002. On May 7, 2002, we received a letter from the FDA requesting further clinical information. We have generated additional clinical information in response to the letter and are uncertain if we 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. As reflected in the results for the fiscal year ended December 31, 2003, diagnostic products are currently our major focus and the Photon(TM) and other extensive research and development projects have been put on hold pending future evaluation when our financial position improves. Our focus is not on any specific diagnostic product or products, but rather on our entire group of diagnostic products.

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We have also received FDA approval to manufacture and export the Photon(TM) laser system internationally. However, we have not yet obtained approval from some foreign countries to market the laser product where approval is necessary. We anticipate that many contemplated applications of our currently existing and planned products will be subject to the lengthy regulatory approval process, including preclinical studies, clinical trials and extensive regulatory review. This process could take many years and require the expenditure of substantial resources.

The Photon(TM) laser system 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 us in 1997. The United States patent expired in September 2004. We secured the exclusive worldwide rights to this patent from PhotoMed by means of a license agreement dated July 7, 1993. The license agreement expires when the United States patent rights expire in September 2004. PhotoMed and Dr. Eichenbaum brought legal action against us on September 11, 2000 involving an amount of royalties that are allegedly due and owing to them from the sale of equipment by us under the license agreement.

We have paid \$14,736 to bring all royalty payments up to date through June 30, 2001. We have been working with PhotoMed and Dr. Eichenbaum to insure that the royalty calculations have been correctly made. It is anticipated that once the parties agree on the correct royalty calculations, the legal action will be dismissed. However, if the parties are unable to agree on a method of calculating royalties, there is risk that PhotoMed and Dr. Eichenbaum may amend the complaint to request termination of the license agreement and, if successful, we would lose our rights to manufacture or sell the Photo(TM) laser system.

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Purchasers of our common shares could experience dilution from our tendering puts under a private equity line of credit agreement with Triton West.

On June 30, 2000, we entered into a private equity line of credit agreement with Triton West Group, Inc., in which Triton agreed to provide an amount up to \$20,000,000 to us in order to purchase put common shares pursuant to the terms and conditions of the agreement. Under the agreement, we may elect for a period of three years from the effective date of December 8, 2000 (the date on which the Securities and Exchange Commission declared effective a registration statement registering shares to be purchased by Triton on put transactions with us) to exercise our right to tender a put notice to Triton. The put notice requires Triton to purchase shares of our common stock at 88% of the market price on the trading day immediately following the valuation period, which is a period of five trading days beginning two days before the trading day on which the put notice is deemed to be delivered and two trading days after such date. Under certain conditions, the purchase price will be reduced to 85% of the market price of our common stock. The agreement provides certain restrictions on the tendering of puts. The maximum amount of each put (which may vary from \$750,000 to \$2,000,000) is to be determined according to a schedule based on the trading price of our common stock at the time and the average 30-day volume of such shares. There must be a minimum of 15 business days between puts. Moreover, a registration statement must be effective registering the shares of common stock covered by the put. There may be significant dilution associated with tendering put notices under the agreement. Because a registration statement is not effective registering the shares issuable under the equity line of credit, our equity line of credit is currently not available as a source of equity. The equity line of credit agreement expired by its terms on December 8, 2003, but the Company is currently in the process of renewing the agreement.

Purchasers of our Common shares will experience dilution if a threatened lawsuit by Douglas A. MacLeod, M.D. and related entities succeeds on its claims and we are required to issue additional common shares and warrants to them.

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

Our products may become obsolete due to rapid technological change.

Our market is subject to rapid technological change. Development by others of new or improved products, processes or technologies may make our products obsolete or less competitive. Accordingly, we must continue investing in research and development on our existing products and to develop new products. Despite such investment, our current or proposed products may be unsuccessful.

Our Photon(TM) laser system could receive competition from other laser systems

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that are well financed with well- recognized trade names.

Our Photon(TM) laser system will potentially receive competition from other laser systems, such as excimer, holmium (Ho:YAG), Erbium (Er:YAG), Nd:YLF (Neodymium:Yttrium-Lithium-Fluoride) or lasers of other wave lengths. Competition may also come from other medical devices and other surgical techniques. Further, the cataract surgical device industry is dominated by a small number of large competitors that are well established in the marketplace, have experienced management, are well financed and have a well recognized trade name related to their product lines. We may be unable to penetrate the existing market and acquire a sufficient market share to be profitable. Significant competitive factors that will affect future sales include regulatory approvals, performance, pricing, timely product shipment, safety, customer support, convenience of use and patient and general market acceptance.

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Our new products may incur unexpected production problems, which would impact our sales and profits.

New ventures, particularly those involved in a highly technical industry such as the medical industry, have substantial inherent risks. These risks are in three general areas: technical, mechanical and human. Notwithstanding any pre-production planning, new products can incur unexpected problems in full-scale production, which cannot always be foreseen or accurately predicted. Designs can become unworkable, for unpredicted reasons. Quality control and component sourcing failures can also be expected from time to time. Any business, including ours, is substantially dependent upon the capabilities and performance of both management, engineering and sales personnel. Mistakes in judgment or performance can be costly and, in certain instances, disabling. Therefore, management skill, experience, character and reliability are of significant importance.

Mistakes may occur in the design and manufacture of our products, which could prevent or limit the sales of such products.

The high-technology product line requires us to deal with suppliers and subcontractors supplying highly specialized parts, operating highly sophisticated and narrow tolerance equipment and performing highly technical calculations. Components must be custom designed and manufactured, which is not only complicated and expensive, but can also require a number of months to accomplish. Slight mistakes in either the design or manufacture can result in unsatisfactory parts that may not be correctable. Because our business requires the talents of various professions, mistakes from very slight oversights or miscommunications can occur, resulting not only in costly delays and lost orders, but also in disagreements regarding liability and, in any event, extended delays in production. Moreover, we rely on suppliers that are related to each other for parts and equipment. When dealing with related suppliers the terms on which parts and equipment are purchased may not be as favorable as could be obtained from unrelated third-party suppliers.

We are dependent upon a limited number of key suppliers for components and parts used in our products and the interruption in the supply of these components and parts could impede our ability to deliver our products to market.

We currently purchase components and parts used in our products from a limited number of key suppliers. Although we maintain alternative suppliers, our reliance on our 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

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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 our revenues to decline. In addition, any interruption or discontinuance in the supply of components or parts could have an adverse effect on our business, results of operation and financial condition. Further, a significant price increase from any of our principal suppliers could cause our profitability to decline if we cannot increase the prices of our products to our customers. Our principal suppliers include Capistrano Labs, U.S. Ultrasound and Anello.

No independent marketing studies have been made to confirm the commercial demand for the Photon(TM) laser system and the Blood Flow Analyzer(TM).

We believe that there is substantial commercial demand for our Photon(TM) laser system and our Blood Flow Analyzer(TM) for the eyes at a profitable price. However, this belief is solely based on our management's experience and judgment. At this time, there have been no independent marketing studies by independent professional marketing firms to reliably confirm the extent of this demand, the price ranges within which it exists and the amount of promotion necessary to exploit whatever demand does exist.

Our Photon(TM) laser system may not be accepted in the marketplace because it does not remove hard cataracts.

Our products may not be accepted in the marketplace. Such acceptance will depend on a number of factors including receiving regulatory approvals, demonstrating the safety, and advantages of our products over existing systems and techniques. Our Photon(TM) laser system may never gain market acceptance since the system does not effectively remove hard (dense or impacted) cataracts. Further, we may be unable to successfully market our products even if they perform successfully in clinical applications. Our Precisionist ThirtyThousand(TM) Workstation(TM) may not gain acceptance unless we can reduce or eliminate the vacuum surge and develop additional, complementary surgical devices for installation in that host system. Vacuum surge is a phenomenon that occurs when the tip of the ultrasonic needle is obstructed by target tissue, allowing pressure to build up and, if the pressure is not released, a rush of fluid goes from the chamber of the eye into the needle to equalize the pressure. The result can be complications to the eye such as posterior capsule rupture, iris capture and chamber collapse. We believe this phenomenon affects all other ultrasonic cataract removal systems currently on the market.

Our pending patents may not be perfected and our present or future patents may infringe upon the patents of others, which could restrict or prevent the manufacture and sale of our products.

We depend on our ability to license and obtain patents and on the adherence to confidentiality agreements executed by employees, consultants and third-parties to maintain the proprietary nature of our technology and to operate without infringing on the proprietary rights of others. A United States patent issued in 1987 to Daniel M. Eichenbaum, M.D. protects our laser probe. These patent rights expire in September 2004. Patents have also been granted to the Blood Flow Analyzer(TM) in the United States and the United Kingdom, to the Dicon(TM) Topographer in the United States, and to the Dicon(TM) Perimeter in the United States, the United Kingdom, Germany and Switzerland. The pending patents may not be perfected. Also, our present or future products may be found to infringe upon the patents of others. If our products are found to infringe on the patents, or otherwise impermissibly utilize the intellectual property of

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others, our development, manufacture and sale of such products could be severely restricted or prohibited. We may be required to obtain licenses to utilize such patents or proprietary rights of others and acceptable terms may be unavailable. If we do not obtain such licenses, the development, manufacture or sale of products requiring such licenses would be materially adversely affected. In addition, we could incur substantial costs in defending ourselves against challenges to our patents or infringement claims made by third parties or in enforcing any patents we may obtain.

Because patents only provide limited protection, others could produce and distribute products similar to the Photon(TM) laser system and the Blood Flow Analyzer(TM).

We rely on the protections for our products that we hope to realize under the United States and foreign patent laws. However, patents provide limited protections. We have a United States and Japanese patent on the hand-held probe design and applications for various foreign patents are either pending or planned, and the patents for the Blood Flow Analyzer(TM) for the eyes are reported by Ocular Blood Flow, Ltd. to have been approved in the United States and the United Kingdom. Similar devices, however, could be designed that do not infringe on our patent rights, but that are similar enough to compete against our patented products. Moreover, it is possible that an unpatented but prior existing device or design may exist that has never been made public and therefore is not known to us or the industry in general. Such a device could be introduced into the market without infringing on our current patent. If any such competing non-infringing devices are produced and distributed, our profit potential would be seriously limited, which would seriously impair our viability.

Some of our products may be denied reimbursement by third-party payors, such as government programs and private insurance plans.

We anticipate that our medical devices will generally be purchased by ophthalmologists and hospitals that will then bill various third-party payors, such as government programs and private insurance plans, for the health care services provided to their patients. Government agencies generally reimburse at a fixed rate based on the procedure performed. Some of the potential procedures for which our medical devices may be used, however, may be denied reimbursement as elective. In addition, third-party payors may deny reimbursement if they determine that the use of our products was unnecessary, inappropriate, not cost-effective, experimental or used for a non-approved indication. Certain purchasers of our Blood Flow Analyzer, (TM), for example, have had difficulty in obtaining reimbursement from insurance carriers. Even if we receive FDA clearances for our products, third-party payors may nevertheless deny reimbursement. Furthermore, third-party payors increasingly challenge the prices charged for medical products and services. Reimbursement from third-party payors may be unavailable or if available, that reimbursement may be limited when compared with reimbursement for competitive procedures, thereby materially adversely affecting our ability to profitably sell products. The market for our products could also be adversely affected by recent federal legislation that reduces reimbursements under the capital cost pass-through system utilized in connection with the Medicare program. Failure by hospitals and other users of our products to obtain reimbursement from third-party payors or changes in government and private third-party payors' policies toward reimbursement for procedures employing our products would have a material adverse effect on us.

Congress may introduce legislation that could result in price limits and utilization controls on our products.

Members of Congress have introduced legislation to change aspects of the delivery and financing of health care services. Such legislation to control or reduce public (Medicare and Medicaid) and private spending on health care, to

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reform the methods of payment for health care goods and services by both the public and private sectors, and to provide universal access to health care may be passed. We cannot predict what form this legislation may take or the effect of such legislation on our business. It is possible that the legislation ultimately enacted by Congress will contain provisions resulting in price limits and utilization controls which may reduce the rate of increase in the growth of the ophthalmic laser market or otherwise adversely affect our business. It is also possible that future legislation could result in modifications to the nation's public and private health care insurance systems that will affect reimbursement policies in a manner adverse to us. We also cannot predict what other legislation relating to our business or the health care industry may be enacted, including legislation relating to third-party reimbursement, or what effect legislation may have on the results of our operations.

Our product liability insurance could be inadequate to cover liabilities if we face significant product liability claims against us.

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The nature of our business exposes it to risk from product liability claims and there can be no assurance that we can avoid significant product liability exposure. We maintain product liability insurance providing coverage up to \$2,000,000 per claim with an aggregate policy limit of \$2,000,000. There is substantial doubt that this amount of insurance would be adequate to cover liabilities should we face significant claims. A successful products liability claim brought against us could have a material adverse effect on our business, operating results and financial condition. Further, product liability insurance is becoming increasingly expensive, and there can be no assurance that we will successfully maintain adequate product liability insurance at acceptable rates, or at all. Should we be unable to maintain adequate product liability insurance, our ability to market our products would be significantly impaired. Any losses that we may suffer from future liability claims or a voluntary or involuntary recall of our products and the damage that any product liability litigation or voluntary or involuntary recall may do to the reputation and marketability of our products would have a material adverse effect on our business, operating results and financial condition.

Our future products sales in foreign countries could be adversely affected by a significant increase in value of the U.S. dollar against local currencies, economic and political instability, and changes in the regulatory processes and other regulations.

We anticipate that a significant portion of our future product sales will be in foreign countries. Because we quote prices for our products and accept payment on sales principally in U.S. dollars, any significant increase in the value of the U.S. dollar against local currencies may make our products less competitive with foreign products. The economic and political instability of some foreign countries also may affect the ability of ophthalmologists and others to purchase our products, or the ability of potential customers to pay for the procedures for which our products are used. In addition, other specific risks in doing business in foreign countries include changes in the regulatory processes affecting our products, in controls governing foreign payments by our customers, and in regulations, taxes and customs duties or requirements that may be imposed on the purchase of our products. The foreign countries where our products are sold include but are 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. Certain of countries may experience political, economic or

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social instability, which could adversely affect our sales.

The market price of our securities could fluctuate significantly.

Our common stock and Class A warrants were delisted on The Nasdaq SmallCap Market effective June 26, 2003 and currently trade on the OTC Bulletin Board. Factors such as announcements by us of the regulatory status of products, quarterly variations in our financial results, the gain or loss of material contracts, changes in management, regulatory changes, trends in the industry or stock market and announcements by competitors, among other things, could cause the market price of such securities to fluctuate significantly.

We may issue preferred shares with preferences in an equal or prior rank to existing preferred shares.

