# PARADIGM MEDICAL INDUSTRIES INC Form SB-2/A

December 11, 2006

As filed with the Securities and Exchange Commission on December 8, 2006 Commission File No. 333-137334

> SECURITIES AND EXCHANGE COMMISSION Washington, D.C. 20549

> > 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 (State or jurisdiction of (Primary Standard Industrial (I.R.S. Employer incorporation or organization) Classification Code Number) Identification

87-0459536 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)

Raymond P.L. Cannefax, President and Chief Executive Officer Paradigm Medical Industries, Inc. 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. |X|

If this Form is filed to register additional securities for an offering pursuant to Rule 462(b) 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 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 this Form is a post-effective amendment filed pursuant to Rule  $462\,(d)$  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, check the following box. [ ]

CALCULATION OF REGISTRATION FEE

Title of each Proposed Proposed class of Number of maximum maximum Am securities to be Shares to be offering price aggregate registered registered(1) per Share(2) offering price

Common Stock, \$.001 par value per share.... 60,000,000 .006 \$ 360,000 \$

- Includes shares of our common stock, \$.001 par value per share, which may be offered pursuant to this registration statement, which shares are issuable upon conversion of callable secured convertible notes held by the selling stockholders. Pursuant to an agreement with the holders of the convertible notes, we are required to register for resale up to but no greater than 60,000,000 shares of our common stock issuable upon conversion of the notes even though additional shares might be issued to the noteholders upon conversion of their notes. Thus, should the conversion ratio result in our having insufficient shares registered for the resale of the additional shares that might be issued to the noteholders upon conversion of their notes, we will not file a new registration statement to cover the resale of such additional shares should that become necessary.
- (2) Estimated solely for purposes of calculating the registration fee in accordance with Rule 457(c) and Rule 457(g) under the Securities Act of 1933, as amended, using the last reported sale price on the OTC Bulletin Board on September 6, 2006, which was \$.006 per share.

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 of 1933 or until this Registration Statement shall become effective on such date as the Commission, acting pursuant to such Section 8(a), may determine.

PRELIMINARY PROSPECTUS SUBJECT TO COMPLETION, DATED DECEMBER , 2006

Up to 60,000,000 Shares of Common Stock

#### PARADIGM MEDICAL INDUSTRIES, INC.

This prospectus relates to the resale by the selling stockholders of up to 60,000,000 shares of our common stock issuable upon conversion of the callable secured convertible notes in the principal amount of \$1,500,000(consisting of \$1,000,000 in convertible notes that were sold to four investors pursuant to a securities purchase agreement dated February 26, 2006, plus \$500,000 in notes to be sold to the investors upon the effectiveness of a registration statement to register 60,000,000 shares of our common stock issuable upon conversion of such notes). The \$1,500,000 in convertible notes are convertible into our common stock at the lower of (i) \$.02 or (ii) 60% of the average of the three lowest intraday trading prices for our common stock on the OTC Bulletin Board for the 20 trading days before but not including the conversion date. The selling stockholders may sell common shares from time to time in the principal market on which the stock is traded at the prevailing market price or in negotiated transactions. The selling stockholders may be deemed underwriters of the shares of common stock that they are offering. We will pay the expenses of registering these shares.

Our common stock is registered under Section 12(g) of the Securities Exchange Act of 1934, as amended, and is quoted on the Over-the-Counter Bulletin Board under the symbol PMED.OB. On November 15, 2006, the last reported sale price of our common stock was \$.005 per share.

Investing in our common stock involves substantial risks that are described in the "Risk Factors" section beginning on page 7 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 information in this prospectus is not complete and may be changed. This prospectus is included in the registration statement that was filed by Paradigm Medical Industries, Inc. with the U.S. Securities and Exchange Commission. The selling stockholders may not sell these securities until the registration statement becomes effective. This prospectus is not an offer to sell these securities and is not soliciting an offer to buy these securities in any state where the sale is not permitted.

The date of this prospectus is December \_\_\_, 2006.

#### 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.

As reflected in the results for the fiscal years ended December 31, 2005 and 2004, diagnostic products are currently our major focus and the Photon(TM) laser system 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. We sell our 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 United Arab Emirates . Both the Photon(TM) laser system and the Precisionist ThirtyThousand (TM) are manufactured as an Ocular Surgery Workstation(TM). At present, because the Photon(TM) laser system has not received FDA approval, it does not provide significant revenues to us. 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. Any possible future efforts to complete the clinical trials on the Photon(TM) would depend on our obtaining adequate funding. Thus, due to the uncertainty surrounding the timetable for obtaining FDA approval and the lack of significant revenues from other surgical products, we have recorded an inventory reserve against the majority of inventory associated with the Photon(TM) laser system and Precisionist Thirty Thousand(TM).

Our diagnostic products include a P55 pachmetric analyzer, a P37 Ultrasonic A/B Scan, the P40, P45 and P60 UBM Ultrasound Biomicroscopes, a P37 A/B Scan, two perimeters, 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 P37 Ultrasonic A/B Scan and the P40 UBM Ultrasound 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 acquired the 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. In March 2005, we developed and offered for sale the P60 UBM Ultrasound Biomicroscope, the fourth generation of UBM devices, which has better visual clarity and image flexibility than earlier versions. We are currently developing additional applications for all of our diagnostic products.

We rely upon several products for revenues. For the nine months ended September 30, 2006, 45% of our revenues were derived from the Dicon(TM) diagnostic products sales (the perimeter and corneal topographer), 8% of revenues from Blood Flow Analyzer(TM) sales, 18% of revenues from P40, P45 and P60 UBM Ultrasound Biomicroscope sales, 15% of revenues from Humphrey Systems diagnostic product sales (the P55 pachymetric analyzer, the P-20 A-Scan and the P37 Ultrasonic A/B Scan), and 14% of revenues from services, disposables and other sales.

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For the fiscal year ended December 31, 2005, 31% of our revenues were derived from the Dicon(TM) diagnostic products sales (the perimeter and the corneal topographer), 4% of revenues from Blood Flow Analyzer(TM) sales, 43% of revenues from the P40, P45 and P60 UBM Ultrasound Biomicroscope sales, 10% of revenues from Humphrey systems diagnostic products sales (the P55 pachymetric analyzer, the P20 A-Scan and the P37 A/B Scan), and 12% of revenues from services, disposables and other sales.

For the fiscal year ended December 31, 2004, 34% of our revenues were derived from the Dicon (TM) diagnostic products sales (the perimeter and corneal topographer), 18% of revenues from Blood Flow Analyzer(TM) sales, 27% of revenues from P40 and P45 UBM Ultrasound Biomicroscope sales, 12% of revenues from Humphrey Systems diagnostic product sales (the P55 pachymetric analyzer, the P20 A-Scan and the P37 A/B Scan), and 9% 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, 2005 were \$2,201,000 as compared to \$3,062,000 for the comparable period for fiscal 2004.

Unaudited revenues for the nine months ended September 30, 2006 were \$1,600,000 as compared to \$1,963,000 for the comparable period of 2005.

On January 5, 2006, our Board of Directors appointed Raymond P.L. Cannefax as President and Chief Executive Officer of the company, replacing John Y. Yoon who served in those positions from March 18, 2004 to December 31, 2005. Mr. Yoon resigned as President and Chief Executive Officer, effective December 31, 2005, to pursue other opportunities. On March 20, 2006, our Board of Directors appointed Luis A. Mostacero as Vice President of Finance, Treasurer and Secretary. Mr. Mostacero previously served as Controller from June 20, 2000 to September 15, 2005, when he resigned to pursue other opportunities. On April 10, 2006, Michael S. Austin was appointed as Vice President of Sales and Marketing.

On November 15, 2005, Aziz A. Mohabbat resigned as Vice President of Operations and Chief Operating Officer to pursue other opportunities. Mr. Mohabbat served as Vice President of Operations and Chief Operating Officer from March 22, 2004 to November 15, 2005, and as Chief Operating Officer from August 30, 2002 to March 2003. On January 20, 2006, Frederick D. Geiger resigned as Vice President of Engineering to pursue other opportunities. Mr. Geiger served as Vice President of Engineering from May 23, 2005 to January 20, 2006. The Board of Directors has not yet appointed a new Chief Operating Officer since Aziz A. Mohabbat resigned or a new Vice President of Engineering since Mr. Geiger resigned in an effort to conserve our financial resources. Moreover, since Mr. Mohabbat's and Mr. Geiger's resignations, we have endeavored to reduce our operating expenditures, which has resulted in a reduction in the number of our employees. It is our intention to appoint a new Chief Operating Officer and a new Vice President of Engineering in the future when we have adequate funds to do so.

The Offering

Common stock offered by selling stockholders .....

Up to 60,000,000 shares issuable upon conversion of the convertible notes in the principal amount of \$1,500,000. Pursuant to an agreement with the holders of the convertible notes, we are required to register for resale up to but no greater than 60,000,000 shares of our common stock issuable upon conversion of the notes even though additional shares might be issued to the noteholders upon conversion of their notes.

Common stock outstanding prior to the offering(1) ...... 201,956,394 shares.

Common stock outstanding after the offering(1) ...... Up to 261,956,394 shares.

Use of proceeds.....

We will not receive any proceeds from the sale of the common stock hereunder. We received total gross proceeds of \$1,000,000 from the sale of the convertible notes that were sold to four investors pursuant to the securities purchase agreement dated February 28,

2006, and the investors are obligated to purchase from us \$500,000 in additional notes within five days of a registration statement being declared effective by the Securities and Exchange Commission that registers 60,000,000 shares of common stock issuable upon conversion of the notes. The proceeds from the sale of the convertible notes will be used for purchase of inventory, marketing and sales, increasing the number of our direct sales representatives, and working capital.

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

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(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, 13,333 shares of common stock issuable upon conversion of 250 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, 588,235 shares of stock issuable upon conversion of 588,235 shares of Series G preferred stock, options to purchase a total of 7,075,500 shares of common stock issuable upon the exercise of stock options at prices ranging from \$.01 to \$2.75 per share, and warrants to purchase 25,059,392 shares of common stock issuable upon the exercise of warrants at prices ranging from \$.10 to \$6.75 per share.

Outstanding Commitments to Issue Shares

The following table identifies our outstanding commitments to issue shares, including the shares underlying the convertible notes and warrants issuable upon conversion of the notes and exercise of the warrants:

Security	Underlying Share of Common Stock
Notes (1) Warrants (2) Preferred Stock (3) Stock Options (4)	1,048,930,333 25,059,392 873,071 7,075,500
Total	1,081,938,296

(1) Assumes full conversion of \$3,146,791 of notes issued to AJW Partners, LLC, AJW Offshore, Ltd., AJW Qualified Partners, LLC, and New

Millennium Capital Partners II, LLC at a conversion price of \$.003 per share (based upon a market price of \$.005 as of November 15, 2006 with a 40% discount).

