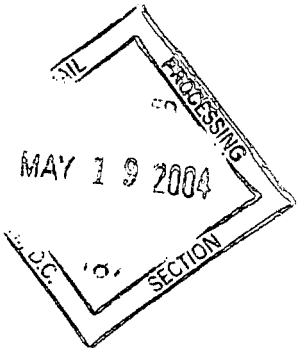

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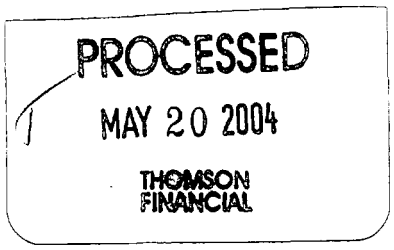
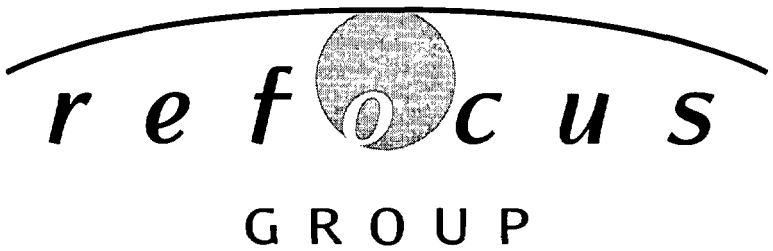
ANNUAL REPORT 2003





Dear Shareholders,

I trust this Refocus Group Annual Report finds you well. In 2003, despite a challenging year that presented unforeseen external pressures, we took several important steps to lay the groundwork for a strong future:

1. We reacquired our worldwide technology license from CIBA Vision.
Due to our former strategic partner's decision to exit the surgical ophthalmics business, Refocus Group had the opportunity to reacquire the license it granted to CIBA Vision. We reacquired our license in January 2004 because it was in the best long-term interest of our shareholders. We now control the final development and commercialization of our PresVIEW™ Scleral Implant (PSI) and PresVIEW Surgical Spacing Procedure (SSP). At the same time, we will continue to explore strategic alternatives to maximize long-term shareholder value.

2. We completed development of the PresVIEW Incision System and received approval to conduct U.S. FDA Phase II clinical trials for presbyopia.
In 2003, we made great strides in advancing our technology for the treatment of presbyopia, ocular hypertension, and primary open angle glaucoma. We completed the redesign of our PresVIEW Incision System, which incorporates automated and disposable components to simplify and enhance the placement of the PSI and provide for more consistent results of the PresVIEW SSP. We also received approval from the FDA to conduct Phase II clinical trials for presbyopia, which officially began with the enrollment of our first patient in mid-February 2004. We are targeting completion of our 150-patient enrollment by fall 2004.

3. We continued preparations for a launch in Europe.
Our strategy to initiate a limited European "seeding" launch at select sites and countries is moving forward. We are making progress toward CE Mark approval of our repackaged PSIs. Our redesigned and automated PresVIEW Incision System already bears the CE Mark certification. In March 2004, we trained a surgeon for our first Center of Excellence in Europe, which is tentatively scheduled to open in the second half of 2004. Funding and final transition/coordination activities, as well as obtaining the CE Mark certification for the PSI, remain the critical paths to the European launch.

4. We secured an important round of new financing.
In December 2003, we raised $2.2 million in a private placement transaction that enabled us to continue to develop our technology and initiate FDA Phase II clinical trials for presbyopia. We are now exploring the initiation of FDA clinical trials in the United States for the treatment of glaucoma, as well as the resumption of our glaucoma clinical trials in Canada, during 2004. Both studies remain key for the development of major business and market opportunities for Refocus Group. Like any development stage company, the lack of positive cash flow remains a limiting factor in our growth plans. Therefore, we intend to explore additional financing opportunities during 2004 to support our initiatives for the balance of the year and into 2005.

We are focused on huge market opportunities.
Some in our industry have called presbyopia the "last frontier in eye care." Others call glaucoma "the sleeping giant of eye care." We believe both are correct. Virtually 100% of the population over 40 will become presbyopic. The predominant standard of care today for presbyopia is reading glasses or bifocals. Refocus believes that the PresVIEW SSP procedure has the potential to significantly reduce or eliminate the need for reading glasses among presbyopes. Regarding glaucoma, over 60 million people suffer from this disorder worldwide. The predominant standard of care for glaucoma is glaucoma medications. Today glaucoma medications represent an estimated market of over $2.3 billion worldwide. Refocus Group believes the PresVIEW SSP has the potential to reduce or eliminate the need for glaucoma medications among this population. And as an added benefit, glaucoma patients over 40 could expect improvement in not only their intraocular pressure (viewed by many as the contributing factor to primary open angle glaucoma) but also their presbyopia—both from the same SSP procedure.

To safeguard our technology, we believe we have excellent worldwide patent positions for our PresVIEW Incision System and the PSI. Refocus Group has 84 issued patents and patent applications worldwide on just the PresVIEW technology alone.

We will continue to face challenges in 2004. Although we believe the reacquisition of our license presents us with significant opportunities, it also adds significant challenges. As I mentioned earlier, we need to obtain additional external financing, and we will continue to seek such financing to implement our business plan. Despite these challenges, we believe we are continuing to make significant progress, and we look forward to further progress in 2004 and beyond.

Finally, we are proud of the contribution made in 2003 by our experienced management team. Thanks also to the board of directors that, except for me, is composed entirely of independent outsiders as defined by the American Stock Exchange.

In the coming year, we will continue to be driven by our mission of *"becoming the surgical standard of care for presbyopia, primary open angle glaucoma and ocular hypertension worldwide."* Thank you for your continued support.

Sincerely,

Terence A. (Terry) Walts
President & CEO
Refocus Group, Inc.