Our certificate of incorporation authorizes the issuance of shares of "blank check" preferred stock, which will have such designations, rights and preferences as our board of directors may determine from time to time. Accordingly, our Board of Directors is empowered, without stockholder approval (but subject to applicable government regulatory restrictions), to issue preferred stock with dividend, liquidation, conversion, voting or other rights that could adversely affect the voting power or other rights of the holders of our common stock. Those terms and conditions may include preferences on an equal or prior rank to existing preferred stock. Those shares may be issued on such terms and for such consideration as the board then deems reasonable and such stock shall then rank equally in all aspects of the series and on the preferences and conditions so provided, regardless of when issued. In the event of such issuance, the preferred stock could be utilized, under certain circumstances, as a method of discouraging, delaying or preventing a change in control of our company. As of January 31, 2005, the following preferred shares were issued and outstanding: 5,627 shares of Series A preferred stock convertible into 6,753 common shares; 8,986 shares of Series B preferred stock convertible into 10,783 common shares; no shares of Series C preferred stock; 5,000 shares of Series D preferred stock convertible into 8,750 common shares; 1,000 shares of Series E preferred stock convertible into 53,333 common shares; 4,598.75 shares of Series F preferred stock convertible into 245,267 common shares; and 1,726,560 shares of Series G preferred stock convertible into 1,726,560 common shares.

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Our preferred shares have rights that amount to a preference over the shares of this offering.

Our preferred shares have dividend and liquidation rights that amount to preferences over the shares of this offering. We must pay any cash dividends to our holders of preferred shares before paying cash dividends to the holders of the shares of this offering. The dividend rights of our preferred shares are as follows: for Series A and Series B preferred shares, \$.24 per share per annum payable, at our option, in cash from surplus earnings; for Series C preferred shares, 12% non-cumulative preferred shares payable, at our option, in common stock or cash from surplus earnings; and for Series D, E, F and G preferred shares, 8% non-cumulative preferred dividends payable, at our option, in common stock or cash from surplus earnings. Upon our liquidation, we must pay preferential distributions to our preferred shareholders before paying any distributions to holders of the shares of this offering. The liquidation rights of our preferred shares are as follows: for Series A preferred shares, \$1.00 per share, plus accrued and unpaid dividends; for Series B preferred shares, \$4.00 per share, plus accrued and unpaid dividends; for Series C preferred shares, the stated value of \$100.00 per share, plus declared but unpaid dividends; for

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Series D preferred shares, the stated value of \$1.75 per share, plus declared but unpaid dividends; for Series E, F, and G preferred shares, the greater of (i) the amount of distributions such shares would have received had the holders converted such preferred shares into common stock immediately prior to liquidation, or (ii) the stated value of \$100.00 per share, plus declared but unpaid dividends.

Exercise of outstanding options and warrants will dilute existing stockholders and could decrease the market price of our common stock.

As of January 31, 2005, we had issued and outstanding 27,764,868 shares of our common stock, shares of Series A, B, D, E, F and G preferred stock convertible into 2,051,446 shares of common stock, and outstanding options and warrants to purchase 8,565,444 additional shares of common stock. The existence of the outstanding preferred shares, options and warrants may adversely affect the market price of our common stock and the terms under which we could obtain additional equity capital. Included in the outstanding options is 1,000,000 options issued to John Y. Yoon, our President and Chief Executive Officer, under the terms of his employment agreement with us. These options are exercisable at \$.13 per share and vest in 36 equal monthly installments of 27,778 shares, beginning on April 30, 2004 until such shares are fully vested.

We do not expect to pay any cash dividends in the foreseeable future.

We issued a stock dividend on our Series A preferred stock and Series B preferred stock on January 8, 1996, to stockholders of record as of December 31, 1994. We have not paid any cash dividends on our common shares and do not expect to declare or pay any cash or other dividends in the foreseeable future so that we may reinvest earnings, if any, into the development of the business. The holders of our Series A preferred stock, Series B preferred stock, Series C preferred stock, Series D preferred stock, Series E preferred stock, Series F preferred stock and Series G preferred stock are entitled to non-cumulative cash dividends paid out of surplus earnings.

We may have continuing liability following our rescission offer in 1996 to Series B preferred shareholders.

We issued 493,000 shares of Series B preferred stock in 1994 and 1995. The Series B shares may not have been sold in compliance with certain aspects of California corporate law and federal and state securities laws. Concurrently with our July 1996 public offering, we provided the Series B shareholders with a rescission offer to repurchase all Series B preferred shares or rescission shares owned by the Series B shareholders. The Series B shareholders were offered the right to rescind their purchases and receive a refund of the price paid by them of \$4.00 per share plus an amount equal to the interest thereon at rates ranging from 6% to 12% per annum from the date the rescission shares were purchased to July 25, 1996, the date our public offering closed and each rescinding shareholder was paid by us. The original purchasers of approximately 93% of the Series B shares (460,250 shares) rejected the rescission offer by responding as requested in the rescission offer or by failing to return a response within 30 days of receiving the rescission offer. Two shareholders owning a combined total of 32,750 shares accepted the rescission offer. We purchased the 32,750 shares from the two shareholders accepting the rescission offer from the proceeds from our public offering.

The rescission offer was designed to reduce any type of contingent liability we may be subject to in connection with its private placement of Series B preferred stock. However, the rescission offer may not have fully relieved us from exposure to contingent liability under federal or state securities laws. Not every state statutorily provides for voluntary rescission offers. In addition, other states, although authorizing rescission offers, do not completely limit the liability of the offeror. Thus, we may have continuing

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liability in certain states following the rescission offer. Other than the payments in 1996 to the two shareholders accepting the rescission offer, we have made no additional payments thereunto as no other shareholder has accepted the rescission offer. Moreover, there has been no litigation by a shareholder involving the private offering of Series B preferred stock or the rescission offer. As of January 31, 2005, a total of 484,014 shares of Series B preferred stock have been converted into 580,817 shares of common stock. There are a total of 8,986 shares of Series B preferred stock issued and outstanding, which are convertible into 10,783 shares of common stock.

Because we failed to hold an annual shareholders meeting in fiscal 2003 and fiscal 2004, the Delaware Court of Chancery may order an annual meeting to be held upon request by a shareholder.

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We did not hold an annual meeting of the shareholders for fiscal 2003 or fiscal 2004 in order to avoid the costs of such a meeting, including the cost of preparing and mailing a proxy statement and annual report to each of our shareholders. There were no actions taken in 2003 or 2004 by the board of directors or our management that required shareholder approval. Under Delaware law, we are required to hold an annual shareholders meeting each year. A failure to hold an annual shareholders meeting does not affect otherwise valid corporate acts or work a forfeiture or dissolution of the company. Moreover, under Delaware law, directors continue to serve as directors despite lack of an annual shareholders meeting until the next annual shareholders meeting and until their successors have been elected and qualified. However, if we fail to hold an annual shareholders meeting for a period of 30 days after the date designated in our bylaws for the annual meeting, the Delaware Court of Chancery may order an annual meeting to be held upon the application of any of our shareholders. If an annual meeting is ordered to be held by the court, we would have to incur the costs of holding the meeting, including the cost of preparing and mailing the proxy statement and annual report to each of our shareholders. We anticipate holding an annual shareholders meeting in 2005.

We have indemnification agreements with certain officers and directors that may require us to indemnify them in a civil or criminal action.

Our certificate of incorporation eliminates in certain circumstances the liability of directors for monetary damages for breach of their fiduciary duty as directors. We have entered into indemnification agreements with certain directors and officers. Each such indemnification agreement provides that we will indemnify the indemnitee against expenses, including reasonable attorneys' fees, judgments, penalties, fines and amounts paid in settlement actually and reasonably incurred by him in connection with any civil or criminal action or administrative proceeding arising out of his performance of his duties as a director or officer, other than an action instituted by the director or officer. The indemnification agreements will also require that we indemnify the director or other party thereto in all cases to the fullest extent permitted by applicable law. Each indemnification agreement will permit the director or officer that is party thereto to bring suit to seek recovery of amounts due under the indemnification agreement and to recover the expenses of such a suit if he or she is successful.

Our Board of Directors has the right to issue additional shares of common stock and to create a new series of preferred stock that could dilute holders of common stock.

Our board of directors has the inherent right under applicable Delaware

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law, for whatever value the board deems adequate, to issue additional common shares up to the limit of shares authorized by the certificate of incorporation, and, upon such issuance, all holders of shares of common stock, regardless of when they are issued, thereafter generally rank equally in all aspects of that class of stock, regardless of when issued. Our board of directors likewise has the inherent right, limited only by applicable Delaware law and provisions of the Certificate of Incorporation to increase the number of preferred shares in a series, to create a new series of preferred shares and to establish preferences and all other terms and conditions in regard to such newly-created series. Any of those actions will dilute the holders of common shares and also affect the relative position of the holders of any series of any class. Current stockholders have no rights to prohibit such issuances nor inherent "preemptive" rights to purchase any such stock when offered.

USE OF PROCEEDS

Holders of our warrants are not obligated to exercise any of their warrants and holders of our options are not obligated to exercise any of their options. The closing bid price of our common shares on The Nasdaq SmallCap Market was \$.10 on February 1, 2005. Only 1,013,750 of our common shares underlying the warrants and options are exercisable for less than \$2.00 per share and such warrants are exercisable at between \$.15 and \$.25 per share. As a consequence, most of the outstanding warrants and options are not likely to be exercised unless the trading price increases substantially. All other shares of our common stock being registered are either outstanding or will be issued upon conversion of outstanding preferred stock and we will derive no proceeds from the conversions or subsequent resales of such shares.

If there are any net proceeds from this offering, we will use these net proceeds to fund working capital requirements. In the event sufficient proceeds are not received, our short term plan is to meet cash needs through external financing sources such as bank financing, a public offering of our securities and private offerings of debt and/or equity. We expect the cash flow from operations to provide additional funds for us as operating revenues increase.

The cost, timing and the amount of funds required for such uses by us cannot be previously determined at this time and will be based upon, among other things, competitive developments, the rate of our progress in product development, and the availability of alternative methods of financing. In addition, our Board of Directors has broad discretion in determining how the proceeds of this offering will be allocated.

DIVIDEND POLICY

We have never paid any cash dividends on our common stock and do not anticipate paying any cash dividends on our common stock in the foreseeable future. Dividends paid in cash pursuant to outstanding shares of our Series A, Series C, Series D, Series E, Series F and Series G preferred stock are only payable from our surplus earnings and are non-cumulative and therefore, no deficiencies in dividend payments from one year will be carried forward to the next. We currently intend to retain future earnings, if any, to fund the development and growth of our proposed business and operations. Any payment of cash dividends in the future on the common stock will be dependent upon our financial condition, results of operations, current and anticipated cash requirements, plans for expansion, restrictions, if any, under any debt obligations, as well as other factors that our board of directors deems relevant.

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CAPITALIZATION

The following table sets forth our capitalization on an actual basis as of December 31, 2003 and September 30, 2004.

		December 31, 2003

Long-term obligations.....	\$	61,000
Stockholders' Equity:		
Series A Preferred Stock, \$.001 par value per share; 500,000 shares authorized, 5,627 issued and outstanding.....		-
Series B Preferred Stock, \$.001 par value per share; 500,000 shares authorized, 8,986 issued and outstanding.....		-
Series C Preferred Stock, \$.001 par value per share; 30,000 shares authorized, 0 issued and outstanding.....		-
Series D Preferred Stock, \$.001 par value per share; 1,140,000 shares authorized, 5,000 issued and outstanding.....		-
Series E Preferred Stock, \$.001 par value per share; 50,000 shares authorized, 1,000 issued and outstanding.....		-
Series F Preferred Stock, \$.001 par value per share; 50,000 shares authorized, 5,623.75 and 4,597 issued and outstanding, respectively.....		-
Series G Preferred Stock, \$.001 par value per share; 2,000,000 shares authorized, 1,981,560 issued and outstanding.....		2,000
Common Stock, \$.001 par value per share; 80,000,000 shares authorized, 24,991,432 and 25,509,868 issued and outstanding, respectively.....		25,000
Additional paid-in-capital, common stock.....		57,470,000
Accumulated deficit.....		(56,817,000)
Total stockholders' equity		680,000
Total Capitalization.....	\$	741,000

MARKET FOR COMMON EQUITY AND RELATED STOCKHOLDER MATTERS

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

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Our common stock and Class A warrants trade on the OTC Bulletin Board under the respective symbols of "PMED.OB" and "PMEDW.OB." Prior to July 22, 1996, there was no public market for the common stock. From July 22, 1996 to June 25, 2003, our common stock and Class A warrants were listed on the Nasdaq SmallCap Market. Since June 25, 2003, our common stock and Class A warrants have traded on the OTC Bulletin Board. As of February 1, 2005, the closing sale prices of the common stock and Class A warrants were \$0.10 per share and \$.02 per warrant, respectively. The following are the high and low sale prices for the common stock and Class A warrants by quarter as reported by Nasdaq from January 1, 2000 to June 25, 2003 and by the OTC Bulletin Board since June 25, 2003.

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Period (Calendar Year)	Common Stock Price Range		Class A Warrant Price Range	
	High	Low	High	Low
2000				
First Quarter.....	14.50	6.88	6.50	2.00
Second Quarter.....	10.50	4.19	3.63	1.00
Third Quarter.....	6.19	3.38	2.00	1.00
Fourth Quarter.....	4.94	1.31	1.25	1.00
2001				
First Quarter.....	4.13	1.50	1.00	1.00
Second Quarter.....	3.50	1.61	.74	1.00
Third Quarter.....	2.75	1.86	.45	1.00
Fourth Quarter.....	3.08	1.94	.39	1.00
2002				
First Quarter.....	3.31	2.21	.38	1.00
Second Quarter.....	1.91	.60	.32	1.00
Third Quarter.....	1.50	.16	.20	1.00
Fourth Quarter.....	.30	.13	.10	1.00
2003				
First Quarter.....	.42	.14	.12	1.00
Second Quarter.....	.74	.14	.44	1.00
Third Quarter.....	.42	.18	.18	1.00
Fourth Quarter.....	.24	.15	.10	1.00
2004				
First Quarter.....	.21	.15	.05	1.00
Second Quarter.....	.16	.07	.05	1.00
Third Quarter.....	.12	.09	.03	1.00
Fourth Quarter.....	.12	.08	.02	1.00
2005				
First Quarter (through February 1, 2004).....	.10	.08	.02	1.00

Our Series A preferred stock, Series B preferred stock, Series C

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preferred stock, Series D preferred stock, Series E preferred stock, Series F preferred stock and Series G preferred stock are not publicly traded. As of January 31, 2005, there were 717 record holders of common stock, six record holders of Series A preferred stock, four record holders of Series B preferred stock, no record holders of Series C preferred stock, one record holder of Series D preferred stock, 14 record holders of Series E preferred stock, 52 record holders of Series F preferred stock, and two record holders of Series G preferred stock.

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

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

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SELECTED FINANCIAL DATA

The following table sets forth our selected financial data for the years ended December 31, 2002 and 2003, and the nine months ended September 30, 2003 and 2004. The selected financial data as of and for the years ended December 31, 2002 and 2003 are derived from our financial statements, which have been audited by Tanner & Co. The selected financial data as of and for the nine months ended September 30, 2003 and 2004 are derived from our unaudited quarterly financial statements. The following financial information should be read in conjunction with the Financial Statements, and related notes thereto.