- Consisting of warrants exerciseable at prices ranging from \$.10 per share to \$6.75 per share, including warrants issued to AJW Partners, LLC, AJW Offshore, Ltd., AJW Qualified Partners, LLC, and New Millennium Capital Partners II, LLC to purchase 16,534,392 shares of common stock at an exercise price of \$.20 per share, exerciseable through the period from April 27, 2010 to June 30, 2010, and warrants to purchase 8,000,000 shares of common stock at an exerciseable price of \$.10 per share, exerciseable through the period from February 28, 2011 to June 28, 2011.
- Consisting of 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, 13,333 shares of common stock issuable upon conversion of 250 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, and 588,235 shares of common stock issuable upon conversion of 588,235 shares of Series G preferred stock.
- (4) Consisting of stock options granted to executive officers and employees to purchase 4,825,500 shares of common stock at exercise prices ranging from \$.01 per share to \$2.75 per share, and stock options granted to directors to purchase 2,250,000 shares of common stock at exercise prices ranging from \$.09 per share to \$2.75 per share.

There are a total of 1,081,938,296 shares underlying our convertible notes, warrants, preferred stock and stock options, assuming full conversion of the outstanding notes and preferred stock and the exercise of all the outstanding warrants and stock options. The number of our authorized shares of common stock is 800,000,000 shares. The large number of our shares of common stock underlying our notes, warrants, preferred stock and stock options will require us to increase the number of authorized shares. Failure to obtain stockholder approval to increase the number of authorized shares could result in the noteholders commencing legal action against us and foreclosing on all of our assets to recover damages. Any such action would require us to curtail or cease our operations.

#### Convertible Notes and Warrants

April 27, 2005 Sale of \$2,500,000 in Convertible Notes: To obtain funding for our ongoing operations, we entered into a securities purchase agreement with four accredited investors on April 27, 2005 for the sale of (i) \$2,500,000 in convertible notes and (ii) warrants to purchase 16,534,392 shares of our common stock. The sale of the convertible notes and warrants occurred in three traunches and the investors provided us with an aggregate of \$2,500,000 as follows:

- o \$850,000 was disbursed on April 27, 2005;
- o \$800,000 was disbursed on June 23, 2005 after we filed a registration statement on June 22, 2005 to register the shares of common stock underlying the convertible notes and the warrants; and
- o \$850,000 was disbursed on June 30, 2005, the effective date of the registration statement.

Under the terms of the securities purchase agreement, we agreed not, without the prior written consent of a majority-in- interest of the investors, to negotiate or contract with any party to obtain additional equity financing (including debt financing with an equity component) that involves (i) the

issuance of common stock at a discount to the market price of the common stock on the date of issuance (taking into account the value of any warrants or

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options to acquire common stock in connection therewith), (ii) the issuance of convertible securities that are convertible into an indeterminate number of shares of common stock, or (iii) the issuance of warrants during the lock-up period beginning April 27, 2005 and ending on the later of (A) 270 days from April 27, 2005, and (B) 180 days from the date the registration statement is declared effective.

In addition, we agreed not to conduct any equity financing (including debt financing with an equity component) during the period beginning April 27, 2005 and ending two years after the end of the above lock-up period unless we have first provided each investor an option to purchase its pro-rata share (based on the ratio of each investor's purchase under the securities purchase agreement) of the securities being offered in any proposed equity financing. Each investor must be provided written notice describing any proposed equity financing at least 20 business days prior to the closing of such proposed equity financing and the option must be extended to each investor during the 15-day period following delivery of such notice.

The \$2,500,000 in convertible notes bear interest at 8% per annum from the date of issuance. Interest is computed on the basis of a 365-day year and is payable quarterly in cash, with six months of interest payable up front. The interest rate resets to zero percent for any month in which the stock price is greater than 125% of the initial market price, or \$.0945, for each trading day during that month. Any amount of principal or interest on the convertible notes that is not paid when due will bear interest at the rate of 15% per annum from the date due thereof until such amount is paid. The convertible notes mature in three years from the date of issuance, and are convertible into our common stock at the selling stockholders' option, at the lower of (i) \$.09 or (ii) 60% of the average of the three lowest intraday trading prices for the common stock on the OTC Bulletin Board for the 20 trading days before but not including the conversion date. Accordingly, there is no limit on the number of shares into which the notes may be converted.

The \$2,500,000 in convertible notes are secured by our assets, including our inventory, accounts receivable and intellectual property. Moreover, we have a call option under the terms of the notes. The call option provides us with the right to prepay all of the outstanding convertible notes at any time, provided there is no event of default by us and our stock is trading at or below \$.09 per share. An event of default includes the failure by us to pay the principal or interest on the convertible notes when due or to timely file a registration statement as required by us or obtain effectiveness with the Securities and Exchange Commission of the registration statement. Prepayment of the convertible notes is to be made in cash equal to either (i) 125% of the outstanding principal and accrued interest for prepayments occurring within 30 days following the issue date of the notes; (ii) 130% of the outstanding principal and accrued interest for prepayments occurring between 31 and 60 days following the issue date of the notes; and (iii) 145% of the outstanding principal and accrued interest for prepayments occurring after the 60th day following the issue date of the notes.

The warrants are exercisable until five years from the date of issuance at a purchase price of \$.20 per share. The investors may exercise the warrants on a cashless basis if the shares of common stock underlying the warrants are not then registered pursuant to an effective registration statement. In the event the investors exercise the warrants on a cashless basis, we will not receive any proceeds therefrom. In addition, the exercise price of the warrants

will be adjusted in the event we issue common stock at a price below market, with the exception of any securities issued as of the date of the warrants or issued in connection with the convertible notes issued pursuant to the securities purchase agreement.

The noteholders have agreed to restrict their ability to convert their convertible notes or exercise their warrants and receive shares of our common stock such that the number of shares of common stock held by them in the aggregate and their affiliates after such conversion or exercise does not exceed 4.99% of the then issued and outstanding shares of common stock. However, the noteholders may repeatedly sell shares of common stock in order to reduce their ownership percentage, and subsequently convert additional convertible notes. As of November 30, 2006, a total of \$853,209 in convertible notes have been converted pursuant to conversion notices from the noteholders.

February 28, 2006 Sale of \$1,500,000 in Convertible Notes: To obtain additional funding for our ongoing operations, we entered into a second securities purchase agreement on February 28, 2006 with the same four accredited investors for the sale of (i) \$1,500,000 in convertible notes and (ii) warrants to purchase 12,000,000 shares of its common stock. The sale of the convertible notes and warrants is to occur in three traunches and the investors are obligated to provide us with an aggregate of \$1,500,000 as follows:

- o \$500,000 was disbursed on February 28, 2006;
- o \$500,000 was disbursed on June 28, 2006 after we filed a registration statement on June 15, 2006 to register the shares of common stock underlying the convertible notes. The registration statement was subsequently withdrawn on July 25, 2006; and
- o \$500,000 will be disbursed upon the effectiveness of a registration statement to register 60,000,000 shares of common stock issuable upon conversion of the convertible notes.

Each closing under the securities  $% \left( 1\right) =\left( 1\right) +\left( 1\right) +$ 

- o We deliver to the investors duly executed convertible notes and warrants:
- o No litigation, statute, regulation or order had been commenced, enacted or entered by or in any court, governmental authority or any self-regulatory organization that prohibits consummation of the transactions contemplated by the securities purchase agreement; and

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o No event occurred that could reasonably be expected to have a material adverse effect on our business.

We also agreed not, without the prior written consent of a majority-in-interest of the investors, to negotiate or contract with any party to obtain additional equity financing (including debt financing with an equity component) that involves (i) the issuance of common stock at a discount to the market price of the common stock on the date of issuance (taking into account the value of any warrants or options to acquire common stock in connection therewith), (ii) the issuance of convertible securities that are convertible into an indeterminate number of shares of common stock, or (iii) the issuance of warrants during the lock-up period beginning February 28, 2006 and ending on the later of (a) 270 days from February 28, 2006, or (b) 180 days from the date the registration statement is declared effective.

In addition, we agreed not to conduct any equity financing (including debt financing with an equity component) during the period beginning February 28, 2006 and ending two years after the end of the above lock-up period unless it first provided each investor an option to purchase its pro-rata share (based on the ratio of each investor's purchase under the securities purchase agreement) of the securities being offered in any proposed equity financing. Each investor must be provided written notice describing any proposed equity financing at least 20 business days prior to the closing of such proposed equity financing and the option must be extended to each investor during the 15-day period following delivery of such notice.

The convertible notes bear interest at 8% per annum from the date of issuance. Interest is computed on the basis of a 365-day year and is payable quarterly in cash, with six months of interest payable up front. The interest rate resets to zero percent for any month in which the stock price is greater than 125% of the initial market price, or \$.0275, for each trading day during that month. Any amount of principal or interest on the convertible notes that is not paid when due will bear interest at the rate of 15% per annum from the date due thereof until such amount is paid. The convertible notes mature in three years from the date of issuance, and are convertible into our common stock at the selling stockholders' option, at the lower of (i) \$.02 or (ii) 60% of the average of the three lowest intraday trading prices for the common stock on the OTC Bulletin Board for the 20 trading days before but not including the conversion date. Accordingly, there is no limit on the number of shares into which the notes may be converted.

The convertible notes are secured by our assets, including our inventory, accounts receivable and intellectual property. Moreover, we have a call option under the terms of the notes. The call option provides us with the right to prepay all of the outstanding convertible notes at any time, provided there is no event of default by us and our stock is trading at or below \$.02 per share. An event of default includes the failure by us to pay the principal or interest on the convertible notes when due or to timely file a registration statement as required by us or obtain effectiveness with the U.S. Securities and Exchange Commission of the registration statement. Prepayment of the convertible notes is to be made in cash equal to either (a) 125% of the outstanding principal and accrued interest for prepayments occurring within 30 days following the issue date of the notes; (b) 130% of the outstanding principal and accrued interest for prepayments occurring between 31 and 60 days following the issue date of the notes; or (c) 145% of the outstanding principal and accrued interest for prepayments occurring after the 60th day following the issue date of the notes.

The warrants are exercisable until five years from the date of issuance at a purchase price of \$.10 per share. The investors may exercise the warrants on a cashless basis if the shares of common stock underlying the warrants are not then registered pursuant to an effective registration statement. In the event the investors exercise the warrants on a cashless basis, we will not receive any proceeds therefrom. In addition, the exercise price of the warrants will be adjusted in the event we issue common stock at a price below market, with the exception of any securities issued as of the date of the warrants or issued in connection with the convertible notes issued pursuant to the securities purchase agreement.