U.S. SECURITIES AND EXCHANGE COMMISSION
Washington, D.C. 20549

FORM 10-KSB

[X] ANNUAL REPORT PURSUANT TO SECTION 13 OR 15(d)
OF THE SECURITIES EXCHANGE ACT OF 1934

FOR THE FISCAL YEAR ENDED DECEMBER 31, 2003

[ ] TRANSITION REPORT PURSUANT TO SECTION 13 OR 15(d)
OF THE SECURITIES EXCHANGE ACT OF 1934

COMMISSION FILE NUMBER 0-32543

REFOCUS GROUP, INC.
(Exact name of registrant as specified in its charter)

Delaware	**75-2910096**
(State or other jurisdiction of incorporation or organization)	(I.R.S. Employer Identification No.)
10300 North Central Expressway, Suite 104, Dallas, Texas	**75231**
(Address of principal executive offices)	(Zip Code)

Registrant's telephone number, including area code: 214-368-0200

(Former name or former address, if changed since last report)

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

Securities registered pursuant to Section 12(g) of the Act:
Title of each class
Common Stock, par value $.0001 per share

Check whether the issuer (1) filed all reports required to be filed by Section 13 or 15(d) of the Exchange Act during the past 12 months (or for such shorter period that the registrant was required to file such reports) and (2) has been subject to such filing requirements for the past 90 days. Yes ✓ No__

Check if disclosure of delinquent filers in response to Item 405 of Regulation S-B is not contained in this form, and no disclosure will be contained, to the best of the issuer's knowledge, in definite proxy or information statements incorporated by reference in Part III of the Form 10-KSB or any amendment to this Form 10-KSB. __

Issuer's revenues for the fiscal year ended December 31, 2003 were $0.

On March 26, 2004, the aggregate value of voting stock held by non-affiliates of the registrant was approximately $7,862,000 For purposes of this computation, all officers, directors and 10% stockholders were deemed affiliates. Such determination should not be construed as an admission that such officers, directors and 10% stockholders are affiliates.

On March 26, 2004, there were 23,382,182 shares of the registrant's common stock outstanding.

DOCUMENTS INCORPORATED BY REFERENCE:
The information called for by Part III is incorporated by reference to the definitive Proxy Statement for the Annual Meeting of Stockholders of the Company to be filed with the Securities and Exchange Commission not later than 120 days after December 31, 2003.

Transitional Small Business Disclosure Format (check one): Yes __ No✓

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PART I

Cautionary Statement under the Private Securities Litigation Reform Act of 1995: This Annual Report on Form 10-KSB contains certain "forward-looking statements" within the meaning of the Private Securities Litigation Reform Act of 1995 that are based on the assumptions, beliefs and opinions of our management. When used in this document, the words "anticipate", "believe", "continue", "estimate", "expect", "intend", "may", "should", "plan", "potential" and similar expressions are intended to identify forward-looking statements. Such statements reflect our current views with respect to future events and involve known and unknown risks, uncertainties and other factors that may cause our actual results, levels of activity, performance or achievements to be materially different from what management currently believes. Such risks and uncertainties include, among other things, those described in the "*Cautionary Statements*" section below and elsewhere in this Form 10-KSB. Should one or more of those risks or uncertainties materialize, or should underlying assumptions prove incorrect, our actual results may vary materially from those described herein. The forward-looking statements made in this document speak only to the date on which such statements are made, and we undertake no obligation to update any forward-looking statement to reflect events or circumstances after the date on which such statement is made or to reflect the occurrence of unanticipated events.

ITEM 1. DESCRIPTION OF BUSINESS

Refocus Group, Inc. is a medical device company engaged in the research and development of treatments for eye disorders. Our principal products are the patented PresVIEW Scleral Implant (the "PSI") and the PresVIEW Incision System, which consists of the surgical instruments used to implant the PSI in the surface of the white of the human eye. The PSI and PresVIEW Incision System are utilized in our surgical procedure, the Scleral Spacing Procedure, for the treatment of presbyopia, ocular hypertension and primary open angle glaucoma. Presbyopia, the Greek word for "old eye", is the primary reason that a substantial portion of the population beginning in their early 40s uses bifocals, reading glasses or removes their distance glasses in order to read at a comfortable distance. We believe that our surgical procedure physiologically restores the human eye's natural ability to focus as it did at a younger age. We believe the procedure works by reducing the crowding of the underlying tissues surrounding the crystalline lens, which allows the muscles to once again reshape the lens and thus restore the eye's ability to accommodate or focus. Ocular hypertension, or elevated pressure within the eye, often leads to primary open angle glaucoma, or the progressive loss of central vision potentially leading to blindness. We believe that our same surgical procedure restores the natural base-line tension of the muscle inside the eye, which permits the eye to drain naturally and, thus, lower the intraocular pressure. We received approval from the United States Food and Drug Administration (the "FDA") to begin Phase II FDA clinical trials using the PSI for the treatment of presbyopia in December 2003. We began those trials in the first quarter of 2004. We have also conducted clinical trials in Canada using the PSI for the treatment of ocular hypertension and primary open angle glaucoma. Later this year, we plan to continue our clinical trials in Canada and to potentially start our clinical trials in the United States, pending FDA approval, using the PSI for the treatment of ocular hypertension and primary open angle glaucoma. We may also receive CE Mark certification of the PSI so that we may begin sales of our products in the European Union this year. See "*Business of Refocus Group, Inc.* " below for a complete discussion.

Business Development

On November 21, 2000, VeryBestoftheInternet.com, the predecessor of Refocus Group, Inc., was incorporated in the State of Texas. In February 2003, VeryBestoftheInternet.com reincorporated in Delaware and changed its name to Refocus Group, Inc.

Refocus Group, Inc. ("Refocus") completed a merger on March 6, 2003 (the "Merger Closing Date") of Refocus Acquisition Corp., a Delaware corporation and newly created, wholly-owned subsidiary of Refocus, with and into Presby Corp ("Presby"), a Delaware corporation. Presby is a medical device company based in Dallas, Texas, which is engaged principally in the research and development of surgical treatments for human vision disorders. Presby was the surviving corporation and became a wholly-owned subsidiary of Refocus. The merger was consummated under Delaware law and pursuant to an Agreement of Merger and Plan of Reorganization, dated as of March 6, 2003 (the "Merger Agreement"). In addition, on the Merger Closing Date, Refocus completed the first tranche of a private placement of its common stock. See the discussion of the merger and the private placement in Manage-

ment's Discussion and Analysis or Plan of Operations in Item 6 and in the audited financial statements in Item 7 contained herein. Presby changed its name to Refocus Ocular, Inc. ("Ocular") in April 2003 after the merger. Prior to the merger, Refocus was an internet website ranking service that allowed consumers to identify websites that were most useful to them to minimize the time expended in searching for desired information.