	For the year ended December 31,		For the nine months September 30,	
	2002	2003	2003	2004
	----	----	----	----
Statement of Operations Data: -----				
Net Sales.....	\$5,368,000	\$3,059,000	\$2,225,000	\$2,225,000
Net cost of sales.....	4,210,000	2,086,000	1,237,000	1,237,000
Operating expenses.....	12,277,000	4,549,000	3,526,000	3,526,000
Operating loss.....	(11,119,000)	(3,576,000)	(2,538,000)	(2,538,000)
Other income (expense).....	(36,000)	415,000	(233,000)	(233,000)
Net income (loss).....	(11,155,000)	(3,161,000)	(2,305,000)	(2,305,000)
Net income (loss) applicable to common				

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shareholders.....	(11,155,000)	(3,431,000)	(2,305,000)
Net income (loss) per common share.....	\$ (.63)	\$ (.14)	\$ (.10)
Shares used in computing net loss per share	17,736,000	24,058,000	22,795,000

Balance Sheet Data:	As of December 31, 2002	As of December 31, 2003
-----	-----	-----
Current assets.....	\$3,868,000	\$1,984,000
Current liabilities.....	2,362,000	2,181,000
Working capital (deficit).....	1,506,000	(197,000)
Total assets.....	5,289,000	2,922,000
Accumulated deficit.....	(53,656,000)	(56,817,000)
Stockholder's equity	2,847,000	680,000

MANAGEMENT'S DISCUSSION AND ANALYSIS OR PLAN OF OPERATION

This report contains forward-looking statements and information relating to us that is based on beliefs of management as well as assumptions made by, and information currently available to management. These statements reflect its current view respecting future events and are subject to risks, uncertainties and assumptions, including the risks and uncertainties noted throughout the document. Although we have attempted to identify important factors that could cause the actual results to differ materially, there may be other factors that cause the forward-looking statements not to come true as anticipated, believed, projected, expected or intended. Should one or more of these risks or uncertainties materialize, or should underlying assumptions prove incorrect, actual results may differ materially from those described herein as anticipated, believed, projected, estimated, expected or intended.

Critical Accounting Policies

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

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

2. Delivery and performance have occurred. Unless the purchase order requires specific installation or customer acceptance, we recognize revenue when the product ships. If the purchase order requires specific installation or customer acceptance, we recognize revenue when such installation or acceptance has occurred. Title to the product passes to the customer upon shipment. This revenue recognition policy does not differ among the various different product lines. We guarantee the functionality of its product. If our product does not

function as marketed when received by the customer, we either make the necessary repairs on site or have the product shipped to us for the repair work. Once the product has been repaired and retested for functionality, it is re-shipped to the customer. We provide warranties that generally extend for one year from the date of sale. Such warranties cover the necessary parts and labor to repair the product as well as any shipping costs that may be required. We maintain a reserve for estimated warranty costs based on its historical experience and management's current expectations.

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

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

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

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

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

General

The following Management's Discussion and Analysis of Financial

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

We are engaged in the design, development, manufacture and sale of high technology diagnostic and surgical eye care products. Given the "going concern" status of Paradigm Medical, management has focused efforts on those products and activities that will, in its opinion, achieve the most resource efficient short-term cash flow. As seen in the results for the fiscal year ended December 31, 2003 and the nine months ended September 30, 2004, diagnostic products have been the major focus and the Photon(TM) and other extensive research and development projects have been put on hold pending future evaluation when our financial position improves. We do not focus on a specific diagnostic product or products but, instead, on this entire diagnostic product group. During the fiscal year ended December 31, 2003, management made certain adjustments to the financial statements, including a decrease in the reserve for obsolete or estimated non-recoverable inventory of \$484,000, consisting of an increase in the reserve of \$403,000 offset by a decrease of \$887,000 due to the sale of the SIStem(TM) and Odyssey(TM) product lines, which were fully reserved. We also recorded a net increase in the allowance for doubtful accounts receivable of \$123,000, impairment of intangibles of \$150,000, and increases in accruals to settle outstanding disputes in the amount of \$443,000. Although management believes these adjustments are sufficient, it will continue to monitor and evaluate our financial position and the recoverability of our assets.

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Our ultrasound diagnostic products include a P55 pachymetric analyzer, a P37 Ultrasound A/B Scan, a P40 UBM Ultrasound Biomicroscope and a P45 Plus UBM Biomicroscope, the technology for which was acquired from Humphrey Systems in 1998. We introduced the P45 Plus in the fall of 2000, which combines the A/B Scan, and the Biomicroscope into one machine. In addition, we market our Blood Flow Analyzer(TM) acquired in the purchase of Ocular Blood Flow Ltd. in June 2000. Other diagnostic products are the Dicon(TM) LD 400 Auto Perimeter and the Dicon (TM) CT 200 Corneal Topographer, which were acquired in the acquisition of Vismed d/b/a Dicon in June 2000. We purchased the inventory, design and production rights of the SIStem(TM), the Odyssey(TM) and the Surgetrol from Mentor Corporation in October 1999, which were designed to perform minimally invasive cataract surgery. In November 1999, we entered into a Mutual Release and Settlement Agreement with the manufacturer of the Precisionist ThirtyThousand(TM) in which we purchased the raw materials and finished goods inventory to bring the manufacturing of this product in-house. During the fourth quarter of 2003, we sold all inventory and rights associated with the SIStem(TM) and the Odyssey(TM) for \$125,000. This transaction resulted in sales of \$125,000 with \$0 cost of sales because a reserve for obsolete inventory had been recorded on all SIStem(TM) and Odyssey(TM) inventory.

Because of the "going concern" status of the company, management has focused efforts on those products and activities that will, in its opinion, achieve the most resource efficient short-term cash flow to the company. As reflected in the results for the fiscal year ended December 31, 2003 and the nine months ended September 30, 2004, diagnostic products are currently our major focus and the Photon(TM) and other extensive research and development projects have been put on hold pending future evaluation when the financial position of the company improves. Due to the lack of current evidence to support recoverability, we have recorded an inventory reserve to offset the inventory associated with the Photon(TM) and the Precisionist Thirty Thousand(TM) as well

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as certain other inventory items that are estimated to be non-recoverable due to the lack of significant turnover of such items in recent periods. We do not focus on a specific diagnostic product or products but, instead, on this entire product group.

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

Activities for the twelve months ended December 31, 2003 and 2002 and the nine months ended September 30, 2004, included sales of our products and related accessories and disposable products. In March 2003, the Company named a new president and chief executive officer, Jeffrey F. Poore. Mr. Poore was subsequently replaced by John Y. Yoon as President and Chief Executive Officer on March 18, 2004. The Company named a new vice president of sales and marketing, Ray Cannefax, during the first quarter of 2003, and a new vice president of finance and chief financial officer, Gregory C. Hill, during the second quarter of 2003. Mr. Hill resigned as vice president of finance and chief financial officer on December 5, 2003.

On May 7, 2002, we received a letter from the FDA requesting further clinical information regarding the Photon(TM). We are in the process of generating the additional clinical information in response to the letter. We cannot market or sell the Photon(TM) in the United States until FDA approval is granted. On November 4, 2002, we received FDA approval for expanded indications of use of the Blood Flow Analyzer(TM) for pulsatile ocular blood flow, volume and pulsatility equivalence index. Also, we are continuing our efforts to educate the payers of Medicare claims throughout the country about the Blood Flow Analyzer(TM), its purposes and the significance of our performance in patient care in order to achieve reimbursements to the providers. These efforts should lead to a more positive effect on sales.

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

The impact of this nonpayment by certain payors on our future operations is a lower volume of sales, particularly in those states where reimbursement is not yet approved or is delayed. Currently, there is

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reimbursement by insurance payors in 22 states and partial reimbursement in four other states. As insurance payors have the prerogative whether to provide

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reimbursement to doctors using the Blood Flow Analyzer(TM), we are continuing to work with insurance payors in states where there is no reimbursement to doctors using the CPT code to demonstrate the value of the instrument. However, some insurance payors are currently not providing reimbursement to doctors where a regional or state administrator of Medicare has elected not to provide Medicare coverage for the Blood Flow Analyzer(TM). We are continuing to work with the regional and state administrators of Medicare who have denied Medicare coverage for the Blood Flow Analyzer(TM) to demonstrate the value of the instrument.

There were a number of factors that contributed to the decrease in sales of the Blood Flow Analyzer (TM) and other products. September 11, 2001, the ensuing Afghanistan conflict, and the Iraq war had a significant impact on our international sales. The U.S. recessionary economic trend has impacted our domestic sales. Additionally, we restructured our sales organization and sales channels by decreasing our direct sales force who are full-time employees from 10 direct domestic sales representatives on January 1, 2003, to five direct sales employees on December 31, 2003. As of September 30, 2004, we had four direct domestic sales representatives. The dependent sales force was reduced because we do not have sufficient revenues to justify the larger direct sales force. One of the challenges for fiscal 2004 and 2005 will be the judicious reconstruction of the sales force in anticipation of increased sales. We are projecting an increase in revenues in 2004; however, there can be no assurance that such increase will occur. We are anticipating increased sales through three key activities. First, we plan to increase the number of our direct sales contacts. In our second quarter one full-time direct sales representative was added in Seattle, Washington to serve the Pacific Northwest market. Late in the second quarter we added another direct sales representative in Atlanta, Georgia.

Second, we will resume marketing campaigns with the development of advertising in the third quarter for placement in key industry publications. Additionally we will begin marketing via direct mail and telephone for feature enhancements and service contracts.

Third, we plan to release new products and services. Specifically, at the end of the second quarter, an improved version of the auto-perimeter was introduced as well as revenue-generating software upgrades to the existing base of auto-perimeter customers. Additional new products and partnerships are in development.

As of September 30, 2004, we had four direct domestic sales representatives in the United States, two of whom have been recently hired, and 28 ophthalmic and medical product distributors outside the United States. We hope to benefit from these two recently hired sales representatives in the United States as they gain familiarity, through training, of our diagnostic products. Due to concerns over the budget and the effectiveness of trade shows, we exhibited at only three trade shows during 2003 and one trade show through September 30, 2004. We monitor trade show attendance to determine the extent to which we will exhibit at future trade shows.

In April 2002, we announced the closure of our San Diego facility in anticipation of the termination of the lease for that location. The operations were transferred to the Salt Lake City facility. We incurred a reduction of force of 28 San Diego personnel. The consolidation was intended to save costs and to eliminate duplicities in functions and facilities that occurred with the

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acquisition of Dicon. The cost of the consolidation was approximately \$80,000.

In January 2002, we purchased certain assets and lease obligations of Innovative Optics, Inc. by issuing an aggregate of 1,272,825 shares of our common stock (636,412 shares are held in escrow pending the result of a project to reduce the cost of the disposable razor blades utilized by the microkeratome, which was acquired in the transaction), warrants to purchase 250,000 shares of our 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.

We acquired from Innovative Optics the raw materials, work-in-process and finished goods inventories. Additionally, it acquired the patents and trade name associated with the product, the furniture and equipment of Innovative Optics used in the manufacturing process of the microkeratome console and the inspection and packaging of the disposable blades. We subsequently issued 477,039 shares of common stock that were held in escrow at a value of \$630,000, based on the market price of such shares on the date of issuance. This amount was charged to in-process research and development because the issuance of such shares related to the continuing research and development of the microkeratome blades.

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

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On September 19, 2002, we completed a transaction with International Bio-Immune Systems, Inc., a Delaware corporation, in which we acquired 2,663,254 of its shares, or 19.9% of its outstanding shares, and warrants to purchase 1,200,000 shares of its common stock at \$2.50 per share for a period of two years, through the exchange and issuance of 736,945 shares of our common stock, the lending of 300,000 shares of our common stock to the company, and the payment of certain of its expenses through the issuance of an aggregate of 94,000 shares of our common stock to the company and its counsel. The issuance of 736,945 shares were valued based on the market price of our common stock on the date of the transaction and resulted in an investment in International Bio-Immune Systems, when combined with a cash investment of \$65,000 made in 2000, of \$879,000. The 300,000 shares were also valued at the market price on the date of issuance and were recorded as a stock subscription receivable of \$294,000 because such shares will either be paid for or returned in the future.

International Bio-Immune Systems is a privately held biotechnology based, cancer diagnostic and immunotherapy company, located in Great Neck, New York, with potential clinically effective products for the diagnosis, treatment and imaging of patients with major tumor types (e.g. colon, lung, cervix, pancreas and breast). International Bio-Immune Systems does not produce significant revenues as its products have not received FDA approval. Due to the uncertainty of future cash flows and the fact that the FDA has not approved the products, we were unable to support the value of the investment by substantiated

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methods and determined that the likelihood of recovery of our investment was remote. Therefore, in accordance with generally accepted accounting principles, the investment of \$879,000 was charged to impairment expense in 2002.

On August 3, 2004, we sold our investment in International Bio-Immune Systems, Inc. for \$533,000 pursuant to a stock purchase and sale agreement with William Ungar, a current director and shareholder of International Bio-Immune Systems. The securities sold to Mr. Ungar consisted of 2,663,254 common shares of International Bio-Immune Systems and warrants to purchase 1,200,000 common shares of International Bio-Immune Systems at \$2.50 per share. Because, for book purposes, our investment in International Bio-Immune Systems, had been reduced to \$0, the full amount of the \$533,000 received from the sale of the International Bio-Immune Systems common shares and warrants will be reported as a gain in the quarter ended September 30, 2004.

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

Results of Operations

Nine Months Ended September 30, 2004, Compared to Nine Months Ended September 30, 2003

Net sales increased by \$63,000, or 3%, to \$2,288,000 for the nine months ended September 30, 2004, from \$2,225,000 for the comparable period in 2003. Our diagnostic products sales increased by \$336,000, or 19%, to \$2,085,000, or 91% of revenues, during the first nine months of 2004 compared with \$1,750,000, or 79% of total revenues, for the comparable period of 2003.

In the first nine months of 2004, sales of our P40 and P45 UBM Ultrasound Biomicroscopes were \$639,000, or 28% of total revenues, compared to \$421,000, or 19% of total revenues, in the same period of 2003. Sales from the Blood Flow Analyzer(TM) increased by \$178,000 to \$475,000, or 21% of total revenues, during the first two quarters of 2004 compared with \$297,000, or 13% of total revenues, in the same period of last year.

During the first nine months of 2004, sales from P37 A/B Scan Ocular Ultrasound Diagnostic increased to \$229,000, or 10% of total revenue, slightly up from the \$222,000, or 10% of total revenues, in the same period last year. Sales of the LD 400 and TKS 5000 Autoperimeters and the CT 200 Corneal Topographer were slightly lower in the second quarter, with total revenue of \$741,000, or 32% of total revenues, in the first three quarters of 2004 compared with \$808,000, or 36% of total revenues, during the same period of 2003.

Sales of surgical products are at a standstill pending FDA approval of the Photon(TM) laser system. In the nine month period ended September 30 2004, we realized a loss of \$3,000 in the surgical line consisting of the Precisionist Thirty Thousand (TM) and the Photon(TM) laser system. This compared to \$94,000, for the comparable period of 2003.

Gross profit for the nine months ended September 30, 2004 increased by 18% to 62% of total revenues, compared to 44% of total revenues, for the same period in 2003. The increase was mainly due to an increase in the reserve for inventory obsolescence of \$382,000 in the nine months ended September 30, 2003.