The noteholders have agreed to restrict their ability to convert their convertible notes or exercise their warrants and receive shares of our common stock such that the number of shares of common stock held by them in the aggregate and their affiliates after such conversion or exercise does not exceed 4.99% of the then issued and outstanding shares of common stock. However, the noteholders may repeatedly sell shares of common stock in order to reduce their ownership percentage, and subsequently convert additional convertible notes.

We are required to register 60,000,000 shares of our common stock issuable upon the conversion of the convertible notes that were issued to the noteholders pursuant to the securities purchase agreement we entered into on February 28, 2006. The registration statement must be filed with the Securities and Exchange Commission within 60 days of the February 28, 2006 closing date and the effectiveness of the registration is to be within 135 days of such closing date. Penalties of 2% of the outstanding principal balance of the convertible notes plus accrued interest are to be applied for each month the registration is not effective within the required time. The penalty may be paid in cash or stock at our option.

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Simple Conversion Calculation

The number of shares of common stock issuable upon conversion of the convertible notes is determined by dividing that portion of the principal of the notes to be converted and interest, if any, by the conversion price. For example, assuming conversion of the \$3,146,791 principal amount of notes on November 30, 2006 (consisting of \$3,500,000 in convertible notes that were sold to the four investors pursuant to the securities purchase agreements dated April 27, 2005 and February 25, 2006, plus \$500,000 in notes to be sold to the investors upon the effectiveness of a registration statement, less \$853,209 in notes that were converted during the period from June 30, 2005 to November 30, 2006) and a conversion price of \$.003 per share, the number of shares issuable upon conversion would be:

\$3,146,791/\$.003 = 1,048,930shares.

Our obligation to issue shares upon conversion of our convertible notes is essentially limitless. The following is an example of the amount of shares of our common stock that are issuable upon conversion of the \$3,146,791 principal amount of our convertible notes, based on market prices 25%, 50%, and 75% below the market price, as of November 15, 2006 of \$.005.

% Below Market 	Price Per Share	With 40% Discount	Number of Shares Issuable	% of Outstanding*
25%	\$.00375	\$.00225	1,398,573,778	692.5%
50%	\$.0025	\$.0015	2,097,860,667	1,038.8%
75%	\$.00125	\$.00069	4,560,566,667	2,258.2%

<sup>\*</sup>Based on 201,956,394 shares outstanding.

As illustrated, the number of shares of common stock issuable upon conversion of our convertible notes will increase if the market price of our stock declines, which will cause dilution to our existing stockholders.

See the "Risk Factors" and "Selling Stockholders" sections for a complete description of the convertible notes and warrants.

Summary Financial Information

For the year ended For the nine months ended December 31, September 30,

Statement of Operations Data:	2004	2005	2005	2006
Net Sales	\$3,062,000	\$2,201,000	\$1,963,000	\$1,600,000
Net cost of sales	1,217,000	1,599,000	935,000	841,000
Operating expenses	2,237,000	2,782,000	2,144,000	1,467,000
Operating loss	(392,000)	(2,180,000)	(1,116,000)	(708 <b>,</b> 000)
Other income (expense)	456,000	(3,209,000)	(2,850,000)	(1,118,000)
Net income (loss)	64,000	(5,389,000)	(3,966,000)	(1,826,000)
Net income (loss)				
applicable to common				
shareholders	10,000	(5,389,000)	(3,966,000)	(1,826,000)
Net income (loss) per				
common share	\$0.00	\$(0.13)	\$(0.13)	\$(0.01)
Shares used in computing				
net loss per share	25,405,000	42,033,000	31,472,000	166,459,000

	As of	As of
Balance Sheet Data:	December 31, 2005	September 30, 2006
Current assets	\$1,331,000	\$1,489,000
Current liabilities	1,177,000	1,129,000
Working capital (deficit)	154,000	360,000
Total assets	1,702,000	1,852,000
Accumulated deficit	(62,196,000)	(64,019,000)
Stockholder's equity	(1,513,000)	(1,937,000)

#### 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.

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#### Special Note Regarding Forward-Looking Statements

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, 2005, we had working capital of \$154,000. As of September 30, 2006, our working capital was \$360,000. Our accumulated deficit was \$62,196,000 as of December 31,2005, and \$64,019,000 as of September 30, 2006. We had net income of \$64,000 for the fiscal year ended December 31, 2004, a net loss of \$5,389,000 for the fiscal year ended December 31, 2005, and a net loss of \$1,826,000 for the nine months ended September 30, 2006. 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.

Because our securities trade on the Over-the-Counter 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 Over-the-Counter 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 Nasdag'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

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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 Over-the-Counter Bulletin Board effective June 26, 2003. Because our securities are delisted from the Nasdaq

SmallCap Market and now trade on the Over-the-Counter 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 Over-the-Counter 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 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.

We are limited to registering for resale only up to 60,000,000 shares of our common stock issuable upon conversion of the convertible notes and, absent an ability to register additional shares for resale, we may not be able to repay the outstanding notes, which could result in the noteholders commencing legal action against us that could require us to curtail or cease operations.

As of November 30, 2006, we had \$2,664,791 in convertible notes outstanding and an obligation to sell \$500,000 in convertible notes upon the effectiveness of a registration statement to register 60,000,000 shares of common stock issuable upon conversion of the notes that were sold to four accredited investors pursuant to the securities purchase agreements dated April 27, 2005 and February 28, 2006. These notes bear interest at 8% per annum from the date of issuance. Interest is payable quarterly in cash, with six months of interest payable up front. Any amount of principal or interest on the notes that is not paid when due shall bear interest at the rate of 15% per annum from the date due until such amount is paid.

The notes mature in three years from the date of issuance. The \$1,646,791 in notes outstanding, which were sold pursuant to the securities purchase agreement dated April 27, 2005, are convertible into our common stock at the selling stockholder's option, at the lower of (i) \$.09 or (ii) 60% of the average of the three lowest intraday trading prices for our common stock on the OTC Bulletin Board for the 20 trading days before but not including the conversion date. The \$1,000,000 in notes outstanding, which were sold pursuant to the securities purchase agreement dated February 28, 2006, are convertible into our common stock at the selling stockholders option, at the lower of (x) \$.02 or (y) 60% of the average of the three lowest intraday trading prices for our common stock for the 20 trading days before but not including the conversion date.

Because we are limited to registering for resale only up to 60,000,000 shares of common stock issuable upon conversion of the notes, the notes are expected to be converted over a longer period of time because the shares issuable upon conversion of the notes may only be sold, after 60,000,000 shares being registered for resale are sold upon conversion of the notes, under an exemption available under the Securities Act of 1933, as amended, particularly Rule 144 of the General Rules and Regulations thereunder, which limits the ability of the selling stockholders to sell the shares they receive upon conversion of the notes. Generally, under Rule 144, a person holding restricted shares for a period of one year may, every three months, sell in ordinary brokers' transactions, or in transactions directly with a market maker a number of such shares equal to the greater of (i) one percent of our then outstanding common stock, or (ii) the average weekly trading volume in our common stock during the four calender weeks preceding the sale of such shares.

If the noteholders do not convert their notes to pay the principal and interest on the notes when due, we will be required to pay the principal and interest when due in cash. Absent an ability to register additional shares for

resale, we may not have sufficient cash to repay the outstanding notes, which is likely in view of our losses that are expected to continue, which could result in the noteholders commencing legal action against us and foreclosing on all of our assets to recover the amounts due. Any such action would require us to curtail or cease operations.

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There are a large number of shares underlying our convertible notes and warrants that may be available for future sale, and the sale of these shares may depress the market price of our common stock.

As of November 30, 2006, we had 201,956,394 shares of our common stock issued and outstanding and \$2,646,791 in convertible notes outstanding that may be converted into an estimated 882,263,667 shares of common stock at current market prices, and outstanding warrants to purchase 25,059,392 shares of our common stock. Additionally, we have an obligation to sell \$500,000 convertible notes that may be converted into an estimated 166,666,667 shares of common stock at current market prices and issue warrants to purchase 4,000,000 shares of common stock in the near future. In addition, the number of shares of common stock issuable upon conversion of the outstanding convertible notes may increase if the market price of our stock declines. Up to 60,000,000 shares issuable upon conversion of the notes may be sold without restriction upon the effectiveness of this registration statement. The sale of these shares may adversely affect the market price of our common stock.

The continuously adjustable conversion price feature of our convertible notes could require us to issue a substantially greater number of shares, which will cause dissolution to our existing stockholders.

Our obligation to issue shares upon conversion of our convertible notes is essentially limitless. The following is an example of the amount of shares of our common stock that are issuable upon conversion of the \$3,146,791 principal amount of our convertible notes, based on market prices 25%, 50%, and 75% below the market price, as of November 15, 2006 of \$.005.

% Below	Price Per	With 40%	Number of	% of
Market	Share	Discount	Shares Issuable	Outstanding*
25%	\$.00375	\$.00225	1,398,573,779	692,5%
50%	\$.0025	\$.0015	2,097,860,667	1,038.8%
75%	\$.00125	\$.00069	4,560,566,667	2,258.2%

<sup>\*</sup>Based on 201,356,394 shares outstanding.

As illustrated, the number of shares of common stock issuable upon conversion of our convertible notes will increase if the market price of our stock declines, which will cause dilution to our existing stockholders.

The large number of shares issuable upon conversion of the convertible notes and preferred stock and exercise of warrants and options will require us to increase the number of authorized shares issuable upon full conversion of the convertible notes and exercise of warrants and options, and failure to obtain stockholder approval to increase the number of authorized shares could result in legal action against us, which could require us to curtail or cease operations.

There are a large number of shares underlying our convertible notes. Assuming full conversion of the \$3,146,791 principal amount of the notes on November 30, 2006 (consisting of \$3,500,000 in notes that were sold to the four investors pursuant to the securities purchase agreements dated April 27, 2005 and February 25, 2006, plus \$500,000 in notes to be sold to the investors upon the effectiveness of a registration statement, less \$853,209 in notes that were converted during the period from June 30, 2005 to November 30, 2006), the number of shares issuable upon conversion of the notes would be 1,048,930,333 shares. In addition, there are currently outstanding warrants issued to individuals and entities to purchase a total of 25,059,392 shares of our common stock at exercise prices ranging from \$.10 per share to \$6.75 per share, and options to individuals to purchase a total of 7,075,500 shares of our common stock at prices ranging from \$.01 per share to \$2.75 per share. Further, the number of common shares issuable upon the full conversion of our preferred stock is 873,071 shares. The number of our authorized shares of common stock is 800,000,000 shares. The large number of our shares of common stock underlying our notes, warrants, stock options and preferred stock will require us to increase the number of authorized shares issuable upon full conversion of the notes and preferred shares, and exercise of the warrants and options, and the failure to obtain stockholder approval to increase the number of authorized shares could result in the noteholders commencing legal action against us and foreclosing on all our assets to recover damages. Any such action would require us to curtail or cease operations.