All references to "Refocus", "Presby", "Ocular", "we", "us", "our", or the "Company" means Refocus or Ocular, as the former Presby, separately prior to the Merger Closing Date and Refocus, as successor to the business of Ocular, after giving effect to the merger.

After the merger, Refocus discontinued its previous business as an internet website ranking service, the founders of Refocus resigned their positions, and Refocus succeeded to the business of Ocular. For accounting purposes, the merger was accounted for as a reverse merger, whereby Ocular was deemed to be the accounting acquirer of Refocus since the former stockholders of Ocular owned a majority of the issued and outstanding shares of common stock of Refocus on the Merger Closing Date, including those shares issued in the private placement that closed on that date.

Therefore, all financial information included in this report on Form 10-KSB prior to the Merger Closing Date is that of Ocular as if Ocular had been the registrant. The financial information since the Merger Closing Date is that of Refocus and Ocular consolidated.

In addition, you should be aware that we may not be able to continue as a going concern over the next twelve months if additional funding is not obtained. See the discussion below in Management's Discussion and Analysis or Plan of Operations in Item 6 and in the audited financial statements in Item 7 contained herein.

Business of Refocus Group, Inc.

General

We are a medical device company based in Dallas, Texas, engaged in the research and development of surgical treatments for human vision disorders. We may also use our research and understanding of the human eye to develop and patent technology for use with commercial optical lens applications.

Our principal products are the patented PresVIEW Scleral Implant (the "PSI") and the PresVIEW Incision System, which consists of the surgical instruments used to implant the PSI in the human eye. The PSI and the PresVIEW Incision System are utilized in our surgical technique, the Scleral Spacing Procedure (the "SSP"), for the treatment of presbyopia, ocular hypertension and primary open angle glaucoma in the human eye. Presbyopia, the Greek word for "old eye", is the primary reason that a substantial portion of the population beginning in their early 40s uses bifocals, reading glasses or removes their distance glasses in order to read at a comfortable distance. We believe that the SSP treats presbyopia by reducing the crowding of the underlying tissues surrounding the crystalline lens, which allows the muscles to once again reshape the lens to restore the eye's ability to accommodate or focus. In the case of ocular hypertension and primary open angle glaucoma, we believe that the SSP restores the natural base-line tension of the muscle inside the eye, which permits the eye to drain naturally and, thus, lower the intraocular pressure.

Since the early 1990s, extensive research has been conducted on, and extensive investigational surgeries have been performed utilizing, the PSI. By 1998, we had obtained the European CE Mark and other regulatory approvals necessary to market early versions of our products, including a manual approach to the surgical procedure, in a number of international markets. In that same year, we began selectively selling the early prototypes of the PSI and related customized manual surgical instruments to key surgeons in the European Union and other countries.

In 2000, we received approval from the United States Food and Drug Administration (the "FDA") to conduct Phase I clinical trials of the PSI for the treatment of presbyopia on humans. In that same year, we received approval from Health Canada (the Canadian equivalent of the FDA) to conduct clinical trials of the PSI for the treatment of ocular hypertension and primary open angle glaucoma. We decided to suspend sales in 2001, however, in order to

develop an automated surgical incision device to help simplify, standardize and automate the surgical procedure and to make the outcomes of the surgical procedure less dependent on each physician's surgical skill. Since that time, we have developed the PresVIEW Incision System, which we believe improves the consistency of the results of the SSP

In March 2002, we entered into a license agreement with CIBA Vision AG ("CIBA") pursuant to which CIBA obtained an exclusive license to our patents related to the treatment of presbyopia, ocular hypertension and primary open angle glaucoma in international markets. CIBA also had the right in the license agreement (the "CIBA Agreement") to acquire a license for our products in the United States. We were entitled to receive a percentage royalty on CIBA's worldwide sales of the PSI and related products under the CIBA Agreement. Upon entering into the CIBA Agreement, CIBA paid us $2.0 million in advance royalties and was committed to purchase equity interests in us if we obtained certain other investments from third-parties. Simultaneously with our receipt of third-party investments in March 2003, CIBA purchased 625,000 shares of our common stock and a warrant to purchase 312,500 shares of our common stock at an exercise price of $2.50 per share for an aggregate purchase price of $1.25 million.

Under the CIBA Agreement, CIBA was responsible for manufacturing, marketing and distributing our products worldwide at its expense. CIBA was also responsible for regulatory matters outside the United States and was committed to jointly manage the FDA clinical trials with us. In accordance with the CIBA Agreement, we ceased all direct manufacturing and marketing of the PSI and related products. As a result of the transition of those manufacturing responsibilities to CIBA, the modifications in the packaging of the PSI and the resultant changes to those processes, the CE Mark certification we obtained in 2000 on the PSI is no longer applicable. CIBA has been seeking CE Mark certification of the PSI for its planned marketing efforts in the European Union in early 2004. That CE Mark certification is still pending. Late in 2003, a CE Mark certification of the components of the PresVIEW Incision System was obtained by the suppliers of those components.

In August 2003, CIBA announced that it was seeking strategic alternatives for its surgical business unit, including the sale of that unit. CIBA's surgical business unit marketed a variety of ophthalmic products and was primarily responsible for performing the CIBA Agreement. On December 29, 2003, CIBA informed us that it was exiting the surgical business and expected to complete the sale of the surgical business unit's various product lines to a variety of parties by early 2004. In conjunction with that sale, CIBA received an offer from a third-party to purchase CIBA's rights under the CIBA Agreement. Pursuant to the CIBA Agreement, the transfer of the license required our consent. As a condition to the assumption of CIBA's duties associated with that proposed license assignment, the third-party requested the renegotiation of certain key terms of the license agreement. After deliberation, we declined to renegotiate the license and did not permit the assignment of the license to the third-party. As a result, we began negotiations with CIBA for the transfer of CIBA's rights under the CIBA Agreement back to us and the termination of the license.