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There was a decrease of \$226,000 in the reserve during the nine months ended

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September 30, 2004; however this decrease was the result of a write-off of inventory directly against the reserve. The \$382,000 increase in inventory reserve in 2003 resulted in an increase to cost of sales whereas the \$226,000 reduction in 2004 resulted in a corresponding reduction to inventory and did not have any effect on the statement of operations.

Marketing and selling expenses decreased by \$164,000, or 30%, to \$547,000 for the nine months ended September 30, 2004, from \$711,000 for the comparable period in 2003. This reduction was due primarily to more effective use of marketing programs. During this period two additional full-time salespersons were added, a print advertising campaign initiated, and plans were made to support a major trade show in the fourth quarter of 2004.

General and administrative expenses decreased by \$1,164,000, or 62%, to \$703,000 for the nine months ended September 30, 2004, from \$1,867,000 for the same period in 2003. The favorable reduction in general and administrative expense in 2004 also reflected the ongoing results of the Company's new budget management and cost reduction programs. In addition, during the period ended September 30, 2004, we recorded a reduction in the warranty accrual of approximately \$308,000. This reduction was a result of a comprehensive analysis by management regarding historical warranty costs. Historically we have recorded a monthly warranty expense and related increase to the warranty accrual, however in recent periods the usage of the warranty accrual has continued to decline. After reviewing the recent historical data, management determined that the warranty accrual should be reduced by approximately \$308,000. Management will continue to closely monitor the warranty accrual usage to ensure that the proper amount has been accrued. The general and administrative expenses during the nine months ended September 30, 2003 also included \$443,000 in accruals to settle outstanding disputes and \$83,000 for additional allowance for doubtful accounts receivable.

Research, development and service expenses decreased by \$246,000, or 45%, to \$543,000 for the nine months ended September 30, 2004, from \$789,000 for the same period in 2003. Expenses associated with the development of new products during the first nine months of 2004 decreased compared to the same period in 2003, as a result of our cost reduction program.

There was no impairment of assets for the nine months ended September 30, 2004, compared to \$159,000 in impairment of assets recorded in the same period of 2003.

Other income mainly consists of a gain recorded from the sale of our investment in International Bioimmune Systems, Inc. In July 2004, we sold our investment in International Bioimmune Systems, Inc. (IBS) for \$532,000 cash. Because, for book purposes, our investment in IBS had previously been reduced to \$0, the full amount of \$532,000 was recorded as a gain in the quarter ended September 30, 2004.

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

Net sales decreased by \$2,309,000, or 43%, to \$3,059,000 for the twelve months ended December 31, 2003, from \$5,368,000 for the comparable period in 2002. Sales of our diagnostic products and related accessories were \$2,484,000, or 81% of total revenues, during the twelve months of 2003 compared with \$4,015,000, or 75% of total revenues, for the comparable period of 2002. Sales

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of surgical products and related accessories totaled \$324,000, or 11% of total revenues, for the twelve months of the current year in comparison with \$556,000, or 10%, of total revenues in the comparable period of 2002. Surgical product sales for 2003 include the sale of the SIStem(TM) and Odyssey(TM) product lines for \$125,000 in cash. In 2003, sales of the P40 and P45 UBM Ultrasound Biomicroscope and related accessories were \$615,000, or 20% of total revenues, compared to \$1,303,000, or 24% of total revenues, in the same period of 2002. Sales from the Blood Flow Analyzer(TM) and related accessories decreased by \$121,000 to \$499,000, or 16% of total revenues, during the year ended December 31, 2003 compared with \$620,000, or 12% of total revenues, in the same period of last year. During the twelve months of 2003, sales from other ultrasound products and related accessories totaled \$270,000, or 9% of total revenues, compared with \$606,000, or 11% of total revenues, in the same period last year. Sales of the perimeter and corneal topographer and related accessories generated \$1,100,000, or 36% of total revenues, in 2003 compared with \$1,487,000, or 28% of total revenues, during the same period of 2002.

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

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

Other reasons for the decrease in sales were the uncertainties resulting from our efforts to reduce costs and constraints on availability of funds that reduced our ability to upgrade and enhance its products and pursue further regulatory approvals for its products. Our objective is to focus our sales efforts on the products with the highest potential for sales and strong margins.

Gross profit for the year ended December 31, 2003 was 32% of total revenues, compared to 22% for the same period in 2002. Cost of goods sold for the year ended December 31, 2003 was \$2,086,000 as compared to \$4,210,000 for the same period in 2002, a reduction of \$2,124,000. Cost of goods sold for the year ended December 31, 2003 included an increase in the reserve for obsolete or estimated non-recoverable inventory of \$403,000. Cost of goods sold for 2002 included an increase in the reserve for obsolete or estimated non-recoverable

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inventory of \$1,755,000. Since its inception, we have purchased several complete lines of inventory. While our initial intention was to utilize the substantial majority of inventory acquired in the manufacture of our products, in some circumstances we have been unable to utilize certain items acquired.

On a quarterly basis, we attempt to identify inventory items that have shown relatively no movement or very slow movement. Generally, if an item has shown little or no movement for over a year, it is determined not to be recoverable and a reserve is established for that item. In addition, if we identify products that have become obsolete due to product upgrades or enhancements, a reserve is established for such products. Such analysis resulted in material increases in the reserve for obsolete or estimated non-recoverable inventory in 2003 and 2002. There can be no assurance that we will not identify further obsolete inventory due to significant declines in sales of certain products or technological advances of products in the future. We intend to make efforts to sell these items at significantly discounted prices. If items are sold, the cash received would be recorded as revenue, but there would be no cost of sales on such items due to the reserve that has been recorded. At the time of sale, the inventory would be reduced for the item sold and the corresponding inventory reserve would also be reduced. We do not expect the sales of these items to be significant in the future. During 2003, we sold all inventory, rights, and technology related to the SIStem and Odyssey product lines for \$125,000. All of the inventory sold in this transaction had previously been fully reserved. Therefore, upon the sale, we reduced inventory by \$887,000 for the original book value of the inventory, reduced the reserve for \$887,000, and recorded revenue for the cash received of \$125,000.

Marketing and selling expenses decreased by \$1,875,000, or 67%, to \$920,000 in 2003, from \$2,795,000 in 2002 due primarily to the lower headcounts of sales persons and travel related and associated sales expenses.

General and administrative expenses decreased by \$1,256,000, or 34%, to \$2,446,000 in 2003, from \$3,702,000 in 2002, reflecting the results of our efforts to reduce costs, specifically costs associated with maintaining two manufacturing facilities and consulting costs. As noted above, in April 2002, we announced the closure of our San Diego facility in anticipation of the termination of the lease for that location. All operations associated with the San Diego facility were transferred to the Salt Lake City facility. We incurred a reduction of force of 28 San Diego personnel. The consolidation was intended to save costs and to eliminate duplicities in functions and facilities that occurred with the acquisition of Dicon. The cost of the consolidation was approximately \$80,000. We believe that the annual cost savings of the closure of the San Diego facility are approximately \$2 million. Administrative salaries and wages decreased from approximately \$786,000 in 2002 to approximately \$321,000 in 2003. Depreciation and amortization expense, which includes amortization of leasehold improvements, decreased by approximately \$305,000, or 49%, to \$319,000 in 2003 compared to the same period of last year. General and administrative expenses for 2003 included \$123,000 for additions to the allowance for doubtful accounts and increases in accruals of \$443,000 to settle outstanding disputes.

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

Research, development and service expenses decreased by \$1,786,000, or

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63%, to \$1,033,000 in 2003, from \$2,819,000 in 2002. This decrease was mainly due to the issuance of common stock to Innovative Optics in the fourth quarter of 2002, which was valued at \$630,000 and expensed as in-process research and

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development costs. Expenses associated with the development of new products during the twelve months of 2003 decreased compared to the same period in 2002 as a consequence of our efforts to reduce costs and focus on products that are fully developed and have the highest potential for sales and strong margins.

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

Due to our ongoing cash flow difficulties, during 2003 most vendors and suppliers were contacted with attempts to negotiate reduced payments and settlement of outstanding accounts payable. While some vendors refused to negotiate and demanded payment in full, some vendors were willing to settle for a reduced amount. The accounts payable forgiven by vendors and suppliers resulted in a gain of \$436,000.

Other income and (expense) increased by \$15,000 to net expense of \$21,000 in 2003, from expense of \$(36,000) for the same period in 2002. During 2003, interest income was \$3,000 compared with \$10,000 during 2002. We had a \$22,000 reduction in interest expense to \$(24,000) in 2003, from \$(46,000) in 2002 due to a decrease in interest expense related to capital leases.

Liquidity and Capital Resources

We used \$440,000 cash in operating activities for the nine months ended September 30, 2004, compared to \$712,000 for the nine months ended September 30, 2003. The decrease in cash used by operating activities for the nine months ended September 30, 2004 was primarily attributable to significant reduction in net loss and a decrease in inventory, partially offset by a decrease in accrued expenses and deposits. Our efforts to substantially reduce costs and manage current assets and current liabilities continued to minimize cash used for operating activities. Net cash used in financing activities was \$42,000 for the nine months ended September 30, 2004, versus cash provided of \$726,000 in the same period in 2003. During the nine months ended September 30, 2004, we did not sell any shares of common or preferred stock. In the past, we have relied heavily upon sales of our common and preferred stock to fund operations. There can be no assurance that such equity funding will be available on terms acceptable to us in the future.

We had working capital of \$33,000 as of September 30, 2004. In the past, we have relied heavily upon sales of our common and preferred stock to fund operations. There can be no assurance that such equity funding will be available on terms acceptable to us in the future. We will continue to seek funding to meet our working capital requirements through collaborative arrangements and strategic alliances, additional public offerings and private placements of our securities; and bank borrowings. In July 2004, we sold our investment in International Bio-Immune Systems, Inc. for \$532,000 cash. We are uncertain whether or not the combination of the cash received from the sale of

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International Bio-Immune Systems, Inc. stock and the benefits from sales of our products will be sufficient to assure our operations through March 31, 2005. We will continue to seek funding through the sale of common and preferred stock.

As of September 30, 2004, we had net operating loss carry-forwards (NOLs) of approximately \$36 million. These carry-forwards are available to offset future taxable income, if any, and have begun to expire in 2001 and extend for twenty years. Our ability to use net operating loss carryforwards (NOLs) to offset future income is dependant upon certain limitations as a result of the pooling transaction with Vismed and the tax laws in effect at the time of the NOLs can be utilized. The Tax Reform Act of 1986 significantly limits the annual amount that can be utilized for certain of these carryforwards as a result of change of ownership.

As of September 30, 2004, we had accounts payable of \$653,000, a significant portion of which is over 90 days past due. We have contacted many of the vendors or companies that have significant amounts of payables past due in an effort to delay payment, renegotiate a reduced settlement payment, or establish a longer-term payment plan. While some companies have been willing to renegotiate the outstanding amounts, others have demanded payment in full. Under certain conditions, including but not limited to judgments rendered against us in a court of law, a group of creditors could force us into bankruptcy due to our inability to pay the liabilities arising out of such judgments at that time. In addition to the accounts payable noted above, we also have non-cancelable capital lease obligations and operating lease obligations that require the payment of approximately \$172,000 in 2005, and \$14,000 in 2006.

We have taken numerous steps to reduce costs and increase operating efficiencies. These steps consist of the following:

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1. We closed our San Diego facility. In so doing, numerous manufacturing, accounting and management responsibilities were consolidated. In addition, such closure resulted in significant headcount reductions as well as savings in rent and other overhead costs.

2. We have significantly reduced the use of consultants, which has resulted in a large decrease to these expenses.

3. We have reduced our direct sales force to five representatives, which has resulted in less payroll, travel and other selling expenses.

Because we have significantly fewer sales representatives, our ability to generate sales has been reduced.

We have taken measures to reduce the amount of uncollectible accounts receivable such as more thorough and stringent credit approval, improved training and instruction by sales personnel, and frequent direct communication with the customer subsequent to delivery of the system. The allowance for doubtful accounts was 37% of total outstanding receivables as of September 30, 2004 and 40% as of December 31, 2003. The allowance for doubtful accounts has decreased from \$470,000 at December 31, 2003 to \$424,000 at September 30, 2004. The downturn in the economy worldwide has resulted in increased difficulty in collecting certain accounts. Certain international dealers have some aged unpaid invoices that have not been resolved. We have addressed our credit procedures and collection efforts and have instituted changes that require more payments at the time of sale through letters of credit and not on a credit term basis.

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We intend to continue our efforts to reduce the allowance for doubtful accounts as a percentage of accounts receivable. We have ongoing efforts to collect a significant portion of the sales price in advance of the sale or in a timely manner after delivery. The majority of the receivables included in the allowance for doubtful accounts are a result of sales before we implemented the various changes to improve the collectibility of our receivables. During the nine months ended September 30, 2004, we had a net recovery of receivables previously allowed for of \$46,000 and during the twelve months ended December 31, 2003, we added a net of \$123,000 to the allowance for doubtful accounts. We believe that by requiring a large portion of payment prior to shipment, it has greatly improved the collectibility of our receivables.

We carried an allowance for obsolete or estimated non-recoverable inventory of \$1,416,000 at September 30, 2004, or approximately 65% of total inventory, respectively. This inventory reserve was decreased by \$226,000 during the nine months ended September 30, 2004 due to management's evaluation of the recoverability of certain inventory items. Our means of expansion and development of product has been largely from acquisition of businesses, product lines, existing inventory, and the rights to specific products. Through such acquisitions, we have acquired substantial inventory, some of which the eventual use and recoverability was uncertain. In addition, we have a significant amount of inventory relating to the Photon(TM) laser system, which does not yet have FDA approval in order to sell the product domestically. Therefore, the allowance for inventory was established to reserve for these potential eventualities.

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

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

Effect of Inflation and Foreign Currency Exchange

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

Impact of New Accounting Pronouncements

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In November 2003, the EITF reached a consensus on Issue No.00-21, Revenue Arrangements with Multiple Deliverables. EITF Issue No. 00-21 provides guidance on how to account for certain arrangements that involve the delivery or performance of multiple products, services and/or rights to use assets. The provisions of EITF Issue No. 00-21 will apply to revenue arrangements entered into in fiscal periods beginning after June 15, 2003. The adoption of EITF Issue No. 00-21 did not have a material impact on our operating results or financial condition.

In December 2003, the FASB issued Interpretation No. 46 ("FIN 46R") (revised December 2003), Consolidation of Variable Interest Entities, an Interpretation of Accounting Research Bulletin No. 51 ("ARB 51"), which addresses how a business enterprise should evaluate whether it has a controlling interest in an entity though means other than voting rights and accordingly should consolidate the entity. FIN 46R replaces FASB Interpretation No. 46 (FIN 46), which was issued in January 2003. Before concluding that it is appropriate to apply ARB 51 voting interest consolidation model to an entity, an enterprise must first determine that the entity is not a variable interest entity (VIE). As of the effective date of FIN 46R, an enterprise must evaluate its involvement with all entities or legal structures created before February 1, 2003, to determine whether consolidation requirements of FIN 46R apply to those entities. There is no grandfathering of existing entities. Public companies must apply either FIN 46 or FIN 46R immediately to entities created after January 31, 2003 and no later than the end of the first reporting period that ends after March 15, 2005. The adoption of FIN 46 had no effect on our consolidated financial position, results of operations or cash flows.