The continuously adjustable conversion price feature of our convertible notes may encourage investors to make short sales in our common stock, which could have a depressive effect on the price of our common stock.

The convertible notes are convertible into shares of our common stock at a 40% discount to the trading price of the common stock prior to the conversion. The significant downward pressure on the price of the common stock as the selling stockholders convert and sell material amounts of common stock could encourage short sales by investors. This could place further downward pressure on the price of the common stock. The selling stockholders could sell common stock into the market in anticipation of covering the short sale by converting their securities, which could cause the further downward pressure on the stock price. In addition, not only the sale of shares issued upon conversion or exercise of notes, warrants and options, but also the mere perception that these sales could occur, may adversely affect the market price of the common stock.

The issuance of shares upon conversion of the convertible notes and exercise of outstanding warrants may cause immediate and substantial dilution to our existing stockholders.

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The issuance of shares upon conversion of convertible notes and exercise of warrants may result in substantial dissolution to the interests of other stockholders since the selling stockholders may ultimately convert and sell the full amount issuable on conversion. Although the selling stockholders may not convert their convertible notes and/or exercise their warrants if such conversion or exercise price would cause them to own more than 4.99% of our outstanding common stock, this restriction does not prevent the selling stockholders from converting and/or exercising some of their holdings and then converting the rest of their holdings. In this way, the selling stockholders could sell more than this limit while never holding more than this limit. There is no upper limit on the number of shares that may be issued, which will have the effect of further diluting the proportionate equity interest and voting

power of holders of our common stock, including investors in this offering.

If we are required for any reason to repay our outstanding convertible notes, we would be required to deplete our working capital, if available, or raise additional funds. Our failure to repay the convertible notes, if required, could result in legal action against us, which could require us to curtail or cease our operations.

On April 27, 2005, we entered into a securities purchase agreement for the sale of an aggregate of \$2,500,000 principal amount of convertible notes. These convertible notes are due and payable, with 8% interest, three years from the date of issuance, unless sooner converted into shares of our common stock. As of November 30, 2006, a total of \$853,209 of these convertible notes have been converted into shares of our common stock, reducing the outstanding principal amount of the notes to \$1,646,791. On February 28, 2006, we entered into a securities purchase agreement for the sale of an aggregate \$1,500,000 in principal amount of convertible notes. These convertible notes are due and payable, with 8% interest, three years from the date of issuance, unless sooner converted into shares of our common stock. Although we currently have \$1,000,000 in convertible notes outstanding pursuant to the securities purchase agreement we entered into on February 28, 2006, we are obligated to sell additional convertible notes to the convertible noteholders in the aggregate amount of \$500,000. Any event of default such as our failure to repay the principal or interest when due, our failure to issue shares of common stock upon conversion by the holder, our failure to timely file a registration statement or to have such registration statement declared effective, breach of any covenant, representation or warranty in the securities purchase agreement or related convertible notes, the assignment or appointment of a receiver to control a substantial part of our property or business, the filing of a money judgment, writ or similar process against us in excess of \$50,000, the commencement of a bankruptcy, insolvency, reorganization or liquidation proceeding against our company, and the delisting of our common stock could require the early repayment of the convertible notes, including a default interest rate of 15% on the outstanding principal balance of the notes if the default is not cured within the specified grace period. We anticipate that the full amount of convertible notes will be converted into shares of our common stock, in accordance with the terms of the notes. However, if we are required to repay the notes, we would be required to use our limited working capital and raise additional funds. If we were unable to repay the notes when required, the noteholders could commence legal action against us and foreclose on all of our assets to recover the amounts due. Any such action would require us to curtail or cease operations.

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 further, 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.

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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 premarketing 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 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.

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 expired when the United States patent rights expired 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 \$15,717, which we believe brings all payments current as of the date of the last payment on January 7, 2005. We have been working with PhotoMed and Dr. Eichenbaum to insure that the royalty calculations have been correctly made on the royalties paid as well as the proper method of calculations for the future.

It is anticipated that once the parties agree on the correct royalty calculations, the legal action will be dismissed. An issue in dispute concerning the method of calculating royalties is whether royalties should be paid on returned equipment. Since July 1, 2001, only one Photon(TM) laser system has been sold and no systems returned. Thus, the amount of royalties due, according to our calculations, is \$981. We made payment of this amount of Photomed and Dr. Eichenbaum on January 5, 2005 and, as a result, seek to have the legal action 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.

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.

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

Our new products may incur unexpected  $\mbox{production}$   $\mbox{problems,}$  which would impact our sales and  $\mbox{profits.}$ 

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  $\mbox{manufacture}$  of our products,  $\mbox{which}$  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 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, the Blood Flow Analyzer(TM), and the P40, P45 and P60 Ultrasound Biomicroscopes.

We believe that there is substantial commercial demand for our Photon(TM) laser system, our Blood Flow Analyzer(TM), and our P40, P45 and P60 Ultrasound Biomicrocopes 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.

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Our Photon(TM) laser system may not be accepted in the  $\mbox{marketplace}$  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 expired 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 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 dis tributed, 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.

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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 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.

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 social instability, which could adversely affect our sales.

The market price of our securities could fluctuate significantly.

Our common stock was delisted on The Nasdaq SmallCap Market, effective June 26, 2003, and currently trades 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.

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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 November 30, 2006, 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; 250 shares of Series E preferred stock convertible into 13,333 common shares; 4,598.75 shares of Series F preferred stock convertible into 245,267 common shares; and 588,235 shares of Series G preferred stock convertible into 588,235 common shares.

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% noncumulative 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% noncumulative 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 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 November 30, 2006, we had issued and outstanding 201,956,394 shares of our common stock, shares of Series A, B, D, E, F and G preferred stock convertible into 873,071 shares of common stock, and outstanding options and warrants to purchase 36,166,892 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 4,500,000 options issued to Raymond P.L. Cannefax, our President and Chief Executive Officer, under the terms of his employment agreement with us. These options are exercisable at \$.01 per share and vest in 12 equal monthly installments of 375,000 shares, beginning on February 5, 2006 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 noncumulative 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

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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 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 November 30, 2006, 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.

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 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

This prospectus relates to shares of our common stock that may be offered and sold from time to time by the selling stockholders. We will not receive any proceeds from the sale of shares of common stock in this offering.

In addition, we have received total gross proceeds of \$1,000,000 from the sale of the convertible notes on February 28, 2006 and the investors are obligated to provide us with an additional \$500,000 upon the effectiveness of a registration statement to register the shares of common stock underlying the convertible notes and the warrants. The \$500,000 in additional proceeds to be provided by the investors after the registration statement is declared effective will be used for the purchase of inventory, marketing and sales, increasing the number of our direct sales representatives, and working capital.

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#### 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 B, Series C, Series D, Series E, Series F and Series G preferred stock are only payable from our surplus earnings and are noncumulative 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.

#### CAPITALIZATION

The following table sets forth our capitalization on an actual basis as of December 31, 2005 and September 30, 2006.

	De	ecember 31, 2005	September 30, 2006
Long-term obligations	\$	2,038,000	\$ 2,660,000
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, 250 issued and outstanding		-	-
Series F Preferred Stock, \$.001 par value per share; 50,000 shares authorized, 4,598.75			

issued and outstanding	_	_
Series G Preferred Stock, \$.001 par value per share; 2,000,000 shares authorized, 588,235 issued and outstanding	1,000	1,000
Common Stock, \$.001 par value per share; 250,000,000 shares authorized, 96,389,295 and 199,956,828 issued and outstanding, respectively	96,000	197,000
Additional paid-in-capital, common stock	60,586,000	61,873,000
Accumulated deficit	(62,196,000)	(64,091,000)
Total stockholders' equity	(1,513,000)	(1,937,000)
Total capitalization	\$ 525,000	\$ 723,000

#### MARKET FOR COMMON EQUITY AND RELATED STOCKHOLDER MATTERS

Our authorized capital stock consists of 800,000,000 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 Over-the-Counter 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 has traded on the Over-the-Counter Bulletin Board. As of November 15, 2006, the closing sale price of the common stock was \$.005 per share. The following are the high and low sale prices for the common stock by quarter as reported by the Over-the-Counter Bulletin Board since January 1, 2004.

	Common Stock Price Range			
Period (Calendar Year)	High	Low		
2004				
First Quarter	\$ .21	\$ .15		
Second Quarter	.16	.07		
Third Quarter	.12	.09		
Fourth Quarter	.12	.08		
2005				
First Quarter	.10	.08		
Second Quarter	.09	.07		
Third Quarter	.10	.001		
Fourth Quarter	.048	.001		
2006				

First Quarter	.047	.001
Second Quarter	.014	.006
Third Quarter	.007	.004
Fourth Ouarter (through November 15, 2006)	.005	.004

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 not publicly traded. As of November 30, 2006, there were 4,781 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, one record holder of Series E preferred stock, 18 record holders of Series F preferred stock, and one record holder 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 noncumulative 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.

#### SELECTED FINANCIAL DATA

The following table sets forth our selected financial data for the years ended December 31, 2004 and 2005, and the nine months ended September 30, 2005 and 2006. The selected financial data as of and for the nine months ended September 30, 2005 and 2006 are derived from our unaudited quarterly financial statements, which have been reviewed by Chrisholm, Bierwolf & Nilson. The following financial information should be read in conjunction with the Financial Statements, and related notes thereto.

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# Summary Financial Information

		year ended ember 31,		ne months ended tember 30,
Statement of Operations				
Data:	2004	2005	2005	2006

Net Sales	\$3,062,000	\$2,201,000	\$1,963,000	\$1,600,000
Net cost of sales	1,217,000	1,599,000	935,000	841,000
Operating expenses	2,237,000	2,782,000	2,144,000	1,467,000
Operating loss	(392,000)	(2,180,000)	(1,116,000)	(708,000)
Other income (expense)	456,000	(3,209,000)	(2,850,000)	(1,118,000)
Net income (loss)	64,000	(5,389,000)	(3,966,000)	(1,826,000)
Net income (loss)				
applicable to common				
shareholders	10,000	(5,389,000)	(3,966,000)	(1,826,000)
Net income (loss) per				
common share	\$0.00	\$(0.13)	\$(0.13)	\$(0.01)
Shares used in computing				
net loss per share	25,405,000	42,033,000	31,472,000	166,459,000

	As of	As of
Balance Sheet Data:	December 31, 2005	September 30, 2006
Current assets	\$1,331,000	\$1,489,000
Current liabilities	1,177,000	1,129,000
Working capital (deficit)	154,000	360,000
Total assets	1,702,000	1,852,000
Accumulated deficit	(62,196,000)	(64,019,000)
Stockholder's equity	(1,513,000)	(1,937,000)

# 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 exits. Prior to shipment of product, we required a signed purchase order and, depending upon the customer, a down payment toward the final invoiced price or full payment in advance with certain international product distributors.
- 2. Delivery and performance have occurred. Unless the purchase order requires specific installation or customer acceptance, 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 our customer upon shipment. This revenue recognition policy does not differ among our various different product lines. We guarantee the functionality of our product. If our product do 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 our historical experience and management's current expectations.