In January 2004, we entered into an agreement with CIBA, the License Transfer and Transition Services Agreement (the "Transfer Agreement"). Pursuant to the Transfer Agreement, we reacquired all worldwide license rights to our patents that were granted to CIBA under the CIBA Agreement, and CIBA was released from all future financial commitments, including its obligations associated with manufacturing, marketing, distribution and regulatory matters. Under the Transfer Agreement, CIBA has agreed to provide us with certain transition services during 2004, including efforts to finalize the CE Mark certification of the PSI. These transition services will help us transfer the manufacturing, distribution and marketing functions back to us from CIBA. If CIBA obtains CE Mark certification of the PSI, CIBA and we will enter into a technical agreement, which will permit us to directly sell our products in CIBA packaging during 2004 in the European Union while we seek our own CE Mark certification. As consideration for the acquisition of CIBA's license rights, the forgiveness of the $2.0 million in prepaid royalties we received under the CIBA Agreement and the transition services to be performed by CIBA under the Transfer Agreement, we agreed to pay CIBA an aggregate of $3.0 million in twelve quarterly installments commencing in the first calendar quarter of 2006. We, however, are entitled to prepay and extinguish our payment obligations by paying an aggregate amount of $2.0 million to CIBA prior to January 1, 2006.

Under the Transfer Agreement, CIBA has also agreed to return the warrant to purchase 312,500 shares of our common stock that it acquired in the March 2003 private placement. While it will retain the 625,000 shares of common stock acquired at the same time, these shares will be subject to certain restrictions on their transfer.

We expect that the transition under the Transfer Agreement will result in a significant increase in costs for us related to performing functions that CIBA had assumed under the CIBA Agreement. Conversely, however, we will be entitled to all gross proceeds from the sale of our products instead of a royalty based on a percentage of sales as previously specified in the CIBA Agreement. Even assuming that CIBA obtains the CE Mark certification of the PSI, our ability to directly market our products in the European Union is currently limited. The anticipated date of the initial sale of our products in the European Union is likely to be delayed, and the number of PresVIEW Incision System and PSI units sold is likely to be reduced, in the short term and especially in 2004, relative to the number of unit sales that could have been achieved by CIBA. We may seek to market the PSI and PresVIEW Incision System in the European Union and elsewhere directly or through other distribution, license or strategic arrangements. Therefore, as a result of the increased expenses and potential for delayed revenues, we believe that the Transfer Agreement may have a material adverse impact on our financial condition in the short term. We believe the reacquisition of the license will be in the best long-term interest of our stockholders.

In November 2002, we, along with CIBA, submitted to Health Canada an application seeking approval to commercialize the PSI in surgery for the treatment of ocular hypertension, primary open angle glaucoma and presbyopia. In June 2003, Health Canada informed us that it had determined that the sample size submitted in our application was insufficient for approval, and denied the application. Based on further discussions with Health Canada in October 2003, we will need to perform further clinical trials at more sites and with significantly more patients in order to receive approval for commercial sales. We are uncertain, at this time, as to when we may receive Health Canada's approval, but we believe it will not be until at least 2005 before the results of these additional clinical trials can be resubmitted. We remain committed to reinitiating the clinical trials in Canada at such time as funding is available and we establish the ability to coordinate those trials with the planned United States FDA clinical trials for the treatment of ocular hypertension and primary open angle glaucoma. Our immediate focus, however, is currently on the FDA clinical trials for the treatment of presbyopia.

In March 2003, we filed an investigational device exemption application with the FDA to obtain approval to initiate our Phase II clinical trials for the surgical treatment of presbyopia utilizing the PSI and SSP. This application was followed by later amendments. In December 2003, we received approval to begin our Phase II clinical trials of the PSI and SSP for the treatment of presbyopia. The FDA approval was conditioned on our submittal of certain final documentation concurrent with the initiation of the clinical study. We started these clinical trials during the first quarter of 2004.

We have additional products in early-stage research, including a medical device for the treatment of dry age-related macular degeneration ("ARMD") and a single element variable focus lens ("SEVFL") for use in commercial optical lens applications.

We have had no significant revenue since 2000 from our core lines of business. We have incurred losses every year since we began operations. Those losses resulted primarily from expenses associated with research and development activities, clinical trials, obtaining regulatory approvals in international markets and general and administrative expenses. To become profitable, we must generate sufficient income from future product sales, either directly or through potential future strategic partners.

We have a limited operating history and have not commercially produced any significant quantities of our products to date. We have not yet achieved, and may never achieve, profitability. In addition, we expect to incur net losses in the foreseeable future, and those losses may be substantial. Moreover, we have significant future capital requirements related to the regulatory approval of our products. If we are unable to fund these requirements, our business could be seriously harmed.

You should be aware that we may not be able to continue as a going concern for the next twelve months if additional financing is not obtained. There can be no assurances, however, that additional financing will be obtained on reasonable terms, or at all. We may seek a merger partner or sale of assets if additional financing is not available. Our inability to obtain additional financing could have a material adverse effect on us.

History of Refocus Ocular, Inc.

Ocular was incorporated in 1994 to conduct research on, and develop a surgical treatment for, presbyopia in the human eye. Extensive research and investigational surgeries were conducted, and by 1998, Ocular had obtained the European CE Mark and other regulatory approvals necessary to market versions of the technology in a number of international markets. Ocular began selectively selling the early prototypes of the PSI and related customized surgical instruments to key surgeons in the European Union and other countries. Ocular marketed the medical device as the "Scleral Expansion Band". We intend to market the device under a new name, the "PresVIEW Scleral Implant". References to the PSI in periods prior to the change to the current name should be understood to refer to the medical device under its previous name.