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

In May 2003, the FASB issued SFAS 150, Accounting for Certain Financial Instruments with Characteristics of Both Liabilities and Equity. SFAS 150 clarifies the accounting for certain financial instruments with characteristics of both liabilities and equity and requires that those instruments be classified as liabilities in statements of financial position. Previously, many of those financial instruments were classified as equity. SFAS 150 is effective for financial instruments entered into or modified after May 31, 2003 and otherwise is effective at the beginning of the first interim period beginning after June 15, 2003. On November 7, 2003, FASB Staff Position 150-3 was issued, which indefinitely deferred the effective date of SFAS 150 for certain mandatory redeemable non-controlling interests. As we do not have any of these financial instruments, the adoption of SFAS 150 did not have any impact on our financial statements.

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

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BUSINESS

General

We develop, manufacture, source, market and sell ophthalmic surgical and diagnostic instrumentation and related accessories, including disposable products. Our surgical equipment is designed for minimally invasive cataract treatment. We market two cataract surgery systems with related accessories and disposable products. Our 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 our 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, we have 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. Our focus is not on any specific diagnostic product or products, but rather on our entire group of diagnostic products. The Photon(TM) can be sold in markets outside of the United States. Both the Photon(TM) and the Precisionist ThirtyThousand(TM) are manufactured as an Ocular Surgery Workstation(TM). We are considering marketing the Photon(TM) and other lasers for use in eye care.

Our diagnostic products include a pachymeter, the P55 Pachymetric Analyzer, the P37 A/B Scan Ocular Ultrasound Diagnostic, the P40 UBM Ultrasound Biomicroscope, the P45 Plus UBM Biomicroscope, the Dicon(TM) LD 400 Autoperimeter, the Dicon(TM) TKS 500 Autoperimeter, the Dicon(TM) CT 200 Corneal

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Topographer and the Blood Flow Analyzer(TM). The diagnostic ultrasound products including the P55 pachymeter, the P37 A/B Scan, the P40 biomicroscope and the P45 Plus biomicroscope were acquired from Humphrey Systems, a division of Carl Zeiss in 1998. We developed and offered for sale in the fall of 2000 the P45, which combines the P37 A/B Scan and the UBM biomicroscope into one machine. The perimeter and the corneal topographer were added when we acquired the outstanding shares of the stock of Vismed, Inc. d/b/a/ Dicon(TM) in June 2000. We 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 treatment of glaucoma. We are currently developing additional applications for all of our 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

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cataract while still in the eye and remove it in pieces by suction through a small incision.

In June 1997, we 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. Our 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, we 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, we 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, we 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 Ultrasonic 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, we 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 our common stock, we 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 us 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 our cataract surgical equipment and our 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. We 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, we purchased Mentor's surgical product line, consisting of the Phaco SISem(TM), the Odyssey(TM) and the Surg-E-Trol(TM). This acquisition was an attempt to round out our cataract surgery product line by adding entry-level, moderately priced cataract surgery products. The transaction was paid for with \$1.5 million worth of our 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

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products. During the fourth quarter of 2003, we sold all inventory and rights associated with the SIStem(TM) and Odyssey(TM) for \$125,000 in cash.

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On June 5, 2000, we 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, we 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 our 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. We acquired from Innovative Optics raw materials, work in process and finished goods inventories. Additionally, we acquired the furniture and equipment used in the manufacturing process of the microkeratome console and the inspection and packaging of the disposable blades.

We were unsuccessful in supplying the disposable blades. We discontinued the marketing and sales efforts of this product during the third quarter of 2002. On April 1, 2002, we 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, we issued him a total of 43,684 shares of our common stock, representing payment of \$100,000 in stock for his services. On October 9, 2003, an additional 300,000 shares of our common stock was issued to Dr. Casebeer in settlement of a lawsuit he brought against us for additional consideration due under the consulting agreement. 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, we completed a transaction with International Bio-Immune Systems, Inc., a Delaware corporation, in which we 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 of at \$2.50 per share for a period of two years, through the exchange and issuance of 736,945 shares of our common stock, the lending of 300,000 shares of our common stock to the company and the payment of certain of its expenses through the issuance of an aggregate of 94,000 shares of our common stock to the company and its counsel.

International Bio-Immune Systems, Inc. may sell the 300,000 shares of our common stock loaned by us and the proceeds therefrom shall be deemed a loan from us 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

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sold, to us. International Bio-Immune Systems currently controls the voting decisions regarding these shares. The President and Chief Executive Officer of International Bio-Immune Systems is Leslie F. Stern, who exercises sole voting and investment powers regarding the shares.

On August 3, 2004, we sold our investment in International Bio-Immune Systems, Inc. for \$533,000 pursuant to a stock purchase and sale agreement with William Ungar, a current director and shareholder of International Bio-Immune Systems. The securities sold to Mr. Ungar consisted of 2,663,254 common shares of International Bio-Immune Systems and warrants to purchase 1,200,000 common shares of International Bio-Immune Systems at \$2.50 per share.

On December 3, 2003, we 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 us by American Optisurgical for the assets was \$125,000. The purchase agreement also contained a noncompete provision in which we 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, we 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 us: (i) review of and make recommendations regarding our business plan and promotional materials; (ii) identify and contact potential investors in the United States and Europe for potential investment in our securities; (iii) organize meetings with potential investors and participate in such meetings; and (iv) assist us in future financings, mergers, acquisitions and potential buyouts.

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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 our common stock at \$.15 per share. The warrants are exercisable, on a cashless basis, over a two year period from the date of issuance.

Background

Corporate History: Our business originated with Paradigm Medical, Inc., a California corporation formed in October 1989. Paradigm Medical, Inc. developed our present ophthalmic business and was operated by our 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, we were 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, we caused a 1-for-7.96 reverse stock split of our shares of common stock. We then acquired all of the issued and outstanding shares of common stock of Paradigm Medical,

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Inc. using shares of our own common stock as consideration. As part of the merger, we changed our 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, we caused a 1-for-5 reverse stock split of our shares of common stock. In February 1996, we 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 pressure in the eye), corneal disorders such as scars, defects and irregular surfaces and vitreoretinal disorders such as the attachment of membrane growths to the retina causing blood leakage within the eye. All of these disorders can impair vision. Many refractive disorders can be corrected through the use of eyeglasses and contact lenses. Myopia (nearsightedness), hyperopia (farsightedness) and presbyopia (inability to focus) are three of the most common refractive disorders.

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

Surgical use of ultrasonics in ophthalmology is limited to treatment of cataract lenses in the eye through a procedure called phacoemulsification or "phaco." A primary objective of cataract surgeries is the removal of the opacified (cataract) lens through an incision that is as small as possible. The opacified lens is then replaced by a new synthetic lens intraocular implant. Phaco technology involves a process by which a cataract is broken into small pieces using ultrasonic shock waves delivered through a hollow, open-ended metal needle attached to a hand-held probe. The fragments of cataracts tissue are then removed through aspiration. Phaco systems were first designed in the late 1960's after various attempts by surgeons to use other techniques to remove opacified lenses, including crushing, cutting, freezing, drilling and applying chemicals to the cataract. By the mid-1970's, ultrasound had proven to be the most effective technology to fragment cataracts. Market Scope's (Manchester, Missouri), "The 2001 Report on the Worldwide Cataract Market", January 2001

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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.

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

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

Products

Our principal proprietary surgical products are systems for use by ophthalmologists to perform surgical treatment procedures to remove cataracts. We have complete ownership of each product with no technological licensing limitations.

Precisionist ThirtyThousand(TM): The Precisionist ThirtyThousand(TM) is our core phaco surgical technology. The Precisionist(TM) was placed into production and offered for sale in 1997. As a phaco cataract surgery system, we believe 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 our 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

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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 our 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% and 3% of the total revenues in the fiscal years 2003 and 2002, respectively, and 0% of the total revenues for the nine months ended September 30, 2004.

Ocular Surgery Workstation(TM): The Ocular Surgery Workstation(TM) comprises the base system of the Precisionist ThirtyThousand(TM) and is the first system to our 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 us and controlled by a proprietary software system developed by us 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 our 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

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equipment. However, there is no guarantee that the Workstation(TM) will be accepted in the marketplace. If the FDA approves the Photon(TM), we will refer to the Workstation(TM) as the Photon(TM) Ocular Surgery Workstation(TM). To date, we have 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 our 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

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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. Our 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 and the nine months ended September 30, 2004, diagnostic products are currently our major focus and the Photon(TM) and other extensive research and development projects have been put on hold pending future evaluation when our 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, we have recorded an inventory reserve against the majority of the inventory associated with the Photon(TM) and the Precisionist Thirty Thousand(TM). Our focus is not on any specific diagnostic product or products, but rather on our entire group of diagnostic products.

At some point in the future, we 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, we intend 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 far as we 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.

Our 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, our 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, our Photon(TM) laser cataract system should only affect tissues with which it comes into direct contact.

In October of 2000, we 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

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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 FDA. 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

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Ultrasound Biomicroscope, perimeter, CT 50 Corneal Topographer, and Blood Flow Analyzer(TM) are currently our 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. Our 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 our 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 11% and 4% of the total revenues for fiscal years 2003 and 2002, respectively, and 0% of the total revenues for the nine months ended September 30, 2004. On December 3, 2003, we 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, our 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. We intend to expand its disposable accessories as it further penetrates the cataract surgery market and expands the treatment applications for its Workstation(TM). These products contributed approximately 0% and 3% of the total revenues for 2003 and 2002, respectively, and 0% of the total revenues for the nine months ended September 30, 2004.

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, we received FDA clearance to

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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. Our 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 our 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.

We market 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 we commenced selling the system in September 1997. In addition to the Humphrey products, this diagnostic product allowed us 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 our surgical systems.

In April 2001, we 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 our 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). We are continuing our 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. We are 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, we received FDA approval on our 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

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vascular health of the eye. Also, we are continuing our 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 our Blood Flow Analyzer(TM). Sales of the Blood Flow Analyzer(TM) and related accessories accounted for approximately 16% and 12% of total revenues for the fiscal years ended December 31, 2003 and 2002, respectively, and 21% of total revenues for the nine months ended September 30, 2004.

Dicon(TM) Perimeters: Dicon(TM) perimeters consist of the LD 400, the TKS 5000, the SST(TM), FieldLink(TM), FieldView(TM) and Advanced FieldView. Perimeters are used to determine retinal sensitivity testing the visual pathway. Perimeters have become a standard of care in the detection and monitoring of glaucoma worldwide. Perimetry is reimbursable worldwide. The Dicon(TM) perimeters feature patented kinetic fixation and voice synthesis now in 27 different languages. Software programs are sold to assist in the analysis of the test results. Sales of the perimeters and related accessories generated approximately 27% and 20% of the total revenues for 2003 and 2002, respectively, and 28% of the total revenues for the nine months ended September 30, 2004.

LD 400FT: The LD 400FT, or Fast Threshold Autoperimeter, is the successor to the LD 400. The device is an autoperimeter used to measure patient visual fields. The LD 400FT is identical in hardware to the LD 400 but it uses new software to enable a fast threshold test. This test reduces the time required by ophthalmologists and optometrists conducting autoperimetry tests by more than 40% by running an abbreviated test at light levels determined to be sufficient to be seen in normal patients. The procedure currently takes more than 15 minutes. The fast threshold test by the LD 400FT is similar to tests by other devices on the market. Healthy patients will pass the test. Patients with reduced visual fields will be flagged by the test enabling the device to automatically run a more comprehensive examination to determine the extent of the visual field loss. All existing LD 400s can be upgraded to support the new fast threshold test through the purchase of a software package.

Dicon(TM) Corneal Topographers: Dicon(TM) corneal topographers include the CT 200(TM) and the CT 50. Corneal topographers are used to determine the shape and integrity of the cornea, the anterior surface of the eye. Clinical applications for corneal topographers include refractive surgery that eliminates the need for eyeglasses and optometric applications including contact lens fitting. Revenues from the topographer and related accessories were 9% and 7% of the total revenues for 2003 and 2002, respectively, and 4% of the total revenues for the nine months ended September 30, 2004. An enhanced version of the CT 200(TM), the CT 2000(TM), is scheduled to be introduced during the fourth quarter of 2003. We are 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. We are also revising our upgrade to offer the CT 200(TM) with Windows 2000 software rather than the Windows XP software that we announced in August 2003.

P55 Pachymetric Analyzer: The ultrasonic pachymeter is used for measurement of corneal thickness. The Model P55 is positioned as a standard office pachymeter. This device is targeted to the refractive surgery market and contributed approximately 3% of the total revenues for both 2003 and 2002, and 3% of the total revenues for the nine months ended September 30, 2004.

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

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both 2003 and 2002, and 0% of the total revenues for the nine months ended September 30, 2004.

P37 A/B Scan Ocular Ultrasound Diagnostic: The A/B Scan is used by retinal sub-specialists to identify foreign bodies in the posterior chamber of the eye and to evaluate the structural integrity of the retina. The A/B Scan is attractive to the general ophthalmic community at large because of its lower price point. Sales from this product were approximately 4% and 7% of the total revenues for 2003 and 2002, respectively, and 6% of the total revenues for the nine months ended September 30, 2004.

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 us the proprietary rights to this device. The P40 biomicroscope creates a high-resolution computer image of the unseen parts of

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the eye that is a "map" for the glaucoma surgeon. The P40 biomicroscope is an "enabling technology" for the ophthalmologist, one that we have repositioned for broader market sales penetration. Formerly sold only to glaucoma sub-specialty practitioners, we 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 us with our proprietary P40 biomicroscope and to our 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 we introduced the P45 UBM Ultrasound Biomicroscope, which combines the P40 biomicroscope and the P37 A/B Scan Ocular Ultrasound Diagnostic in one instrument. We believe that by combining functions, the P45 biomicroscope will appeal to a broader market. The P40 biomicroscope and related accessories sales were approximately 7% and 12% of the total revenues for 2003 and 2002, respectively, and 12% of the total revenues for the nine months ended September 30, 2004. The P45 UBM Ultrasound Biomicroscope and related accessories sales contributed approximately 13% and 12% of the total revenues for 2003 and 2002, respectively, and 17% of the total revenues for the nine months ended September 30, 2004.

On October 25, 2004, we 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 us the exclusive right to manufacture, market, sell and distribute an ultrasound biomicroscope. Upon execution of the agreement, we paid \$30,000 to E-Technologies for engineering costs associated with the development of the biomicroscope. Once the biomicroscope receives FDA approval, we agree to pay E-Technologies an additional fee of \$45,000.

In consideration for the exclusive right to manufacture and distribute the biomicroscope, we agree to pay E-Technologies the sum of \$5,000 for each of the first 25 biomicroscopes sold by us. Thereafter, we agree to pay E-Technologies the sum of \$4,000 for each biomicroscope sold. As an additional condition, we agree 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

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other party before the end of any term of the agreement.