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- 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 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 our "going concern" status, 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 nine months ended September 30, 2006, 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 the entire diagnostic product group.

Results of Operations

Nine Months Ended September 30, 2006, Compared to Nine Months Ended September 30, 2005

Net sales for the nine months ended September 30, 2006 decreased by \$363,000, or 18%, to \$1,600,000 as compared to \$1,963,000 for the same period of 2005. This reduction in sales was primarily due to reduced sales of the P40, P45 and P60 UBM Ultrasound Biomicroscopes and the P37 A/B Scan Ocular Ultrasound Diagnostics.

For the nine months ended September 30, 2006, sales from our diagnostic products totaled \$1,374,000, or 86% of total revenues, compared to \$1,771,000, or 90% of total revenues for the same period of 2005. The remaining 14% of sales, or \$226,000 during the nine months ended September 30, 2006 was from parts, disposables, and service revenue.

Sales of the P40, P45 and P60 UBM Ultrasound Biomicroscopes decreased to \$293,000 during the nine months ended September 30, 2006, or 18% of total quarterly revenues for the period, compared to \$1,096,000 or 56% of total revenues, for the same period last year. Sales of the Blood Flow Analyzer(TM) increased by \$52,000 to \$128,000, or 8% of total revenues, for the nine months

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ended September 30, 2006, compared to net sales of \$76,000, or 4% of total revenues, during the same period in 2005. Sales from the P37 A/B Scan Ocular Ultrasound Diagnostic increased to \$191,000, or 12% of total revenues, for the nine month period ended September 30, 2006, down compared to \$128,000, or 7% of total revenues, for the same period in 2005. Combined sales of the LD 400 and TKS 5000 autoperimeters and the CT 200 Corneal Topographer were \$715,000, or 45% of the total revenues, for the nine months ended September 30, 2006, compared to \$471,000, or 24% of total revenues, for the same period of 2005.

Our sales have been lower during the nine months ended September 30, 2006 due to a variety of reasons. Sales of the P40, P45 and P60 UBM Ultrasound Biomicroscope decreased primarily as a result of ongoing software development and hardware configuration problems with the new P60, which received FDA 510(k) premarket approval on May 26, 2005 that allowed the device to be sold in the United States. The hardware configuration problems have since been resolved and we continue to work on resolving the software development problems. We anticipate reversing the downward trend in sales through additional efforts by

us to gain more widespread support for the P60 through increased clinical awareness, product development and improved marketing plans.

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, 2006, we realized no sales in the surgical line consisting of the Precissionist Thirty Thousand(TM) and the Photon(TM) laser system. There were also no sales in the surgical line for the comparable period of 2005.

For the nine months ended September 30, 2006, gross profit decreased slightly by 5% to 47% of total revenues, compared to 52% of total revenues for the same period in 2005.

Marketing and selling expenses decreased by \$202,000, or 40%, to \$307,000, for the nine months ended September 30, 2006, from \$509,000 for the comparable period in 2005. The reduction was due primarily to a reduced number of sales representatives and lower travel related and associated sales expenses.

General and administrative expenses decreased by \$192,000, or 20%, to \$772,000 for the nine months ended September 30, 2006, from \$964,000 for the comparable period in 2005. The decrease in general and administrative expenses was primarily due to a reduction in management salaries and in the number of employees, and enhanced operating efficiencies.

In addition, during the first quarter of 2005, we issued 515,206 shares of common stock to two shareholders that had purchased shares of our Series G convertible preferred stock in a private offering. Under the terms of the private offering, we were required to file a registration statement with the Securities and Exchange Commission for the purpose of registering the common shares issuable to the Series G preferred stockholders upon conversion of their Series G preferred shares and exercise of their warrants. The shares were issued as a penalty for our not having a registration statement declared effective within 120 days of the initial closing of the private offering.

Also during 2005, we collected \$1,000 in receivables that were previously allowed in the allowance for doubtful accounts. During 2005, we increased allowance for doubtful accounts by \$100,000.

Research, development and service expenses decreased by \$81,000, or 38\$, to \$130,000 for the nine months ended September 30, 2006, compared to \$211,000 in the same period of 2005. Most of the reduction was due to the reduced costs of product development for the nine months ended September 30, 2006, as compared to the increased costs of development and compliance with regulatory requirements in releasing the new P60 UBM that were incurred during the same period in 2005.

Due to our ongoing cash flow difficulties, most of our vendors and suppliers were contacted during 2004 and 2005 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 \$12,000 and \$206,000 during the years ended December 31, 2005 and 2004, respectively. In 2006 we are continuing our negotiations with some vendors and suppliers.

Fiscal Year Ended December 31, 2005 Compared to Fiscal Year Ended December 31, 2004

Net sales for the twelve months ended December 31, 2005 decreased by \$861,000, or 28%, to \$2,201,000 as compared to \$3,062,000 for the same period of 2004. This reduction in sales was primarily due to reduced sales of the Blood

Flow Analyzer(TM) and a softening of sales of the  $\operatorname{Dicon}(TM)$  perimeters and corneal topographers.

For the twelve months ended December 31, 2005, sales from our diagnostic products totaled \$1,949,000, or 89% of total revenues, compared to

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\$2,780,000, or 91% of total revenues for the same period of 2004. The remaining 11% of sales, or \$252,000 during the twelve months ended December 31, 2005, was from parts, disposables, and service revenue.

Sales of the P40, P45 and P60 UBM Ultrasound Biomicroscopes increased to \$967,000 during the twelve months ended December 31, 2005, or 43% of total quarterly revenues for the period, compared to \$855,000, or 28% of total revenues, for the same period last year. Sales of the Blood Flow Analyzer(TM) decreased by \$464,000 to \$97,000, or 4% of total revenues, for the twelve months ended December 31, 2005, compared to net sales of \$561,000, or 18% of total revenues during the same period in 2004. Sales from the P37 A/B Scan Ocular Ultrasound Diagnostic decreased to \$181,000, or 8% of total revenues, for the twelve month period ended December 31, 2005, down compared to \$265,000, or 9% of total revenues, for the same period last year. Combined sales of the LD 400 and TKS 5000 autoperimeters and the CT 200 Corneal Topographer were \$671,000, or 31% of the total revenues, for the twelve months ended December 31, 2005, compared to \$1,022,000, or 34% of total revenues, for the same period of 2004.

Sales have been lower for us due to a variety of reasons. Sales of the Blood Flow Analyzer(TM) decreased due in part from the reorganization of our sales force. We anticipate reversing the downward trend in sales through additional efforts by us to gain more widespread support for the Blood Flow Analyzer(TM) though increased clinical awareness, product development and improved marketing plans.

Sales of surgical products are at a standstill pending FDA approval of the Photon(TM) laser system. In the twelve month period ended December 31, 2005, we realized no sales in the surgical line consisting of the Precissionist Thirty Thousand(TM) and the Photon(TM) laser system. There were also no sales in the surgical line for the comparable period of 2004.

Gross profit for the twelve months ended December 31, 2005 decreased to 27% of total revenues, compared to 60% of total revenues for the same period in 2004. The decrease in gross profit in 2005 was mainly due to issuance of new product demonstration equipment and physician testing and analysis for the new P60 UBM, as well as pricing adjustments related to the P60 product introduction during the twelve months ending December 31, 2005. There was no increase or decrease to cost of sales as a result of a change to the reserve for obsolete inventory in 2005.

Marketing and selling expenses decreased by \$160,000, or 20%, to \$641,000, for the twelve months ended December 31, 2005, from \$801,000 for the comparable period in 2004. The reduction was due primarily to a reduced number of sales representatives and lower travel related and associated sales expenses.

General and administrative expenses increased by \$422,000, or 48%, to \$1,296,000 for the twelve months ended December 31, 2005, from \$874,000 for the comparable period in 2004. The increase in general and administrative expenses was primarily due to the additional employees who were hired to assist in the development, testing, marketing and sales of the new UBM.

In addition, during the first quarter of 2005, we issued 515,206 shares of common stock to two shareholders that had purchased shares of our Series G

convertible preferred stock in a private offering. Under the terms of the private offering, we were required to file a registration statement with the Securities and Exchange Commission for the purpose of registering the common shares issuable to the Series G preferred stockholders upon conversion of their Series G preferred shares and exercise of their warrants. The shares were issued as a penalty for us not having a registration statement declared effective within 120 days of the initial closing of the private offering.

Also during 2005, we collected \$1,000 in receivables that were previously allowed in the allowance for doubtful accounts. During 2005, we increased allowance for doubtful accounts by \$100,000.

Research, development and service expenses increased by \$87,000, or 11%, to \$855,000 for the twelve months ended December 31, 2005, compared to \$768,000 in the same period of 2004. Most of the increase was due to the costs of development and compliance with regulatory requirements in releasing the new P60 UBM.

Due to our ongoing cash flow difficulties, most of our vendors and suppliers were contacted during 2004 and 2005 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 \$12,000 and \$206,000 during the years ended December 31, 2005 and 2004, respectively.

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

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Liquidity and Capital Resources

We used \$766,000 in cash in operating activities for the nine months ended September 30, 2006, compared to \$2,493,000 for the nine months ended September 30, 2005. The decrease in cash used for operating activities for the nine months ended September 30, 2006 was primarily attributable to our net loss and decreases in accounts payable and accrued liabilities and an increase in inventory, specifically for the P60 UBM. We used \$19,000 in investing activities for the nine months  $\,$  ended  $\,$  September  $\,$  30,  $\,$  2006,  $\,$  compared to  $\,$  \$-0- for the nine months ended September 30, 2005. Net cash received in financing activities was \$986,000 for the nine months ended September 30, 2006, versus cash provided from financing activities of \$2,611,000 in the same period in 2005. We had working capital of \$360,000 as of September 30, 2006, compared to working capital of \$1,221,000 as of September 30, 2005. In January 2005, we sold 2,000,000 shares of our common stock to an accredited investor for \$150,000 in cash. 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.

As of September 30, 2006, we had net operating loss carry-forwards (NOLs) of approximately \$53 million. These loss carry-forwards are available to offset future taxable income, if any, and have begun to expire in 2001 and extend for twenty years. 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, 2006, we had accounts payable of \$336,000, a significant portion of which was over 90 days past due, compared to accounts payable of \$530,000 as of September 30, 2005. 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 required the payment of approximately \$194,000 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:

- 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 four 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 25% of total outstanding receivables as of September 30, 2006 and 20% as of December 31, 2005 compared to 3% of total outstanding receivables as of September 30, 2006. The allowance for doubtful accounts decreased from \$100,000 at December 31, 2005 to \$95,000 at September 30, 2006.