On March 6, 2003, Refocus completed the merger of Refocus Acquisition Corp., a Delaware corporation and newly-created, wholly-owned subsidiary of Refocus, with and into Ocular. Ocular was the surviving corporation and became a wholly-owned subsidiary of Refocus.

Business and Industry Overview

Presbyopia. Presbyopia (the Greek word for "old eye") is the primary reason that nearly everyone beginning in their early 40s uses bifocals, reading glasses or removes their distance glasses in order to read at a comfortable distance. According to Dain Rauscher Wessels in May 2001, presbyopia ultimately affects 100% of the population, with the first effects of presbyopia generally occurring at about the age of 40 and nearly fully prevalent after age 45. There are approximately 120 million Americans who currently suffer from presbyopia and, based on widely available estimates, the United States population over the age of 40 continues to grow. External lenses such as bifocals and reading glasses are currently the principal alternatives available to counter the effects of presbyopia. We believe the SSP will be particularly attractive to the approximately 4 million Americans who, since 1996, have already demonstrated a willingness to reduce or eliminate their need for glasses via LASIK and laser vision correction procedures—only to find that they need glasses again for reading as they become presbyopic after age 40.

A February 1999 study conducted by Business Valuation Services, an independent consulting firm commissioned by us, revealed that while only about 40% of the United States population under age 40 wear vision corrective lenses, over 90% of the United States population over the age of 55 require vision correction, including reading glasses. This increased need for vision correction is primarily due to the onset of presbyopia. We believe that a significant segment of the population from ages 40 to 65 will benefit significantly from the SSP and may be able to discontinue or reduce the need for vision correction. The study commissioned by us estimated the number of patients ideally suited, by age, vision and income qualifications, to be in excess of 50 million people worldwide. We believe that this market will continue to refresh and grow as more people reach the age of 40.

Widely publicized laser surgical techniques, such as LASIK and LASEK, are generally designed to treat other refractive imperfections of the eye, primarily nearsightedness (myopia), farsightedness (hyperopia) and astigmatism. These techniques generally do not compete with the SSP and do not directly treat presbyopia. In fact, the SSP is complementary to these laser surgical procedures. We expect that ophthalmologists, optometrists and other eye care professionals will aggressively market this elective procedure in similar fashion to laser procedures, especially since it complements those laser surgery procedures, which are marketed to the baby-boomer population.

Ocular Hypertension and Primary Open Angle Glaucoma. Ocular hypertension is a medical condition involving elevated pressure within the eye and may lead to serious damage to vision. Ocular hypertension is caused by a buildup of fluid pressure in the eye and is primarily associated with the inability of the eye to properly drain itself of fluids. Just as with high blood pressure, abnormally high levels of ocular pressure must be medically treated. Advanced or prolonged ocular hypertension is believed to damage the optic nerve in the back of the eye and can result in an initial loss of peripheral vision. This condition is deemed primary open angle glaucoma as loss of vision begins to occur. Continued loss of peripheral vision shrinks the person's field of vision and eventually leads to tunnel vision and then blindness. Ocular hypertension and primary open angle glaucoma are considered to be genetic and related to the tissue of the eye. The initial stages of ocular hypertension are not noticeable to a patient. Consequently, early diagnosis is extremely important because damage from primary open angle glaucoma is irreversible.

Ocular hypertension and primary open angle glaucoma are currently treated primarily with pharmaceutical drops and pills with varying success. These medications have substantial side effects, are costly, not continuous in their action and are not fully effective due to the patient's lack of compliance with the proper use of the medication. Many of these medications have to be taken several times each day on a strict schedule for the rest of the patient's life.

Patients with more advanced stages of primary open angle glaucoma must undergo other types of surgical treatments that involve artificial methods to drain the fluid from the eye. These surgical methods may have significant complications and side effects and typically have varying success.

According to the National Institutes of Health in June 2002, it is estimated that more than five million Americans have ocular hypertension. It also estimated that glaucoma affects three million Americans and many more people worldwide and is the second leading cause of irreversible blindness. According to a recent study by SG Cowen, glaucoma medications represent approximately 40% of ophthalmic medication revenues. According to published reports by Alcon and SG Cowen in 2000, the ophthalmic pharmaceutical industry has annual revenues exceeding $2.0 billion in the United States.

We believe that the SSP treats ocular hypertension and primary open angle glaucoma by restoring the natural spacing between the muscle and the lens, which also restores the natural base-line tension of the muscle inside the eye. Assuming that a significant number of patients that undergo the SSP for the treatment of ocular hypertension demonstrate the same surgical results that has been shown in clinical studies, the SSP could become the first-line preferred treatment for ocular hypertension and primary open angle glaucoma. Since these eye disorders are considered to be genetic, the SSP could become the first preventive procedure in ophthalmology.

Age-Related Macular Degeneration. ARMD is estimated to affect up to 10 million Americans and is the leading cause of irreversible severe central vision loss in Caucasians 50 years and older in the United States and in most of the developed world. The incidence and progression of ARMD increase significantly with age. According to the 2001 American Academy of Ophthalmology Preferred Practice Pattern, approximately 10% of patients age 66 to 74 have ARMD, and the prevalence increases to approximately 30% of patients age 75 to 85. Certain companies have developed drug related treatments for "Wet" ARMD. Wet ARMD involves the growth of abnormal blood vessels under the central part of the retina, called the macula. These vessels cause photoreceptor damage and a loss of central vision. According to the American Macular Degeneration Foundation in 2001, about 85% of patients, however, suffer from "Dry" ARMD. Dry ARMD involves similar damage to photoreceptors; however, the cause is unclear and is the subject of extensive medical debate. Our research has resulted in the development of the Macular Enhancing Device ("MED"), which may be the first device designed for use in the treatment of Dry ARMD. We have received three issued United States patents on the device. Considerable additional research and development needs to be conducted on this device. Due to our funding limitations, we have not devoted any resources to this project since 2002, other than research that may be conducted by Dr. Ronald A. Schachar, our founder and former Chief Scientist, under his consulting agreement. If we obtain adequate funding, we may resume additional research on this project in order to develop the device for later commercialization.