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

Parts and Services: The parts and services revenue from the repair and service of equipment sold accounted for approximately 8% and 11% of the total revenues in 2003 and 2002, respectively, and 9% of the total revenues for the nine months ended September 30, 2004.

Sales of other products represented 0% and 4% of the total revenues in 2003 and 2002, respectively, and 0% of the total revenues for the nine months ended September 30, 2004.

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:

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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%

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LD 400FT Autoperimetry System	Perimeter, Automatic AC-Powered Diagnostic	Complete	Yes	0%
TKS 5000 Autoperimetry System	Perimeter, Automatic AC-Powered, Diagnostic	Complete	Yes	3%
Precisionist Thirty Thousand(TM), Ocular Surgery Workstation with Surgical Equipment and Disposables	Phacofragmentation	Complete	Yes	0%
SISem(TM) and Odyssey(TM) (3)	Phacofragmentation	Sold	Yes	11%
Photon(TM) Laser, Ocular Surgery Workstation with Surgical Equipment and Disposables(4)	Phacoemulsification BFA tips	In-Process (5)	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) Sales for 2004 are for the nine months ended September 30, 2004.
- (3) Due to the lack of recent sales volume, the inventory associated with the Precisionist Thirty Thousand (TM), the SISem(TM) and the Odyssey(TM) has been deemed obsolete and a reserve has been recorded to offset such inventory.
- (4) Due to the lack of recent evidence to support the recoverability of inventory associated with the Photon(TM), we have recorded a reserve to offset the majority of such inventory on hand.
- (5) The Photon(TM) is in-process and not complete because we have 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

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**** 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, our current products are developed and available for sale in the footnote (1) of the table. Our possible future efforts to finalize development of the Photon(TM) and obtain the necessary regulatory approvals would depend on our 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 we would not receive as expected. The "Use of Proceeds" section provides information on the estimated application of proceeds for Research and Development. We anticipate that a majority of the estimated costs for Research and Development will be used for the enhancement and upgrading of our current products approved for sale. We are 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) laser system and obtain the necessary regulatory approvals would depend on 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 we would not receive as expected. The "Use of Proceeds" section provides information on the estimated application of proceeds for research and development. We anticipate that a majority of the estimated costs for research and development will be used for the enhancement and upgrading of our current products being offered for sale. We estimate that the liquidity needed to complete the clinical trials on the Photon(TM) in order to obtain the necessary FDA regulatory approval to be approximately \$225,000.

We currently purchase components and parts used in our products from a limited number of key suppliers. Our reliance on our 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 our revenues to decline. In addition, any interruption or discontinuance in the supply of components or parts could have an adverse effect on our business, results of operation and financial condition. Our 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

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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.

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Current Market Acceptance and Potential: The principal purchasers of our products have been ophthalmologists, optometrists and clinics in many countries throughout the world. We believe that the market for our 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 our laser system.

Marketing Organization: We market our 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, we had ten direct domestic sales representatives in the United States and 65 foreign dealers. As of November 30, 2004, we had four direct domestic sales representatives in the United States and 28 foreign dealers. These sales representatives are assigned exclusive territories and have entered into contracts with us that contain performance quotas. Domestic sales channels have been expanded to include independent sales representatives and distributors who began training on our products in August 2003. We also plan to continue to market our products by identifying customers through internal market research, trade shows and direct marketing programs. We also utilize 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 our 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 our technology and products, as evidenced by several recent front-page articles in these publications.

Manufacturing and Raw Materials: Currently, we maintain a 23,238 square foot facility in Salt Lake City. We 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, we consolidated and closed the San Diego operations into the Salt Lake City facility. The facility accommodates our manufacturing, marketing and engineering capabilities. We manufacture under systems of quality control and testing, which comply with the Quality System Requirements established by the FDA, as well as similar guidelines established by foreign governments, including the CE Mark and ISO-9001.

We subcontract the manufacturing of some of its ancillary instruments, accessories and disposables through specified vendors in the United States.

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These products are contracted in quantities and at costs consistent with our financial purchasing capabilities and pricing needs. We manufacture certain accessories and fluidics surgical tubing sets at our facility in Salt Lake City.

Product Service and Support: Service for our products is overseen from our Salt Lake City location and is augmented by our 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. We provide 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. We maintain adequate parts inventory and provides overnight replacement parts shipments to its dealers.

On July 11, 2002, we 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 us 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, we are to issue 100,000 shares of our 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, we have 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. We have issued a total of 100,000 shares of our 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 our 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 us in the sale of our Photon(TM) laser system in Asia, he has not been successful to date in selling our Photon(TM) laser system to any customers in China or other Asian countries.

Research and Development

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

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We believe our research and development capabilities provide us with the ability to respond to regulatory developments, including new products, new product features devised from our users and new applications for our products on a timely and proprietary basis. We intend to continue investing in research and development and to strengthen our 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

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

From December 1, 2000 to November 30, 2002, we 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, we issued Dr. Limberg a total of 48,000 shares of our 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 our 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 our president and chief executive officer from March 19, 2003 to March 18, 2004, decided not to utilize the clinical advisory board. Instead, he consulted with former members of the advisory board on an informal basis. John Y. Yoon, who currently serves as our president and chief executive officer, has also decided not to utilize the clinical advisory board. We currently have no agreements with any former members of the clinical advisory board and none of these former members hold or own any rights to our products or technologies.

Competition

General. We are 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. We believe 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, we anticipate 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

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sales of these cassettes and accessories. Our 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 us 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.

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Ultrasound Equipment Manufacturers. As a relatively recent entrant into the cataract surgical equipment market with a newer equipment line, we are establishing ourself and, as yet, do not hold a significant share of the market. We currently recognize Bausch & Lomb, Alcon Laboratories, and Allergan Medical Optics as our 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. We also believe that our 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, we are seeking to exploit these opportunities. Depending upon further developments, we may ultimately exploit those opportunities through a merger with a stronger entity already established or one that desires to enter the medical industry.

We believe that our ability to compete successfully will depend on our capability to create and maintain advanced technology, develop proprietary products, attract and retain scientific personnel, obtain patent or other proprietary protection for our 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

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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.

We are 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 we believe account for the majority of diagnostic equipment sales. We continue 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 our analyzer retail at comparable prices. Thus, we believe that we can compete in the diagnostic market place based upon the lower price and improved diagnostic functions of the analyzer.

Intellectual Property Protection

Our cataract surgical products are proprietary in design, engineering and performance. Our 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.

We did acquire proprietary intellectual property in the transaction with Humphrey Systems when we 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 we purchased, is subject to a license agreement dated September 27, 1990, with Sunnybrook Health Science Center. Under the terms of the license agreement, we have the exclusive worldwide rights to manufacture and sell the UBM biomicroscope, for which we are 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 we had a royalty free world-wide license to use and sell the P40 UBM Ultrasound Biomicroscope. However, we have 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 us 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 expired in September 2004.

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We 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 us 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. We are required each

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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, we have 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 we would receive royalty payments equal to 1% of the proceeds from the net sales of products utilizing the patent. The license agreement expired when the United States patent rights expired 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, we have 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 us on September 11, 2000 involving an amount of royalties that are allegedly due and owing to them from the sale of equipment by us. We have paid \$14,736 to bring all royalty payments up to date through June 30, 2001. We have been working with PhotoMed and Dr. Eichenbaum to ensure that the royalty calculations have been correctly made. It is anticipated that once the parties agree on the correct royalty calculations, the legal action will be dismissed. However, if the parties are unable to agree on a method for calculating royalties, there is a risk that PhotoMed and Dr. Eichenbaum might amend the complaint to request termination of the license agreement and, if successful, we would lose our 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 us 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.

Our trademarks are important to our business. It is our policy to pursue trademark registrations for its trademarks associated with its products as appropriate. Also, we rely on common law trademark rights to protect its unregistered trademarks, although common law trademark rights do not provide us 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.

We also rely on trade secret law to protect some aspects of our intellectual property. All of our key employees, consultants and advisors are

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required to enter into a confidentiality agreement with us. Most of our third-party manufacturers and formulators are also bound by confidentiality agreements with us.

Regulation

The FDA under the Food, Drug and Cosmetics Act regulates our 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 us to show reasonable assurance of safety and effectiveness regarding our 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 we not be allowed to enter into government contracts and criminal prosecution may also be made.

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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 we will obtain Section 510(k) pre-marketing clearance for any of the future devices for which we seek 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

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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 our market introduction of our products and could have a material adverse effect on our 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

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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 our 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 us 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 our 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 our products may be regulated by various state agencies. All lasers manufactured for us are subject to the Radiation Control for Health and Safety Act administered by the Center for Devices and Radiological Health of the FDA. The law requires laser manufacturers to file new product and annual reports and to maintain quality control, product testing and sales records, to incorporate certain design and operating features in lasers sold to end users pursuant to specific performance standards, and to comply with labeling and certification requirements. Various warning labels must be affixed to the laser, depending on the class of the product, as established by the performance standards.

Although we believe that we currently comply 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, we are 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 we 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 our ability to conduct business.

We and the manufacturers of our 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, we cannot predict the content of any federal health care program, if any is passed by Congress, or its effect on us and our 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 our 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 our business could result in volatility of the market price of our common stock.

Furthermore, the introduction of our products in foreign countries may

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require us to obtain foreign regulatory clearances. We believe 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. Our two ultrasound systems, the Photon(TM) laser cataract system we are 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 our effectiveness in obtaining the necessary approvals. Having an approved Investigational Device Exemption allows us to export a product to qualified investigational sites.

Regulatory Status of Products

All of our 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 our products have been accepted for import into CE countries and various non-CE countries.

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We 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 us 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 our belief that the surgical treatment method used with the Photon(TM) laser is similar to the current ultrasound cataract treatment employed by ophthalmologists.

We 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 we 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. We began human clinical trials in April 1996 and completed the Phase I study in November 1997. We started Phase II trials in September 1998 and completed numerous cases of treatment group and control group patients, which were included in our submission to the FDA.

We 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 our Photon(TM) Laser Cataract System. The warning letter concerns the conditions found by the FDA during several audits at our clinical sites. The FDA's comments were isolated to the administrative procedures of compiling data from the clinical sites. We responded to the warning letter in a submission dated September 27, 2000. In the submission we 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,

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2000 to us, the FDA granted conditional approval provided that we correct certain deficiencies. After providing several additional submissions to the FDA, we 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, we received approval to continue our clinical trials, the results of which were included in our 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, we received a preliminary review from the FDA regarding the supplemental submission. As a result of that preliminary review, we submitted additional clinical information to the FDA on February 6, 2002. The application is receiving ongoing review by the FDA. On May 7, 2002, we received a letter from the FDA requesting further clinical information. We have generated additional clinical information in response to the letter and are uncertain if we 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. Our diagnostic products are currently our major focus and the Photon(TM) and other extensive research and development prospects have been put on hold pending future evaluation when our financial position improves. Our focus is not on any specific diagnostic product or products, but rather on our entire group of diagnostic products.

Facilities

Our 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, we renegotiated a three-year lease with Eden Roc at a monthly rate of \$9,295 plus a \$1,859 common area maintenance fee for the year 2003, with rate increases to \$9,574 for 2004 and to \$9,861 for 2005. Pursuant to the lease, we pay all real estate and personal property taxes and the insurance costs on the premises.

We believe that these facilities are adequate and satisfy our needs for the foreseeable future.

Employees

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

In December 2001, we initiated the first phase of a corporate downsizing program to reduce our operating expenses. We implemented the second phase of our downsizing program in the second quarter of 2002, by closing and transferring our manufacturing from our 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 our employees has been reduced by 75% from 112 to 30 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, we incurred additional one-time expenses of approximately \$18,000 for housing accommodations for key employees working in Salt Lake City. We realized a net cost savings from downsizing in excess of \$2 million during each of the years 2003 and 2002.

Legal Proceedings

An action was brought against us 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 we owe Mr. Wiseman 6,370 shares of our common stock plus costs, attorney's fees and a wage penalty (equal to 1,960 additional shares of our common stock) pursuant to Utah law. The action is based upon an extension of a written employment agreement. We dispute the amount allegedly owed and intend to vigorously defend against the action.

An action was brought against us on 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 attorney's fees. Discovery has taken place and we have paid royalties of \$14,736 to bring all payments up to date through June 30, 2001. We have been working with PhotoMed and Dr. Eichenbaum to ensure that the calculations have been correctly made on the royalties paid as well as the proper method of calculation for the future.

It is anticipated that once the parties can agree on the correct calculations on the royalties, the legal action will be dismissed. The issue in dispute concerning the method of calculating royalties is whether royalties should be paid on returned equipment. Since July 1, 2001, only one Photon(TM) laser system has been sold and no systems returned. Thus, the amount of royalties due, according to our calculations, is \$981. We intend to make payment of this amount to PhotoMed and Dr. Eichenbaum and, as a result, to have the legal action dismissed. However, if the parties are unable to agree on a method for calculating royalties, there is a risk that PhotoMed and Dr. Eichenbaum might amend their complaint to request termination of the license agreement and, if successful, we would lose our right to manufacture and sell the Photon(TM) laser system.

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

More specifically, the complaint alleges that we falsely stated in our Securities and Exchange Commission filings and press releases that we had received authorization to use an insurance reimbursement CPT code from the CPT Code Research and Development Division of the American Medical Association 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 we never received the CPT code from the American Medical Association at any time. Nevertheless, it is alleged that we continued to misrepresent in our SEC filings and press releases that we had received the CPT

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code. It is also alleged that we have never made a full, corrective disclosure with respect to this alleged misstatement.

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

We dispute 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, we issued a press release that stated we had received authorization to use common procedure terminology or CPT code number 92120 for our Blood Flow Analyzer(TM). This press release was based on a letter we received from the CPT Editorial Research and Development Department of the American Medical Association 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 our Blood Flow Analyzer(TM).

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Currently, there is reimbursement by insurance payors to doctors using the Blood Flow Analyzer(TM) in 22 states and partial reimbursement in four other states. The amount of reimbursement to doctors using the Blood Flow Analyzer(TM) generally ranges from \$56.00 to \$76.00 per patient, depending upon the insurance payor. Insurance payors providing reimbursement for the Blood Flow Analyzer(TM) have the discretion to increase or reduce the amount of reimbursement. We are endeavoring to obtain reimbursement by insurance payors in other states where there is currently no reimbursement being made. We believe we have continued to correctly represent in our Securities and Exchange Commission filings that the CPT Editorial Research and Development Department of the American Medical Association has advised us that CPT code number 92120 is the appropriate CPT code for our Blood Flow Analyzer(TM), for reimbursement purposes for doctors using the device.

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

On September 13, 2002, the board of directors issued a press release regarding the status of our product sales to the Mexican ophthalmic practitioners. In that press release the board stated that we had been in discussions for the prior nine months with Westland Financial Corporation, aimed

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

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 our common stock was artificially inflated and the persons who purchased our 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 our securities in the class action suit filed on July 11, 2003, stated that our 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 our 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 our securities in the consolidated class action. On June 28, 2004, a consolidated amended class action complaint was filed on behalf of purchasers of our securities. The consolidated complaint is similar to the three class action complaints and alleges that we made false representations regarding the CPT code for the Blood Flow Analyzer(TM), but it includes additional allegations that we 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 we made false statements regarding the purchase order from Westland Financial Corporation and Valdespino Associates Enterprises. We believe the consolidated complaint is without merit and intend to vigorously defend and protect our interests in the case.