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. During the nine months ended September 30, 2006, we added a net of \$-0- to the allowance for doubtful accounts. We believe that by requiring a large portion of payment prior to shipment, we have greatly improved the collectibility of our receivables.

We carried an allowance for obsolete or estimated non-recoverable inventory of \$1,333,000 at September 30, 2006 and \$1,371,000 at September 30, 2005, or 60% and 51% of total inventory, respectively. 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 is 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.

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.

As of November 30, 2006, we had \$2,646,791 in convertible notes outstanding and an obligation to sell \$500,000 in convertible notes upon the effectiveness of a registration statement to register 60,000,000 shares of common stock issuable upon conversion of the notes. Because we are limited to registering for resale only up to 60,000,000 shares of common stock issuable upon conversion of the notes, the notes are expected to be converted over a longer period of time because the shares issuable upon conversion of the notes may only be sold, after 60,000,000 shares being registered for resale are sold upon conversion of the notes, under a limited number of exemptions available under the Securities Act of 1933, as amended, particularly Rule 144 of the General Rules and Regulations thereunder, which limits the ability of the selling stockholders to sell the shares they receive upon conversion of the notes.

If the noteholders do not convert their notes to pay the principal and interest on the notes when due, we will be required to pay the principal and interest when due in cash. Absent an ability to register additional shares for resale, we may not have sufficient cash to repay the outstanding notes, which is likely in view of our losses that are expected to continue, that could result in the noteholders commencing legal action against us and foreclosing on all of our assets to recover the amounts due. Any such action would require us to curtail or cease our operations.

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

In May 2005, the FASB issued SFAS No. 154, Accounting Changes and Error Corrections. This statement replaces APB Opinion No. 20 and SFAS No. 3. APB Opinion No. 20 previously required that most voluntary changes in accounting principle be recognized by including the cumulative effect of changing to the new accounting principle in the net income of the period of the change. SFAS No. 154 requires retrospective application to prior periods' financial statements of changes in accounting principle, unless it is impracticable to determine either the period-specific effects or the cumulative effect of the change. When it is impracticable to determine the period-specific effects of an accounting change on one or more individual prior periods presented, this statement requires that the accounting principle be applied to the balances of assets and liabilities as of the beginning of the earliest period for which retrospective application is practicable and that a corresponding adjustment be made to the opening balance of retained earnings for that period, rather than being reported in an income statement. The new standard will be effective for accounting changes and corrections of errors made in fiscal years beginning after December 15, 2005. We believe the adoption of new standard will not have a material effect on our financial position, results of operations, cash flows, or previously issued financial reports.

In February 2006, the FASB issued SFAS No. 155, Accounting for Certain Hybrid Financial Instruments. This statement is an amendment of FASB Statements Nos. 133 and 140 to address what had been characterized as a temporary exemption from the application of the bifurcation requirements of Statement No. 133 to beneficial interests in securitized financial assets. Prior to the effective date of Statement No. 133, the FASB received inquiries on the application of the exception in paragraph 14 of Statement No. 133 to beneficial interests in securitized financial assets. In response to the inquiries, Implementation Issue D1 indicated that, pending issuance of further guidance, entities may continue

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to apply the guidance related to accounting for beneficial interests in paragraphs 14 and 362 of Statement No. 140. Those paragraphs indicate that any security that can be contractually prepaid or otherwise settled in such a way that the holder of the security would not recover substantially all of its recorded investment should be subsequently measured like investments in debt securities classified as available-for-sale or trading under FASB Statement No. 115, Accounting for Certain Investments in Debt and Equity Securities, and may not be classified as held-to-maturity. Further, Implementation Issue D1 indicated that holders of beneficial interests in securitized financial assets that are not subject to paragraphs 14 and 362 of Statement No. 140 are not required to apply Statement No. 133 to those beneficial interests until further guidance is issued. We believe the adoption of new standards will not have a material effect on our financial position, results of operations, cash flows, or previously issued financial reports.

In March 2006, the FASB issued SFAS No. 156, Accounting for Servicing of Financial Assets. This statement amends FASB Statement No. 140, Accounting for Transfers and Servicing of Financial Assets and Extinguishments of Liabilities, with respect to the accounting for separately recognized servicing assets and servicing liabilities. In this statement the board decided to broaden the scope of the project to include all servicing assets and servicing liabilities. Servicing assets and servicing liabilities may be subject to significant interest rate and prepayment risks, and many entities use financial instruments to mitigate those risks. Currently, servicing assets and servicing liabilities are amortized over the expected period of estimated net servicing income or loss and assessed for impairment or increased obligation at each

reporting date. The board acknowledged that the application of the lower of carrying amount or fair value measurement attribute to servicing assets results in asymmetrical recognition of economic events, because it requires recognition of all decreases in fair value but limits recognition of increases in fair value to the original carrying amount.

Statement No. 156 requires that all separately recognized servicing assets and servicing liabilities be initially measured at fair value, if practicable. The board concluded that fair value is the most relevant measurement attribute for the initial recognition of all servicing assets and servicing liabilities, because it represents the best measure of future cash flows. This statement permits, but does not require, the subsequent measurement of servicing assets and servicing liabilities at fair value. An entity that uses derivative instruments to mitigate the risks inherent in servicing assets and servicing liabilities is required to account for those derivative instruments at fair value. Under this statement, an entity can elect subsequent fair value measurement of its servicing assets and servicing liabilities by class, thus simplifying its accounting and providing for income statement recognition of the potential offsetting changes in fair value of the servicing assets, servicing liabilities, and related derivative instruments. An entity that elects to subsequently measure servicing assets and servicing liabilities at fair value is expected to recognize declines in fair value of the servicing assets and servicing liabilities at fair value is expected to recognize declines in fair value of the servicing assets and servicing liabilities more consistently than by reporting other-than- temporary impairments. We believe the adoption of new standards will not have a material effect on our financial position, results of operations, cash flows, or previously issued financial reports.

In September 2006, the FASB issued SFAS No. 158, Employers' Accounting for Defined Benefit Pension and Other Postretirement Plans, an amendment of FASB Statements No. 87, 88, 106, and 132(R) ("SFAS 158"). Under SFAS 158, companies must recognize a net liability or asset to report the funded status of their defined benefit pension and other postretirement benefit plans on their balance sheets. The effective date of the recognition and disclosure provisions for calendar-year public companies is for calendar years ending after December 15, 2006. We are currently evaluating the impact of this new standard but it is not expected to have a significant effect on the consolidated financial statements for the year ended December 31, 2006.

In September 2006, the FASB issued SFAS No. 157, Fair Value Measurements ("SFAS 157"). SFAS 157 defines fair value, establishes a framework for measuring fair value, and expands disclosures about fair value measurements. SFAS 157 will be applied prospectively and is effective for fiscal years beginning after November 15, 2007, and interim periods within those fiscal years. SFAS 157 is not expected to have a material impact on our consolidated financial statements.

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 PhotonTM 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, 2005, 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.

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At present, the Photon(TM) has not received FDA approval 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 financing. 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. 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).

Our diagnostic products include a P55 pachymetric analyzer, a P37 A/B Scan, the P40, P45 and P60 UBM Ultrasound Biomicroscopes, a P37 A/B Scan, two perimeters, a corneal topographer and the Blood Flow Analyzer(TM). The diagnostic ultrasound products including the P55 pachymeter analyzer, the P37 A/B Scan, and the P40 UBM Ultrasound 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 Plus biomicroscope, which combines the P37 Ultrasonic A/B Scan and the P40 UBM Ultrasound 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 the 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. In March 2005, we developed and offered for sale the P60 UBM Ultrasound Biomicroscope, the fourth generation of UBM devices, which has better vision clarity and image flexibility than earlier versions. 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 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 Ultrasound Pachymeter Model 855, and the Ultrasound Biomicroscope Model 840, and all accessories, packaging and end-user collateral materials for each of the product lines for the sum of \$500,000, payable in the form of 78,947 shares of common stock which were issued to Humphrey Systems and 26,316 shares of common stock which were issued to business broker Douglas Adams. If the net proceeds received by Humphrey Systems from the sale of the shares issued pursuant to the Agreement was less than \$375,000, after payment of commissions, transfer taxes and other expenses relating to the sale of such shares, 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. Because 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.

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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 UBM Ultrasound Biomicroscope in the fall of 2000, which combines the P37 Ultrasonic A/B Scan, and the Ultrasonic Biometer into one machine.

On October 21, 1999, we purchased Mentor's surgical product line, consisting of the Phaco SIStem(TM), the Odyssey(TM) and the Surg-E-Trol(TM). This acquisition was an attempt to round out 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 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.

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. During 2004, we sold all 2,663,254 shares of International Bio-Immune Systems stock for net proceeds of \$505,000.

International Bio-Immune Systems, Inc. may sell the 300,000 shares of 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 did not sell the shares by September 19, 2004, it was required to return the shares, or any amount which has not been sold, to us. International Bio-Immune Systems currently controls the voting decisions regarding these shares. The President and Chief Executive Officer of International Bio-Immune Systems is Leslie F. Stern, who exercises sole voting and investment powers regarding the shares.

On December 3, 2003, 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.

The term of the agreement was for a period of three months, which was 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 be paid 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 exerciseable, on a cashless basis, over a two year period from the date of issuance. We provided notice to Alpha Advisory Services of our intention to terminate the agreement, effective as of January 28, 2006. During the four month period the agreement was in effect, we paid Alpha Advisory Services a total of \$12,000 pursuant to the terms of the agreement.

In March 2005, we introduced the P60 UBM Ultrasound Biomicroscope. The P60 UBM Ultrasound Biomicroscope represents the fourth generation of UBM devices and has better visual clarity and image flexibility than earlier versions. On March 1, 2005, we were awarded the CE Mark for the P60, which enables us to market the device in 19 Western European countries, most of the Middle East and India, and some parts of Asia and the Pacific Rim. On May 26, 2005, we received FDA 510(k) premarket approval for the P60, which allows it to be sold in the United States. On February 9, 2006, we received a Canadian device license for the P60, which allows it to be sold in Canada.

On June 12, 2006, we entered into a Worldwide OEM Agreement with MEDA Co., Ltd., one of China's leading developers and producers of ultrasound devices. Under the terms of the agreement, MEDA agrees to jointly engineer, develop and manufacture our next generation of the Ultrasound BioMicroscope, as well as other proprietary new products and enhancement of our current products. The products to be manufactured by MEDA, at agreed upon costs, and supplied to us for resale include the following new products: an Ultrasound BioMicroscope, two Ultrasound A/B Scans, a Biometric A-Scan and a pachymeter.