Current and Future Products

PresVIEW Scleral Implant and PresVIEW Incision System

The PSI consists of four separate tiny plastic segments, each about the size of a grain of rice, made from polymethylacrylate, or PMMA. PMMA has been implanted in the eye for other types of surgical procedures (intraocular lenses, hard contact lenses) for over fifty years. The PresVIEW Incision System, which consists of the surgical instruments used to implant the PSI in the human eye, contains a mechanized device used to make incisions in the human eye for implant of the PSI. The PresVIEW Incision System includes a control box, cabling, incision hand piece, disposable blade, footplate actuator and other related items. The surgeon uses the PresVIEW Incision System to make four superficial incisions in the quadrants of the sclera (white of the eye). The PSI is inserted into the superficial tunnels, causing a slight lift in the sclera that in turn reduces the crowding of the underlying muscles. The surgery is an outpatient surgical procedure performed under topical or local anesthesia.

We believe that the SSP provides:

- long-term improved near or reading vision;
- a low risk surgical solution for presbyopia;
- a minimally invasive procedure, which we believe is fully reversible; and
- a reduction in intraocular pressure in patients with ocular hypertension and/or primary open angle glaucoma.

Macular Enhancing Device

MED is a device in early stage research developed for the treatment of Dry ARMD. We have received three issued United States patents on the device. Considerable additional research is required for the project, and assuming the availability of adequate funding, we may conduct further research and may develop the device for commercialization or licensing in the future. To date, we have not licensed this device.

Single Element Variable Focus Lens

Our research and understanding of the human lens has led to the development of the SEVFL, which we believe duplicates the functionality of the human eye. Variable focus commercial lens systems in cameras and other applications currently involve multiple lenses, which must be moved relative to each other in order to produce variations in optical power. We may try to develop a SEVFL prototype that will demonstrate that these same large optical effects can be produced with microscopic movement in a single uniquely shaped lens. SEVFL is expected to be smaller, lighter and less complex than a multiple lens system. Commercial applications may include cameras, robotics or other uses. We have obtained domestic and international patents on this technology. A considerable amount of the research conducted to date on this project was conducted under our supervision at a local university. Due to our funding limitations, we suspended research on this project in 2002; however, we may resume work on this promising technology upon receiving adequate funding. To date, we have not licensed this technology.

Strategic Alliances

CIBA Vision Corp.

In the summer of 2001, CIBA began an extensive period of due diligence on our SSP and concluded that the PSI and the related SSP represented significant market potential.

Negotiations between CIBA and us concluded with a license agreement in March 2002, pursuant to which CIBA had the right to obtain an exclusive worldwide license to market, distribute and sell the PSI, the PresVIEW Incision System and related products developed for the surgery. The CIBA Agreement was subject to a number of terms and conditions, including a requirement for CIBA to purchase equity interests in us. Our products were to be marketed under the PresVIEW trademark.

Under the CIBA Agreement, we were to receive a percentage royalty on CIBA's worldwide sales of the PSI and related products. CIBA had the option to make minimum royalty payments totaling approximately $13.6 million during years two through six of its agreement with us if it wished to maintain its rights to an exclusive license of the PSI, the PresVIEW Incision System and related products. CIBA paid us $2.0 million in advance for future royalties. CIBA also purchased 625,000 shares of our common stock and a warrant to purchase 312,500 shares of our common stock for an aggregate cost of $1.25 million in the first tranche of a March 2003 private placement, and had committed to purchase, subject to the satisfaction of certain conditions precedent, an additional $1.25 million of our common stock and warrants in the second tranche of that private placement. Subject to certain conditions precedent, CIBA was also to purchase an additional $2.5 million of our common stock within 60 days following the enrollment of the first patient in our Phase III FDA clinical trial. Further, CIBA had agreed to pay us additional amounts totaling $4.0 million upon the achievement of certain FDA-related milestones. In addition, CIBA had agreed to assume responsibility for the legal defense of our worldwide PresVIEW patent portfolio against patent infringement, subject to mutual agreement between CIBA and us. CIBA also assumed full responsibility for the manufacturing, distribution and marketing of our products at their expense.

At the time the CIBA Agreement was executed in March 2002, we had invented and produced a prototype of an incision device to simplify the surgical procedure and improve the surgical outcomes. In preparation for future marketing, we and CIBA decided to make further enhancements and improvements to the incision device. CIBA invested a significant amount of time and money in the further development of the device resulting in the PresVIEW Incision System. Late in 2003, a CE Mark certification of the components of the PresVIEW Incision System was obtained by the suppliers of those components.

In August 2003, CIBA announced that it was seeking strategic alternatives for its surgical business unit, including the sale of that unit. CIBA's surgical business unit marketed a variety of ophthalmic products and was primarily responsible for performing the CIBA Agreement. On December 29, 2003, CIBA informed us that it was exiting the surgical business and expected to complete the sale of the surgical business unit's various product lines to a variety of parties by early 2004. In conjunction with that sale, CIBA received an offer from a third-party to purchase CIBA's rights under the CIBA Agreement. Pursuant to the CIBA Agreement, the transfer of the license required our consent. As a condition to the assumption of CIBA's duties associated with that proposed license assignment, the third-party requested the renegotiation of certain key terms of the license agreement. After deliberation, we declined to renegotiate the license and did not permit the assignment of the license to the third-party. As a result, we began negotiations with CIBA for the transfer of CIBA's rights under the CIBA Agreement back to us and the termination of the license.

On January 30, 2004, we entered into the Transfer Agreement. Pursuant to the Transfer Agreement, we reacquired all worldwide license rights to our patents that were granted to CIBA under the CIBA Agreement, and CIBA was released from all future financial commitments, including its obligations associated with manufacturing, marketing, distribution and regulatory matters. Under the Transfer Agreement, CIBA has agreed to provide us with certain transition services during 2004, including efforts to finalize the CE Mark certification of the PSI. The transition services will help in the transfer of manufacturing, distribution and marketing functions to us from CIBA. As consideration for the acquisition of CIBA's license rights, the forgiveness of the $2.0 million in prepaid royalties we received under the CIBA Agreement and the transition services to be performed by CIBA under the Transfer Agreement, we agreed to pay CIBA an aggregate of $3.0 million in twelve quarterly installments commencing in the first calendar quarter of 2006. We, however, are entitled to prepay and extinguish our payment obligations by paying an aggregate amount of $2.0 million to CIBA prior to January 1, 2006.