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

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We have paid \$30,000 to U.S. Fire toward satisfaction of the \$250,000 retention that is applicable to the consolidated cases. We have advised U.S. Fire that we cannot pay the \$250,000 retention due to our current financial circumstances. As a consequence, on January 8, 2004, we entered into a non-waiver agreement with U.S. Fire in which U.S. Fire agreed to fund and advance our retention obligation in consideration for which we have agreed to reimburse U.S. Fire the sum of \$5,000 a month for a period of six months, with the first of such payments due on February 15, 2004. Thereafter, commencing on August 15, 2004, we are 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. We have made payments to U.S. Fire in the aggregate amount of \$30,000 of which our 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 we or our former officers and directors named in the consolidated cases are not entitled to coverage under the policy, or that it is entitled to rescind the policy, or should we be declared in default under the non-waiver agreement, for not making the monthly payments in a timely manner that are owed to U.S. Fire, then we agree to pay U.S. Fire, on demand, the full amount of all costs advanced by U.S. Fire, except for those amounts that we may have reimbursed to U.S. Fire pursuant to the monthly payments due under the non-waiver agreement. Moreover, if U.S. Fire denies coverage for the consolidated cases under the policy, we would owe our 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.

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

On July 10, 2003, a complaint was filed in the United States District Court, District of Utah captioned Innovative Optics, Inc. and Barton Dietrich Investments, L.P. v. Paradigm Medical Industries, Inc., Thomas Motter, Mark Miehle and John Hemmer, Case No. 2:03 CV 00582DB. The complaint claims that Innovative and Barton entered into an asset purchase agreement with us on January 31, 2002, in which we agreed to purchase all the assets of Innovative in consideration for the issuance of 1,310,000 shares of the Company's common stock to Innovative. The complaint claims we breached the asset purchase agreement. The complaint also claims that we allegedly made false and misleading statements pertaining to the Blood Flow Analyzer(TM) and concerning a purchase order from Valdespino Associates Enterprises and Westland Financial Corporation. The purpose of these statements, according to the complaint, was to induce Innovative to sell its assets and purchase the shares of our common stock at artificially inflated prices while simultaneously deceiving Innovative and Barton into believing that the Company's shares were worth more than they actually were. The complaint contends that had Innovative and Barton known the truth they would not have sold Innovative to us, would not have purchased our stock for the assets of Innovative, or would not have purchased the stock at the inflated prices that they allegedly paid. The complaint further contends that as a result of the allegedly false statements, Innovative and Barton suffered substantial damages in an amount to be proven at trial.

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

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

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

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

On December 8, 2004, we announced that verbal agreements have been made to settle certain lawsuits brought against us and our former executive officers, Thomas F. Motter, Mark R. Miehle and John W. Hemmer. The following are the lawsuits that have been verbally settled:

- o The class action lawsuit filed on May 14, 2003 by Richard Meyer, individually and on behalf of all others similarly situated, against us and certain former executive officers in the United States District Court for the District of Utah, which was consolidated into a single action on June 28, 2004 with two other class action lawsuits -- the class action lawsuit filed by Michael

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Marone on June 2, 2003 and the class action lawsuit filed by Lidia Milian on July 21, 2003 against us and our former executive officers in the same court. The consolidated action is captioned In re Paradigm Medical Industries Securities Litigation, with lead plaintiffs Rock Solid Investments of Miami, Inc., Brito & Brito Accounting, Inc. and Joseph Savanjo.

- o The class action lawsuit filed on October 14, 2003 by Albert Kinzinger, Jr., individually and on behalf of all others similarly situated, in the Third District Court for the State of Utah against us and certain former executive officers.
- o The lawsuit filed on July 10, 2003 by Innovative Optics, Inc. against us and certain former executive officers.

Under the terms of the settlement agreements, U.S. Fire Insurance Company, which issued a Directors and Officers Liability and Company Reimbursement Policy to us for the period from July 10, 2002 to July 10, 2003, has agreed to pay \$2,500,000 in cash to the classes in the class action lawsuits and to Innovative Optics, Inc. in settlement of these lawsuits. Under the terms of settlement, we are to pay U.S. Fire the sum of \$220,000, representing the remaining amount owing under a \$250,000 retention obligation in the insurance policy, and to execute a policy release in favor of U.S. Fire as to coverage under the insurance policy.

The parties to the settlement and their respective legal counsel are in the process of preparing written settlement agreements to memorialize the terms of the verbal agreements. Settlement of the lawsuits is subject to certain conditions, which include but are not limited to the following:

- o Each of the settlement classes shall, in their respective actions and at their own expense, obtain preliminary approval of the terms of settlement by both the court in the federal action and the court in the state action.
- o After obtaining a court order granting preliminary approval of the terms of settlement in the respective actions, each of the classes are required, in their respective actions and at their own expense, to provide notice to all persons that are potential members of the federal settlement class and the state settlement class, respectively.
- o The federal settlement class members and the state settlement class members shall have a period of time from the date of the mailing of such notice in which to "opt-out" of the federal settlement class and state settlement class, respectively.

Under the terms of the settlement, U.S. Fire has the option to terminate the settlement agreements if the cumulative dollar value of the claims held by individuals or entities that "opt-out" of the federal settlement class or the state settlement class exceeds \$250,000. However, if such "opt-outs" exceed \$250,000, the parties in the class have a period of time to cure by reducing the amount of "opt-outs" to less than \$250,000. The remaining retention obligation of \$220,000 is payable in monthly installments of \$10,000 until the entire amount owing is paid.

If U.S. Fire exercises its option to terminate the settlement agreements in the event the "opt-outs" exceed \$250,000 and the parties are unable to reduce the amount of "opt-outs" within an allowable time period, the terms and conditions of the settlement agreements will have no further force and effect, and all parties will be restored to their respective positions in the various legal actions prior to such settlement.

On January 26, 2005, we entered into a written settlement agreement to settle the lawsuit that Innovative Optics, Inc. and Barton Dietrich Investments, L.P. brought against us and our former executive officers, Thomas F. Motter, Mark R. Miehle and John W. Hemmer. Under the terms of the settlement, U.S. Fire has agreed to pay Innovative Optics, Inc. and Barton Dietrich Investments, L.P. the sum of \$367,500. Payment of this amount by U.S. Fire is contingent, however, upon the settlement of a federal court class action lawsuit and a state court class action lawsuit against us and our former executive officers.

As a condition to the settlement agreement with Innovative Optics, Inc. and Barton Dietrich Investments, L.P., the courts in the federal court class action lawsuit and the state court class action lawsuit must have entered orders granting final approval of the settlements reached in those respective actions, and such orders must have become final and non-appealable. In addition, we and our former executive officers agree to execute a policy release in favor of U.S. Fire. The policy release is to be in a form agreed to by the parties.

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

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

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

An action was filed in June, 2003 in the Third Judicial District Court, Salt Lake County, State of Utah (Civil No. 030914719) by Franklin Funding, Inc. in which it alleges that we had entered into a lease agreement for the lease of certain equipment for which payment is due. It is claimed that there is due and owing approximately \$89,988 after accruing late fees, interest, repossession costs, collection costs and attorneys' fees. On August 28, 2003, we agreed to a settlement of the case with Franklin Funding by agreeing to make 24 monthly payments of \$2,300 to Franklin Funding, with the first monthly payment due on August 29, 2003. As of December 31, 2004, we have made 17 monthly payments of \$2,300 each to Franklin Funding.

We received demand letters dated July 18, 2003, September 26, 2003 and November 10, 2003 from counsel for Douglas A. MacLeod, M.D., a shareholder of

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

On August 3, 2003, a complaint was filed against us by Corinne Powell, a former employee, in the Third Judicial District Court, Salt Lake County, State of Utah (Civil No. 030918364). Defendants consist of the Company and Randall A. Mackey, Dr. David M. Silver and Keith D. Ignatz, directors of the company. The complaint alleges that at the time we laid off Ms. Powell on March 25, 2003, she was owed \$2,030 for business expenses, \$11,063 for accrued vacation days, \$12,818 for unpaid commissions, the fair market value of 50,000 stock options exercisable at \$5.00 per share that she claims she was prevented from exercising, attorney's fees and a continuing wage penalty under Utah law. We dispute the amounts allegedly owed and intend to vigorously defend and protect our interests in the action.

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

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

On August 9, 2004, a third party complaint was brought against us by Wakefield Eye Center. The original action was brought by American Express Business Corporation against Westfield Eye Center on May 27, 2004 in the District Court, Clark County, State of Nevada (Civil No. A486307, Dept. No. XXI) concerning the financing of the purchase of a Blood Flow Analyzer(TM) involving Westfield Eye Center. The transaction took place during the latter half of 2001.

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Westfield Eye Center takes the position that if there is liability of Westfield to American Express this liability is ultimately ours and the other third-party defendants. The amount being sought against Westfield Eye Center by American Express in the original action includes the sum of \$29,765.83, together with interest and attorney's fees. Westfield's alleged claims against us include fraud, breach of contract, promissory estoppel, declaratory relief, negligence, negligent supervision, damages for injuries resulting from actions of employee/contractor, wilful and wanton misconduct, conspiracy, and breach of fiduciary duty as well as costs and attorney's fees. Westfield also seeks punitive damages. We have filed an answer to the third party complaint in which we deny liability. Formal discovery in the matter involving us has not commenced apart from initial disclosure requirements. The case has been referred to arbitration. We intend to vigorously defend the action.

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

MANAGEMENT

Directors and Executive Officers

As of January 31, 2005, our executive officers and directors, their ages and their positions are set forth below:

Name	Age	Position
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John Y. Yoon	40	President and Chief Executive Officer
Aziz A. Mohabbat	44	Vice President of Operations and Chief Operating Officer
Randall A. Mackey, Esq.	59	Chairman of the Board, Secretary and Director
David M. Silver, Ph.D.	61	Director
Keith D. Igotz	54	Director
John C. Pingree	64	Director

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

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

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

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

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

Keith D. Ignatz has been a director since November 2000. He has been President and Chief Operating Officer of SpectRx, Inc., a medical technology company that he founded in 1992, which develops, manufactures and markets alternatives to traditional blood-based medical tests. From 1986 to 1992, Mr. Ignatz was Senior Vice President of Allergan Humphrey, Inc., a medical electronics company. From 1985 to 1986, he was President of Humphrey Instruments Limited-SKB, a medical electronics company, and from 1980 to 1985, Mr. Ignatz was President of Humphrey Instruments GmbH, also a medical electronics company. Mr. Ignatz also served on the Board of Directors of Vismed, Inc., d/b/a Dicon from 1992 to June 2000. Mr. Ignatz received a B.A. degree in Sociology and Political Science from San Jose University and an M.B.A. degree from Pepperdine University. Mr. Ignatz has served as a trustee of Pennsylvania College of Optometry since 1990, as a director for FluoRx, Inc. since 1997, and as a member of the American Marketing Association of the American Association of Diabetes Education.

John C. Pingree has been a director since April 2004. He has been the Executive Director of the Semnani Foundation since August 2001, which funds

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

Appointment of New President and Chief Executive Officer

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

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Appointment of New Chief Operating Officer

On March 23, 2004, Aziz A. Mohabbat was appointed as our Vice President of Operations and Chief Operating Officer, replacing David I. Cullumber who had resigned as Chief Operating Officer and Chief Technical Officer. Mr. Cullumber served as Chief Operating Officer from November 6, 2003 to March 22, 2004. Mr. Mohabbat had previously served as our Chief Operating Officer from August 2002 to March 2003, and as Vice President of Operations from 2001 to March 2003.

Board Meetings and Committees

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

Executive Compensation

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

Summary Compensation Table

Annual Compensation

Other	Restricted	Security
Annual		Underly

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Name and Principal Position -----	Year ----	Salary\$ -----	Bonus (\$) -----	Compen- sation (\$) -----	Stock Awards (\$) -----	Option SARs (-----
John Y. Yoon President and Chief Executive Officer	2004 (1)	\$110,961 (4)		\$18,494 (4)	0	1,000,000
Aziz A. Mohabbat Vice President of Operations and Chief Operating Officer (6)	2004 (1) 2003 (2) 2002 (3)	\$106,244 \$ 24,219 \$126,878	0 0 0	0 0 0	0 0 0	
Jeffrey F. Poore Former President and Chief Executive Officer	2004 (1) 2003 (2)	\$ 41,052 \$136,015	0 0	0 0	0 0	1,000,000
David I. Cullumber, Former Chief Operating Officer and Chief Technical Officer	2004 (1) 2003 (2)	\$ 15,894 \$ 22,312	0 0	\$18,059 (9) \$16,616 (9)	0 0	150,000
Gregory C. Hill Former Vice President of Finance and Chief Financial Officer	2004 (1) 2003 (2)	0 \$34,000	0 0	0 0	0 0	
Thomas F. Motter Former Chairman of the Board and Chief Executive Officer	2004 (1) 2003 (2) 2002 (3)	0 0 \$187,483 (11)	0 0 0	0 0 0	0 0 0	
Mark R. Miehle Former President and Chief Operating Officer	2004 (1) 2003 (2) 2002 (3)	0 0 \$134,202	0 0 0	0 0 0	0 0 0	55,000
Heber C. Maughan Former Vice President of Finance and Chief Financial Officer (16)	2004 (1) 2003 (2) 2002 (3)	0 \$ 36,855 \$114,416	0 0 0	0 0 0	0 0 0	150,000

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- (1) For the fiscal year ended December 31, 2004
 - (2) For the fiscal year ended December 31, 2003
 - (3) For the fiscal year ended December 31, 2002
 - (4) Of the salary payable to Mr. Yoon pursuant to his employment agreement, \$110,961 was paid to him during 2004 and the remaining amount of \$18,494 payable in 2004 was deferred until our board of directors has determined that our financial condition is improved.
 - (5) On March 18, 2004, our board of directors granted Mr. Yoon options to purchase 1,000,000 shares of our common stock at an exercise price of \$.13 per share.
 - (6) Mr. Mohabbat has served a Vice President of Operations and Chief

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Operating Officer since March 22, 2004 and as Chief Operating Officer from August 30, 2002 to March 2003. He was not an officer in prior years.