The agreement provides that we and MEDA agree to jointly develop and collaborate in the improvement and enhancement of our products and, in the interest of product development, enhancement and differentiation, MEDA agrees to give consideration to potential software development or enhancements made available to us for our products. Moreover, in the interest of product improvement, MEDA agrees to collaborate with us and our designated engineers, employees and consultants to consider and potentially implement jointly or individually the development of product enhancements on our products to be manufactured by MEDA.

The software and hardware modifications designed jointly by us and MEDA

will be considered the joint intellectual property of us and MEDA and may be used, without restriction, unless otherwise previously agreed to, by either party. MEDA also agrees to provide a 12 month warranty on all products that it manufactures for us. If defects cannot be corrected at our facilities, the products may be returned to MEDA for the purposes of carrying out such repairs as required, and MEDA agrees to return the repaired products to us or our designated agent or distributor within ten working days from the date of receiving such products, at no cost to us, and MEDA will pay return freight costs.

MEDA further agrees to endeavor to answer any technical inquiries concerning the products it has manufactured. MEDA also agrees to train the Company's technical service engineers and designated international distributors as soon as possible after the signing of this agreement, and as future needs arise and as MEDA can reasonably fit such training into the regular schedules of its employees. MEDA agrees to determine the need for future training on new products as necessary and will offer such training in Tiangin, China. For training conducted outside China, the Company or its designated distributors and/or service centers will be responsible for the traveling, living and hotel expenses for MEDA's engineers. Training is at no charge to the Company. The training will also be made available to the Company's designated repair agencies in order to provide service and repair on a worldwide basis. Such agencies will be considered authorized repair facilities for the products manufactured by MEDA.

The agreement shall be effective for three years from date of execution. At the end of the three year term, representatives of us and MEDA will confer to determine whether to extend the term of the agreement. This will have a practical effect of extending the term of the agreement for an additional 120 days. If mutual agreement for extending the term of the agreement is not reached within 120 days after the end of the three year term, then the agreement

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will be deemed terminated. However, if within the 120 day period, we and MEDA mutually agree to extend the term of the agreement, then thereafter either party may terminate the agreement by providing 12 months prior written notice to the other party. All outstanding orders at the time of notification will be supplied under the terms of the agreement, and MEDA will continue to fulfill all orders from us until the 12 month notice period has expired.

#### 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, 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 vitro-retinal disorders such as the attachment of membrane growths to the retina causing blood leakage within the eye. All of these disorders can impair vision. Many refractive disorders can be corrected through the use of eyeglasses and contact lenses. Myopia (nearsightedness), hyperopia (farsightedness) and presbyopia (inability to focus) are three of the most common refractive disorders.

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

Surgical use of ultrasonics in ophthalmology is limited to treatment of cataract lenses in the eye through a procedure called phacoemulsification or "phaco." A primary objective of cataract surgeries is the removal of the opacified (cataract) lens through an incision that is as small as possible. The opacified lens is then replaced by a new synthetic lens intraocular implant. Phaco technology involves a process by which a cataract is broken into small pieces using ultrasonic shock waves delivered through a hollow, open-ended metal needle attached to a hand held probe. The fragments of cataracts tissue are then removed through aspiration. Phaco systems were first designed in the late 1960's after various attempts by surgeons to use other techniques to remove opacified lenses, including crushing, cutting, freezing, drilling and applying chemicals to the cataract. By the mid-1970's, ultrasound had proven to be the most effective technology to fragment cataracts. Market Scope's (Manchester, Missouri), The 2001 Report on the Worldwide Cataract Market, January 2001 indicates that phaco cataract treatment was the technology for cataract removal used in over 80% of surgeries in the United States and over 20% of all foreign surgeries.

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

Lasers are widely accepted in the ophthalmic community for treatment of certain eye disorders and are popular for surgical applications because of their relatively noninvasive nature. In general, ophthalmic lasers, such as argon, Nd:YAG and excimer (argon-fluoride) are used to coagulate, cut or ablate targeted tissue. The argon laser is used to treat leaking blood vessels on the retina (retinopathy) and retinal detachment. The excimer laser is used in corneal refractive surgery. The Nd:YAG pulsed laser is used to perforate clouded posterior capsules (posterior capsulotomy) and to relieve glaucoma-induced elevated pressure in the eye (iridotomy, trabeulorplasty, transcleral cyclophotocoagulation). Argon, Nd:YAG and excimer lasers are primarily used for one or two clinical applications each. In contrast to these conventional laser systems, 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) 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 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 setups, with a second level of subprogrammed custom modes within each major surgical screen (i.e., ultrasound phaco and irrigation/aspiration modes).

The Precisionist(TM) also 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% of the total revenues in both 2005 and 2004, and 0% of the total revenues for the nine months ended September 30, 2006.

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

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features. Expansion such as our Photon(TM) laser system and hardware for additional surgical applications are easily implemented by means of a preexisting expansion rack, which resides in the base of the Workstation(TM). These expanded capabilities could include, but would not be limited to laser systems, video surgical fiber optic imaging, cutting and electrosurgery equipment. However, there is no guarantee that the Workstation(TM) will be accepted in the marketplace. If the FDA approves the Photon(TM), 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 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 our "going concern" status, management has focused efforts on those products and activities that will, in its opinion, achieve the most resource efficient short-term cash flow to us. As reflected in the results for the fiscal year ended December 31, 2005 and the nine months ended September 30, 2006, 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 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 our "going concern" status, management has focused efforts on those products and activities that will, in

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its opinion, achieve the most resource efficient short-term cash flow to us. As reflected in the results for the fiscal year ended December 31, 2005, diagnostic products consisting mainly of the P40, P45 and P60 UBM Ultrasound Biomicroscopes, P37 A/B Scan, 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, buy rather on the entire group of diagnostic products.

On March 31, 2005, Joseph W. Spadafora filed a complaint against us in the United States District Court, District of Utah, in which he alleges that he was a clinical investigator in the study for the FDA involving our Photon(TM) laser system where he performed numerous surgeries using the Photon(TM). Dr. Spadafora contends that in meetings with our personnel he suggested ways in which the handpiece on the Photon(TM) could be improved. Dr. Spadafora further contends that on August 5, 1999, when we filed a patent application for an improved handpiece with the United States Patent and Trademark Office, he was not named as one of the inventors or a co-inventor on the patent application. On September 24, 2004, we were issued a patent entitled, "Laser Surgical Handpiece with Photon Trap." Because we did not list Dr. Spadafora as one of the inventors or a co-inventor on the patent, Dr. Spadafora requests in his complaint that a court order be entered declaring that he is the inventor or co-inventor of the patent and, as a result, is entitled to all or part of the royalties and profits that we earned or will earn from the sale of any product incorporating or using the improved handpiece.

On June 2, 2006, we entered into a settlement agreement with Dr. Spadafora for the dismissal of the lawsuit. Under the terms of the settlement agreement, we agree to provide Dr. Spadafora with the exclusive right over a three-year period to market and sell our Photon(TM) laser system and its components, including the inventory and intellectual property rights. If Dr. Spadafora is successful in finding a prospective purchaser to acquire the Photon(TM) laser system upon terms acceptable to us, we agree to pay him a commission equal to 10% of the total purchase price. If the purchase price for the Photon(TM) laser system includes a royalty or other payments payable to us on later sales of the Photon(TM) laser system other than its handpiece component, we agree to pay Dr. Spadafora 8% of such royalties or other payments on such later sales through the full term of the purchase agreement. We further agree that if a purchase price includes a royalty or other payments payable to us on later sales of the handpiece component of the Photon(TM) laser system, we agree to pay Dr. Spadafora 15% of such royalties or other payments through the full term of the purchase agreement.

Additionally, the settlement agreement provides that if we are successful through our sole efforts, without any assistance from Dr. Spadafora, in finding a purchaser to acquire the Photon(TM) laser system or its components during the second or third year of Dr. Spadafora's exclusive rights, we agree to pay Dr. Spadafora a commission equal to 1.7% of the total purchase price and of our royalties or other payments on subsequent sales of the Photon(TM) laser system or its components through the full term of the purchase agreement.

Finally, the settlement agreement provides for mutual releases by Dr. Spadafora and us for the benefit of each other, and that we each agree to pay our own costs, expenses and attorney's fees incurred in connection with the lawsuit and the preparation of the settlement agreement.

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 our disposable accessories as it further penetrates the cataract surgery market and expands the treatment applications for its Workstation(TM). These products contributed 0% of the total revenues for both 2005 and 2004, and 0% of the total revenues for the nine months ended September 30, 2006.

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 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

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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 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 4% and 18% of total revenues for the fiscal years ended December 31, 2005 and 2004, respectively, and 8% of total revenues for the nine months ended September 30, 2006.

Dicon(TM) Perimeters: Dicon(TM) perimeters consist of the LD 400, the TKS 5000, 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 28% and 27% of the total revenues for both 2005 and 2004, respectively, and 41% of the total revenues for the nine months ended September 30, 2006.

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 3% and 7% of the total revenues for 2005 and 2004, respectively, and 4% of the total revenues for the nine months ended September 30, 2006. An enhanced version of the CT 200(TM) was introduced during the first quarter of 2004. We have completed upgrades to the CT 200(TM) and the CT 50 Corneal Topographer, which are now operating with Windows XP software rather than the former Windows 95 operating systems.

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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 2% and 3% of the total revenues for 2005 and 2004, respectively, and 2% of the total revenues for the nine months ended September 30, 2006.

P20 A-Scan Biometric Ultrasound Analyzer: The A-Scan was removed from our line of diagnostic products in 2002 but added back as a result of our Worldwide OEM Agreement with MEDA Co., Ltd. in which MEDA has agreed to jointly develop and collaborate in the improvement and enhancement of our 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 0% of the total revenues for both 2004 and 2005, and 1% of the total revenues for the nine months ended September 30, 2006.

P37 A/B Scan Ocular Ultrasound Diagnostic: The A/B Scan is used by retinal subspecialists to identify foreign bodies in the posterior chamber of the eye and to evaluate the structural integrity of the retina. The A/B Scan is attractive to the general ophthalmic community at large because of its lower price point. Sales from this product were approximately 8% and 9% of the total revenues for 2005 and 2004, respectively, and 12% of the total revenues for the nine months ended September 30, 2006.

P40, P45 and P60 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 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 subspecialty 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 9% and 11% of the total revenues for 2005 and 2004, respectively, and 4% of the total revenues for the nine months ended September 30, 2006. The P45 UBM Ultrasound Biomicroscope and related accessories sales contributed 13% and 16% of the total revenues for 2005 and 2004, respectively, and 7% of the total revenues for the nine months ended September 30, 2006.

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 the P60 UBM Ultrasound Biomicroscope. Upon execution of the agreement, we paid \$30,000 to E-Technologies for engineering costs associated with the development of the P60. When the P60 received FDA approval on May 26, 2005, we paid E-Technologies an additional fee of \$45,000.