Under the Transfer Agreement, CIBA has also agreed to return the warrant to purchase 312,500 shares of our common stock that it acquired in the March 2003 private placement. While it will retain the 625,000 shares of common stock acquired at the same time, these shares will be subject to certain restrictions on their transfer.

CIBA's transition services include the continuation of sterilization and packaging processes to result in the delivery to us of all existing PSI inventory. Prior to the CIBA Agreement executed in March 2002, we manufactured a significant quantity of the PSI for future use. We no longer have those manufacturing arrangements in place because CIBA assumed responsibility for manufacturing under the CIBA Agreement. Due to the sufficient PSI inventory, CIBA did not establish an injection molding manufacturing arrangement during the term of the CIBA Agreement. We believe that we will have adequate inventory of the PSI for our expected requirements over the next 12 to 24 months. As a result of the transition of those manufacturing responsibilities to CIBA, the modifications in the packaging of the PSI and the resultant changes to those processes, the CE Mark certification we had obtained in 2000 on the PSI no longer applies.

CIBA has been seeking CE Mark certification of the PSI for its planned marketing efforts in the European Union in early 2004. The CE Mark certification of the PSI is still pending. The Transfer Agreement requires CIBA to continue its efforts to obtain CE Mark certification of the PSI. If CIBA obtains CE Mark certification for the PSI, CIBA and we will enter into a technical agreement, which will allow us to directly sell our products in CIBA packaging during 2004 in the European Union. We cannot be assured, however, that all regulatory requirements will be finalized, and that CIBA can finalize the issuance of the CE Mark certification for our current PSI inventory, since the certification process requires extensive documentation of the manufacturing, packaging and other processes. However, by the end of 2004, we will have to establish our own CE Mark certification on the PSI in order to continue any sales in the European Union. Additionally, we must reestablish an injection molding manufacturing source for additional production of the PSI after existing inventory is exhausted. The PSI is a precisely designed micro-

engineered part that requires special manufacturing expertise, especially to meet the regulatory requirements for use as a medical implant.

We expect that the transition under the Transfer Agreement will result in a significant increase in costs for us related to performing functions that CIBA had assumed under the CIBA Agreement. Conversely, however, we will be entitled to all gross proceeds from the sale of our products instead of a royalty based on a percentage of sales as previously specified in the CIBA Agreement. Even assuming that CIBA obtains the CE Mark certification of the PSI, our ability to directly market our products in the European Union is currently limited. The anticipated date of the initial sale of our products in the European Union is likely to be delayed, and the number of PresVIEW Incision System and PSI units sold is likely to be reduced, in the short term and especially in 2004, relative to the number of unit sales that could have been achieved by CIBA. We may seek to market the PSI and PresVIEW Incision System in the European Union and elsewhere directly or through other distribution, license or strategic arrangements. Therefore, as a result of the increased expenses and potential for delayed revenues, we believe that the Transfer Agreement may have a material adverse impact on our financial condition in the short term. We believe the reacquisition of the license will be in the best long-term interest of our stockholders.

Business Strategy and Intellectual Property

One of our primary strategies has been to develop strong proprietary patents for our products, including the PSI, the PresVIEW Incision System, the MED and the SEVFL. We have 18 issued United States patents and 20 issued or published international patents. We have 14 pending United States patent applications and 56 pending international patent applications. Related only to the PresVIEW technology, we have 11 issued United States patents, 15 issued or published international patents, 9 pending United States patent applications and 51 pending international patent applications. The patents associated with the PresVIEW technology have expiration dates ranging from 2012 to 2020. The patents and patent applications related to our early stage products generally do not expire until after 2015.

We have sought intellectual property rights for the PSI in significant economic markets throughout the world that have a legal system that tends to recognize these rights, and we intend to continue to submit additional patent applications and amendments to maintain and strengthen our patent protection. Our patents protect the PSI, as well as variations of the PSI and the custom hand piece and disposable blade in the PresVIEW Incision System, which are used in the SSP for the treatment of presbyopia, primary open angle glaucoma and ocular hypertension. Due to the nature of the medical discovery, we believe that we have unusually broad patent protection. In 2003, we reduced the number of pending and issued international patents being maintained as a result of a cost-benefit analysis conducted with the assistance of our patent counsel. We also seek to protect our proprietary technology, in part, through confidentiality and nondisclosure agreements with employees, consultants and other parties. In a severance and consulting agreement with Dr. Ronald A. Schachar, our founder and former Chief Scientist, we granted a non-exclusive security interest in our patent rights relating to the ARMD device and the SEVFL as security for the payment of his consulting fees under that agreement.

Competition

We believe that the SSP provides a physiological or natural improvement in the human eye's ability to focus at all near points. Glasses, contact lenses and other optical changes to the eye only compensate for the inability of the older eye to focus. Many people remain dissatisfied with the alternatives discussed below:

- *Glasses.* Presbyopia was initially treated with near vision optical aids using magnifying lenses, reading glasses, and monocles. Patients are constantly removing reading glasses and losing them because the reading glasses interfere with vision at all other distances. In the 1700's, Benjamin Franklin fused the distance lens with the near reading lens to give us bifocals that were later modified to trifocals. The problem with these reading aids is that they only allow sharp near vision at a given distance and the near visual field is limited by the lens. Patients must learn to rotate their eyes downward when reading with bifocals instead of rotating their head. It usually takes weeks for patients to get used to wearing bifocals and most patients remain dissatisfied. Trifocals can be even more of a problem for many patients. Trifocals are needed as the advancement of presbyopia in patients in their 50s also necessitates correction at intermediate distances.

Trifocals take even more time to get used to and still do not provide dynamic clear vision for most distances.