- (7) The amounts under "All Other Compensation" for 2004 consist of payments to Mr. Mohabbat for accrued vacation days prior to his resignation from the Company in March 2003.
- (8) On March 19, 2003, our board of directors granted Mr. Poore options to purchase 1,000,000 shares of our common stock at an exercise price of \$.16 per share. These options were terminated on March 18, 2003 when our board of directors terminated Mr. Poore's employment for cause as defined in the employment agreement.
- (9) We paid A-Mech Engineering, Inc. a total of \$16,616 and \$18,059 for consulting services during 2003 and 2004, respectively. From 1982 to March 2004, Mr. Cullumber served as President of A-Mech Engineering, Inc.
- (10) On November 6, 2003, our board of directors granted Mr. Cullumber options to purchase 150,000 shares of our common stock at an exercise price of \$.21 per share. These options were terminated on June 20, 2003, 90 days after Mr. Cullumber resigned as our Chief Operating Officer and Chief Technical Officer.
- (11) Although Mr. Motter resigned as Chairman and Chief Executive Officer on August 30, 2002, he continued to receive his salary under the terms of his employment agreement through December 16, 2002.
- (12) The amounts under "All Other Compensation" for 2004, 2003 and 2002 include payments related to the operation of automobiles and/or automobiles and insurance by the named executives.
- (13) The amounts under "All Other Compensation" for 2002 include payments related to the residential housing accommodations for our employees, living outside of Utah while they were working at our corporate headquarters in Salt Lake City, leased from Mr. Motter at \$2,500 per month.
- (14) On January 29, 2002, our Board of Directors granted Mr. Miehle options to purchase the 55,000 shares of our common stock at an exercise price of \$2.75 per share. These options were terminated on February 28, 2004, one year after expiration of a six-month consulting agreement with the Company, which expired on February 28, 2003.
- (15) On September 3, 2002, we entered into a consulting agreement with Mr. Miehle in which we are required to pay him monthly consulting fees of \$5,000 over a period of six months. We paid him a total of \$15,000 for consulting services during the months of September, October and November of 2002.
- (16) Mr. Maughan served as Interim Chief Executive Officer from August 30, 2002 to March 19, 2003. He served as Vice President of Finance, Treasurer and Chief Financial Officer from October 1, 2001 until his resignation on May 31, 2003.
- (17) On May 13, 2003, our Board of Directors granted Mr. Maughan options to purchase 150,000 shares of our common stock at an exercise price of \$.16 per share. These options were terminated on August 29, 2003, 90 days after Mr. Maughan resigned as Vice President of Finance and Chief Financial Officer.

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Options

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

Option Grants in Last Fiscal Year

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Name	Number of Securities Underlying Options Granted (#)	Percentage of Total Options Granted to Employees in Fiscal Year(%)	Individual Gr Exer Pe
John Y. Yoon.....	1,000,000 (1)	56.3%	
Aziz A. Mohabbat.....	200,000 (2)	11.3%	

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

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

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

Name	Shares Acquired on Exercise	Value Realized(\$)	Exercisable	Number of Securities Underlying Unexercised Options at December 31, 2004(#)
John Y. Yoon.....	0	0	250,002	749,998
Aziz A. Mohabbat.....	0	0	50,004	149,996

Director Compensation

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

Employee 401(k) Plan

In October 1996, our board of directors adopted a 401(k) Retirement Savings Plan. Under the terms of the 401(k) plan, effective as of November 1, 1996, we may make discretionary employer matching contributions to our employees who choose to participate in the plan. The plan allows the board to determine the amount of the contribution at the beginning of each year. The Board adopted

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a contribution formula specifying that such discretionary employer matching contributions would equal 100% of the participating employee's contribution to the plan up to a maximum discretionary employee contribution of 3% of a participating employee's compensation, as defined by the plan. All persons who have completed at least six months' service with us and satisfy other plan requirements are eligible to participate in the plan.

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1995 Stock Option Plan

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

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

The term of each option shall not be more than ten years (five years in the case of incentive stock options granted to holders of 10% of the voting power of our stock) from the date of grant. The Board of Directors has a right to amend, suspend or terminate the 1995 Stock Option Plan at any time; provided, however, that unless ratified by our shareholders, no amendment or change in the plan will be effective that would increase the total number of shares that may be issued under the plan, materially increase the benefits accruing to persons granted under the plan or materially modify the requirements as to eligibility and participation in the plan. No amendment, supervision or termination of the

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plan shall, without the consent of an employee to whom an option shall heretofore have been granted, affect the rights of such employee under such option.

Employment Agreements

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

We entered into an employment agreement with Mark R. Miehle, which commenced on June 5, 2000, and was to expire on June 4, 2003. The employment agreement required Mr. Miehle to devote substantially all of his working time as our President and Chief Operating Officer, provided that he may be terminated for "cause" (as provided in the agreement) and prohibited him from competing with us for two years following the termination of his employment agreement. The employment agreement provided for the payment of an initial annual base salary of \$150,000, effective as of June 5, 2000, and the issuance of stock options to purchase 150,000 shares of our common stock at \$6.00 per share, to be vested in equal annual amounts over a three year period. The employment agreement also provided for salary increases and bonuses as to be determined at the discretion of the Board of Directors. The stated annual compensation remained in effect through December 31, 2001 and into 2002. The Board of Directors terminated the employment agreement with Mr. Miehle on August 30, 2002. He entered into a six month consulting agreement, which expired on February 28, 2003, for \$5,000 per month. Mr. Miehle was paid \$15,000 in 2002 under the terms of the consulting agreement.

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

On March 18, 2004, our Board of Directors terminated Mr. Poore's employment for cause as defined in the employment agreement. As a result of the termination of the employment agreement, we believe that we have no further obligations to make salary or bonus payments or provide benefits to Mr. Poore and all of his stock options have terminated. On May 25, 2004, Mr. Poore brought

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a lawsuit against us. In his complaint he alleges that we unlawfully terminated his employment and, as a consequence, demands judgment against us for \$350,000, representing his annual salary for the two remaining years under the employment agreement, for money judgment for the value of his benefits for the two remaining years under the employment agreement, and for the value of the stock options granted to him. We dispute the claims in the complaint and believe there was a sufficient basis to terminate Mr. Poore's employment for cause under the terms of the employment agreement.

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

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

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

In the event of a change of control of the company, then all

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

Severance Agreement

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

The termination of the employment agreement also required us to enter into a consulting agreement with Mr. Miehle. Under the terms of the consulting agreement, Mr. Miehle is to provide consulting services to us for a period of six months for a fee of \$5,000 per month. The consulting agreement is to be automatically renewed for an additional six months at a fee of \$3,000 per month unless we deliver written notice to Miehle at least 30 days prior to the end of the initial six month term that we will not renew the agreement. We paid Mr. Miehle a total of \$15,000 under the consulting agreement for consulting services during the months of September, October and November of 2002. We also provided written notice to Mr. Miehle more than 30 days prior to the end of the initial six month term of the consulting agreement of our intention not to renew the agreement.

Consulting Agreement

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

Limitation of Liability and Indemnification

We reincorporated in Delaware in February 1996, in part, to take advantage of certain provisions in Delaware's corporate law relating to limitations on liability of corporate officers and directors. We believe that

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the reincorporation into Delaware, the provisions of its Certificate of Incorporation and Bylaws and the separate indemnification agreements outlined below are necessary to attract and retain qualified persons as directors and officers. Our Certificate of Incorporation limits the liability of directors to the maximum extent permitted by Delaware law. This provision is intended to allow our directors the benefit of Delaware General Corporation Law that provides that directors of Delaware corporations may be relieved of monetary liabilities for breach of their fiduciary duties as directors, except under certain circumstances, including breach of their duty of loyalty, acts or omissions not in good faith or involving intentional misconduct or a knowing violation of law, unlawful payments of dividends or unlawful stock repurchases or redemptions or any transaction from which the director derived an improper personal benefit. Our Bylaws provide that we shall indemnify our officers and directors to the fullest extent provided by Delaware law. Our Bylaws authorize the use of indemnification agreements and we have entered into such agreements with each of our directors and executive officers.

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There is pending litigation against Thomas F. Motter, Mark R. Miehle and John W. Hemmer, former officers of the company, to whom we have indemnification obligations. The pending litigation consists of class action complaints for alleged violations of the federal securities laws filed in the United States District Court, District of Utah, captioned Richard Meyer, individually and on behalf of others similarly situated v. Paradigm Medical Industries, Inc., Thomas Motter, Mark Miehle and John Hemmer, Case No. 2:03 CV00448TC, Michael Marrone v. Paradigm Medical Industries, Inc., Thomas Motter, Mark Miehle, and John Hemmer, Case No. 2:03 CV00513PGC, and Milian v. Paradigm Medical Industries, Inc., Thomas Motter, Mark Miehle and John Hemmer, Case No. 2:03 CV00617PGC. We have retained legal counsel to review the complaints, which appear 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, each of the complaints alleges that we falsely stated in our Securities and Exchange Commission filings and press releases that we had received authorization to use an insurance reimbursement CPT code from the CPT Code Research and Development Division of the American Medical Association in connection with the Blood Flow Analyzer(TM), adding that the CPT code provides for a reimbursement to doctors of \$57.00 per patient for use of the Blood Flow Analyzer(TM). The complaints also allege that on July 11, 2002, we issued a press release falsely announcing that we had received a purchase order from Valdespino Associates Enterprises and Westland Financial Corporation for 200 sets of our entire portfolio of products, with \$70 million in systems to be delivered over a two-year period, then another \$35 million of orders to be completed in the third year. As a result of these statements, the complaints contend that the price of our shares of common stock was artificially inflated during the period from April 25, 2001 through May 14, 2003, and the persons who purchased our common shares during that period suffered substantial damages. The complaints request judgment for unspecified damages, together with interest and attorneys' fees. These three cases have been consolidated into a single action. If we are not successful in defending and protecting our interests in these cases, resulting in a judgment against us for substantial damages, and U.S. Fire Insurance Company denies coverage in the cases under the Directors and Officers Liability and Company Reimbursement Policy, we would not be able to pay the indemnification obligations and, as a result, would be forced to seek bankruptcy protection.

There is also pending litigation against Messrs. Motter, Miehle and Hemmer in an action filed in the United States District Court, District of Utah by Innovative Optics, Inc. The complaint claims that Innovative and Barton

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entered into an asset purchase agreement with us on January 31, 2002, in which we agreed to purchase all the assets of Innovative in consideration for the issuance of 1,310,000 shares of the Company's common stock to Innovative. The complaint also claims that we allegedly made false and misleading statements pertaining to the Blood Flow Analyzer(TM) and concerning a purchase order from Valdespino Associates Enterprises and Westland Financial Corporation. The purpose of these statements, according to the complaint, was to induce Innovative to sell its assets and purchase the shares of our common stock at artificially inflated prices while simultaneously deceiving Innovative and Barton into believing that the Company's shares were worth more than they actually were. Had Innovative and Barton known the truth, the complaint contends, they would not have sold Innovative to us, would not have purchased our stock for the assets of Innovative, or would not have purchased the stock at the inflated prices that were paid. The complaint further contends that as a result of these statements, Innovative and Barton suffered substantial damages in an amount to be proven at trial.

The complaint further claims that 491,250 of the shares to be issued to Innovative in the asset purchase transaction were not issued on a timely basis and we also did not file a registration statement with the Securities and Exchange Commission within five months of the closing date of the asset purchase transaction. As a result, the complaint alleges that the value of the shares of our common stock issued to Innovative in the transaction declined, and Innovative and Barton suffered damages in an amount to be proven at trial. We filed an answer to the complaint and also filed counterclaims against Innovative and Barton for breach of contract. If we are not successful in defending and protecting our interests in this action, resulting in a judgment against us for substantial damages, and U.S. Fire denies coverage in the cases under the Directors and Officers Liability and Company Reimbursement Policy, we would not be able to pay the indemnification obligations and, as a result, would be forced to seek bankruptcy protection.

Finally, there is also pending litigation against Messrs. Motter, Miehle and Hemmer and Randall A. Mackey, Chairman of the Board and Secretary, to whom we have indemnification obligations, in a class action complaint filed in the Third Judicial District Court, Salt Lake County, State of Utah, captioned Albert Kinzinger, Jr., individually and on behalf of all others similarly situated vs. Paradigm Medical Industries, Inc., Thomas Motter, Mark Miehle, Randall A. Mackey, and John Hemmer, Case No. 030922608. We have retained legal counsel to review the complaint, which appears to be focused on alleged false or misleading statements pertaining to the Blood Flow Analyzer(TM). More specifically, the complaint alleges that we falsely stated in 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 in connection with the Blood Flow Analyzer(TM), adding that the CPT code provides for a reimbursement to doctors of \$57.00 per patient for the Blood Flow Analyzer(TM).

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

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the indemnification obligations and, as a result, would be forced to seek bankruptcy protection.

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Except for these litigation matters, there is no pending litigation or proceedings involving a director, officer, employee or other agent of our company as to which indemnification is being sought, nor are we aware of any threatened litigation that may result in claims for indemnification by any director, officer, employee or other agent.

Insofar as indemnification for liabilities arising under the Securities Act of 1933 may be permitted to directors, officers and controlling persons pursuant to the foregoing provisions, or otherwise, we have been advised that in the opinion of the Securities and Exchange Commission, such indemnification is against public policy as expressed in the Securities Act of 1933, as amended, and is, therefore, unenforceable.

Compliance with Section 16(a) of the Securities Exchange Act of 1934

Section 16(a) of the Securities Exchange Act of 1934 requires our executive officers, directors and persons who own more than 10% of any class of our common stock to file initial reports of ownership and reports of changes of ownership of common stock. Such persons are also required to furnish us with all Section 16(a) reports they file. Based solely on our review of the copies of such reports received by us with respect to fiscal 2003, or written representations from certain reporting persons, we believe that all filing requirements applicable to its directors, officers and greater than 10% beneficial owners were complied with.

SECURITY OWNERSHIP OF CERTAIN BENEFICIAL OWNERS AND MANAGEMENT

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

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

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

*Less than 1%.

- (1) Unless otherwise indicated, the address of each listed stockholder is c/o Paradigm Medical Industries, Inc., 2355 South 1070 West, Salt Lake City, Utah, 84119.
- (2) Based on our shareholder records, Dr. McLeod owns 1,218,451 shares and is our largest sole shareholder. Dr. McLeod's beneficial ownership is

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believed to also include 400,000 shares held by the Douglas A. MacLeod, M.D. Profit Sharing Trust, 200,000 shares held by St. Mark's Eye Institute and 720,000 shares held by Milan Holdings, Ltd., which we believe Dr. MacLeod to have sole or shared voting and dispositive powers with regard to such shares. Dr. MacLeod's beneficial ownership further includes shares that may be acquired currently or within 60 days after January 31, 2005 through the exercise of warrants as follows: Dr. MacLeod, 200,000 shares; Douglas A. MacLeod, M.D. Profit Sharing Trust; 100,000 shares; St. Mark's Eye Institute, 50,000 shares; and Milan Holdings, Ltd., 180,000 shares.

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

CERTAIN TRANSACTIONS

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

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

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

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Randall A. Mackey, a director since January 21, 2000, and from September 1995 to September 3, 1998 and chairman of the board since August 30, 2002, is President and a shareholder of the law firm of Mackey Price & Thompson, which rendered legal services in connection with various corporate matters. Legal fees and expenses paid to Mackey Price & Thompson for the fiscal years ended December 31, 2004 and 2003, totaled \$90,000 and \$97,000, respectively. As of December 31, 2004, we owed this firm \$188,705, which is included in accounts payable.

SELLING SECURITYHOLDERS

The following table sets forth information regarding the beneficial ownership of our common stock being registered for resale as of January 31, 2005, (i) by each of the holders of common stock pursuant to registration rights, and (ii) by each of the holders of Series E and Series F Convertible preferred stock, assuming each of the Series E and Series F preferred shareholders elects to c