In consideration for the exclusive right to manufacture and distribute the P60 biomicroscope, we agree to pay E- Technologies the sum of \$5,000 for each of the first 25 P60 biomicroscopes sold by us. Thereafter, we agree to pay E- Technologies the sum of \$4,000 for each P60 biomicroscope sold. As an additional condition, we agree to sell 25 P60 biomicroscopes during the first 12 months after the P60 receives FDA approval. The agreement is effective for a term of two years. After the expiration of the two year period, the agreement is to automatically renew for additional one year periods, unless either party elects to terminate the agreement upon at least 30 days prior written notice to the other party before the end of any term of the agreement.

In March 2005, we introduced the P60 UBM Ultrasound Biomicroscope. The P60 biomicroscope represents the fourth generation of UBM devices and has better visual clarity and image flexibility than earlier versions. On March 1, 2005, we were awarded the CE Mark for the P60, which enables us to market the device in 19 Western European countries and some parts of the Pacific Rim. On May 26, 2005, we received FDA 510(k) premarket approval for the P60, which allows us to sell the P60 in the United States. On February 9, 2006, we received a Canadian device license for the P60, which allows it to be sold in Canada. The P60 biomicroscope and related accessories sales were 21% and 0% of total revenues for 2005 and 2004, respectively, and 7% of the total revenues for the nine months ended September 30, 2006.

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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 2005 and retained ISO 13485 in December 2005 from TUV Essen.

On June 12, 2006, we entered into a Worldwide OEM Agreement with MEDA Co., Ltd., one of China's leading developers and producers of ultrasound devices. Under the terms of the agreement, MEDA agrees to jointly engineer, develop and manufacture our next generation of the Ultrasound BioMicroscope, as well as other proprietary new products and enhancement of our current products. The products to be manufactured by MEDA, at agreed upon costs, and supplied to us for resale include the following new products: an Ultrasound BioMicroscope, two Ultrasound A/B Scans, a Biometric A-Scan and a pachymeter.

The agreement provides that we and MEDA agree to jointly develop and collaborate in the improvement and enhancement of our products and, in the interest of product development, enhancement and differentiation, MEDA agrees to give consideration to potential software development or enhancements made available to us for our products. Moreover, in the interest of product improvement, MEDA agrees to collaborate with us and our designated engineers, employees and consultants to consider and potentially implement jointly or individually the development of product enhancements on our products to be manufactured by MEDA.

Parts and Services: The parts and services revenue from the repair and service of equipment sold accounted for 12% and 9% of the total revenues in both 2005 and 2004, and 14% of the total revenues for the nine months ended September 30, 2006.

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

Product (1)	Product Class	Commercial Development	Reimbursement Status	% 2005 Sales
P55 Pachymetric Analyzer	System, Imaging, Pulsed Echo Diagnostic	Complete	Yes	2%
P20 A-Scan Biometric Ultrasound Analyzer	System Imaging, Pulsed Echo Diagnostic	Complete	Yes	0%
P37 A/B Scan Ocular Ultrasound Diagnostic	Transducer, Ultrasound Diagnostic	Complete	Yes	8%
P40 UBM Ultrasound Biomicroscope	System, Imaging, Pulsed Echo Ultrasound Diagnostic	Complete	Yes	9%
P45 UBM Ultrasound Biomicroscope, Workstation Plus	System, Imaging, Pulsed Echo Ultrasound Diagnostic	Complete	Yes	13%
P60 UBM Ultrasound Biomicroscope,	System, Imaging, Pulsed Echo Ultrasound Diagnostic	Complete	Yes	21%

Workstation Plus BFA Ocular Blood Flow Analyzer(TM) and Disposables	Tonometer, Manual Diagnostic	Complete	Yes***	4%
CT 200 Corneal Topography System	Topographer Corneal AC-Powered Diagnostic	Complete	Yes	3%
LD 400 Autoperimetry System	Perimeter, Automatic AC-Powered Diagnostic	Complete	Yes	23%
TKS 5000 Autoperimetry System	Perimeter, Automatic AC-Powered, Diagnostic	Complete	Yes	5%
Precisionist Thirty Thousand(TM), Ocular Surgery Workstation with Surgical Equipment and Disposables	Phacofragmentation	Complete	Yes	0%
Photon(TM) Laser, Ocular Surgery Workstation with Surgical Equipment and Disposables(3)	Phacoemulsification	In-Process (4)	No	0%
Parts and Services	Perimeter, BFA, Tonometer, Topographer, Ultrasound Workstations,	Complete	Yes	12%

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Systems, Imaging

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<sup>(1)</sup> 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.

<sup>(2)</sup> Sales for 2006 are for the nine months ended September 30, 2006.

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

offset such inventory.

- (4) Due to the lack of recent evidence to support the recoverability of inventory associated with the Photon(TM), the Company has recorded a reserve to offset the majority of such inventory on hand.
- (5) The Photon(TM) is in-process and not complete because the Company has not completed the clinical trials in order to obtain FDA regulatory approval.
- \* FDA 510(K) K844299 represents domestic approval by U.S. Food and Drug Administration
- \*\* ISO 9001: 1994, EN ISO 9001 represents international approval
- \*\*\* IDE G940151 represents approval for international distribution only
- \*\*\*\* Represents full reimbursement in 22 states and partial reimbursement in four other states.

As detailed in the table above, except for the Photon(TM) Laser Ocular Surgery Workstation, which requires additional development and regulatory approvals, our current products are developed and available for sale in footnote (1) of the table. 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. 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.

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#### Marketing and Sales

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

Industry analysts report that the United States ophthalmic surgical device market has been characterized by slower growth in recent years. This has apparently been caused by the potential reforms associated with the health care industry. Further, hospitals have been inclined to keep their older phaco machines longer than expected as they have been forced to mind budgets more

carefully and have become less willing to invest in capital equipment until more information on health care reform becomes available. However, analysts predict that the ophthalmic surgical device market will see renewed growth in the coming years as the health care environment stabilizes and as the growing elderly population produces an increased number of cataract surgeries. As a consequence of these factors, the market should see a greater rate of replacement of older machines that hospitals and surgeons have been postponing for longer than usual.

Current Market Acceptance and Potential: The principal purchasers of 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 November 30, 2006, we had four direct domestic sales representatives in the United States and 57 ophthalmic and medical product distributors outside the United States. 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 with 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.

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 16,926 square foot facility in Salt Lake City. We transferred the manufacturing activities for the Blood Flow Analyzer(TM) to San Diego from Ocular Blood Flow, Ltd. in England during 2001. During the second quarter of 2002, 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. 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, which provides 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.

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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.

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) increased by \$87,000, or 11%, to \$855,000 for the twelve months ended December 31, 2005, from \$768,000 for the same period in 2004. None of the costs of research and development activities during 2005 and 2004 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 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, and John Y. Yoon, who served as President and Chief Executive Officer from March 13, 2004 to December 31, 2005, decided not to utilize the clinical advisory board. Instead, they consulted with former members of the advisory board on an informal basis. Raymond P.L. Cannefax, 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 those 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 aftermarket suppliers. While there is growing market resistance in the United States and internationally to single use cassettes, it is anticipated that manufacturers of ultrasound equipment will continue to develop and enhance their present ultrasound products in order to protect their investments in system and cassette technology and to protect their profits from sales of these cassettes and accessories. 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.

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

Ultrasound Equipment Manufacturers. As a relatively recent entrant into the cataract surgical equipment market with a newer equipment line, 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 the 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 visual 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 near sighted. The  ${\tt Glaucoma\ Research\ Foundation\ recommends}$ that these high-risk individuals be tested regularly for glaucoma. According to the U.S. Census Bureau, in 1995 there were over 30 million adults 65 years of age and older and 8 million African Americans 45 years of age and older. The Glaucoma Research Foundation reports that glaucoma currently accounts for more than 7 million visits to physicians annually.

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 acquired 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 P40 UBM biomicroscope, for which we are required to pay a royalty of \$150 for each licensed product sold. The

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license agreement was automatically terminated by its terms on September 27,

2002, at which time we had a royalty free worldwide 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 PhotonTM 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.

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 worldwide 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 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 salable 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 could 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 were allegedly due and owing to them from the sale of equipment by us. We have paid \$15,717 to bring all royalty payments up to date through January 5, 2005. 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.

An issue in dispute concerning the method of calculating royalties is whether royalties should be paid on returned equipment. Since July 1, 2001, only one Photon (TM) laser system has been sold and no systems returned. Thus, the amount of royalties due, according to our calculations is \$981. We made payment of this amount to Photomed and Dr. Eichenbaum on January 5, 2005 and, as a result, seek to have the legal action dismissed. However, if the partes are unable to agree on a method for calculating royalties, there is a risk that PhotoMed and Dr. Eichenbaum might amend the complaint to request termination of the license agreement and, if successful, 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) was 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 intraocular 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

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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 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 in order to avoid criminal prosecution may also be made.

Following the enactment of the Medical Device Amendments to the Food, Drug and Cosmetics Act in May 1976, the FDA began classifying medical devices in commercial distribution into one of three classes: Class I, II or III. This classification is based on the controls that are perceived to be necessary to reasonably ensure the safety and effectiveness of medical devices. Class I devices are those devices, the safety and effectiveness of which can reasonably be ensured through general controls, such as adequate labeling, advertising, premarketing 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 premarketing 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 premarketing 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 premarketing approval, the manufacturer or distributor may seek FDA Section 510(k) premarketing clearance for the device by filing a Section 510(k) premarketing 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 premarketing clearance for the device. There can be no assurance that we will obtain Section 510(k) premarketing 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 premarketing approval, and allow the proposed device to be marketed in the United States. The FDA may determine, however, that the proposed device is not substantially equivalent, or may require further information, such as additional test data, before the FDA is able to make a determination regarding substantial equivalence. A "not substantially equivalent" determination or a request for additional information could delay 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 premarketing approval from the FDA. If a manufacturer or distributor of a medical device  $\frac{1}{2}$ 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 premarketing approval for the proposed device. A premarketing 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.

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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 premarketing 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 premarketing approval procedure is more complex and time consuming.

Upon receipt of the premarketing 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 premarketing approval is sufficiently complete to permit a substantive review, the FDA will "file" the application. Once the submission is filed, the FDA has by regulation 90 days to review it; however, the review time is often extended significantly by the FDA asking for more information or clarification of information already provided in the submission. During the review period, an advisory committee may also evaluate the application and provide recommendations to the FDA as to whether the device should be approved. In addition, the FDA will inspect the manufacturing facility to ensure compliance with the FDA's Quality System Requirements prior to approval of a premarketing application. While the FDA has responded to premarketing approval applications within the allotted time period, premarketing approval reviews generally take approximately 12 to 18 months or more from the date of filing to approval. The premarketing 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 premarketing approval have never been approved for marketing.

Any products manufactured or distributed by us pursuant to a premarket clearance notification or premarketing 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