- *Multifocal Glasses.* Multifocal lenses produce multiple images at various focal points. Light reflected or emitted by an object must be dispersed by the multifocal lens over all the focal points. This scattering of the light rays entering the eye causes an increase in the number of images hitting the retina. Therefore, the intensity at any given focal point is reduced and the contrast sensitivity diminished. In order to reduce these prismatic effects, the visual field of a multifocal lens is reduced. The patient must learn to select the appropriate image of the several images produced by the lens. Additionally, to avoid image distortion, patients need to look only through the center of the lens reading corridor, which is only a few millimeters in width in many multifocal designs. This requires the patient to learn to move their head instead of their eyes when reading.

- *Bifocal and Multifocal Contact Lenses.* In order to avoid the problems of external bifocal and trifocal glasses, bifocal contact lenses have been developed. Bifocal contact lenses have generally been unsuccessful because the distance and near power of the contact lens must be crowded into an area that can barely cover the pupil. The bifocal must be fit so that the lens translates up to allow the patient to look through the near portion of the contact lens (the bottom of the contact lens) when the patient shifts their gaze down. These lenses are very difficult to fit. Multifocal contact lenses are also available but have the same significant drawbacks as multifocal glasses. An alternate treatment to bifocal or multifocal contact lenses for presbyopia is to wear contact lenses in monovision, i.e., with one lens in one eye for near vision, and one lens in the other eye for distance vision. Monovision can compromise depth perception, as the brain needs both eyes for optimal stereo vision. After 30 years of contact lens usage, we believe that contact lenses remain largely ineffective in addressing presbyopia.

- *Laser Surgery Alternatives.* Some researchers have developed plans for the use of laser refractive surgery to create a bifocal or multifocal cornea. In other words, the laser technique is intended to shape the cornea in the same manner as a multifocal contact lens. This alternative has essentially the same limitations and problems as multifocal glasses and contact lenses. The patient will see multiple images of reduced light intensity, i.e., with decreased contrast sensitivity. This approach would be an irreversible surgical treatment.

- *Monovision.* The use of monovision, or correction of one eye for near vision and correction of the second eye for distance vision, can provide functional vision for some presbyopes. Monovision relies on the brain's ability to recognize the more appropriate image; although, it is important to note that not every patient is able to adjust adequately. Monovision can be achieved through contact lenses and LASIK. While many patients are satisfied with this method, the drawbacks of monovision include reduced night vision, difficulty driving in some cases, a significant decrease in depth perception and less than optimal vision at both near and far distances.

- *Conductive Keratoplasty, or CK.* CK uses a controlled release of radio frequency energy to shrink corneal tissue, which steepens the cornea, reducing farsightedness. CK is not reversible, but does regress over time. CK has been used primarily for the treatment of farsightedness to restore normal distance vision. In March 2004, the FDA approved the use of CK for the treatment of presbyopia. However, reading vision would be improved only if one eye is overcorrected to become near-sighted and, thus, the patient would have monovision.

- *Multifocal IOLs.* During 1997, Allergan received FDA approval for its *Array*™ multifocal intraocular lens ("IOL"), the first multifocal lens indicated for cataract replacement. An IOL is a plastic lens placed inside the eye as a replacement of the natural human lens. As a result of cataract patient satisfaction with the Array lens, some market observers have suggested that non-cataract presbyopes could undergo the procedure (off-label) to help provide some near vision. The implant of an IOL in a patient without cataracts is a procedure called a clear lensectomy. All multifocal IOL designs reduce contrast sensitivity, cause some halo symptoms at night and mildly distort color vision. Some reports have indicated that these patients experience a higher incidence of retinal detachments, which raises ethical concerns surrounding the removal of a healthy lens. An article in the January 2004 issue of *Review of Ophthalmology* reported that, among a sur-

vey of 750 cataract surgeons, 84% of respondents indicated that they do not use multifocal IOLs and two-thirds indicated that they are not interested in using them in the next two years. The reasons cited by the surgeons for their low interest in multifocal IOLs included, among other reasons: constant blur from slight malpositioning, poor optics and decreased contrast sensitivity and visual acuity.

- *Accommodating IOLs.* A handful of companies, including eyeonics, Inc., are investigating the use of an accommodating IOL, which attempts to magnify the accommodative ability of the eye through the use of hinges on either side of the IOL. Eyeonics' *Crystalens*™ IOL was approved by the FDA in late 2003 for use only with cataract patients. Eyeonics believes that changes in vitreous pressure associated with accommodative effort moves the lens forward and backward, effectively providing some limited ability to focus. Surgeons are now considering the use of a modified version of monovision with these lenses to overcome the limited accommodative ability found with this lens system. In the FDA approval, it stated that the Crystalens provides approximately one diopter of monocular accommodation. It is generally recognized that a minimum of 2.5 to 3.0 dioptors of accommodation improvement are required before a patient can become independent of reading glasses for most near reading activities. Problems with the accommodating IOL, as reported in the approved Crystalens "Summary of Safety and Effectiveness Data", include postoperative capsular fibrosis of the lens capsule, or cystoid macular edema, and iritis, a persistent inflammation of the iris, which may limit or retard adoption among cataract patients. The eye care community also has significant ethical and medical issues regarding the removal of healthy or pre-cataract lenses for such purposes. The risks associated with clear lens extraction to treat presbyopia in patients who do not have a cataract and the lack of reversibility and the limited gain in accommodative amplitude mitigate against accommodating IOLs offering any significant competition to the SSP.

- *Anterior Ciliary Sclerotomy (ACS).* ACS is a procedure whereby eight incisions are made in the sclera either with a diamond blade or with a laser, allowing it to expand due to intraocular pressure and ideally produce an accommodative effect. Results are generally limited to less than 1.50 diopters of gain in accommodation, and any benefit appears to be negligible after approximately one year as a result of the healing ability of the sclera. We own issued patents that we believe include this technology; however, due to the limited accommodation achieved with this technique, we do not believe it represents significant competition to the SSP. SurgiLight, Inc ("SurgiLight") has announced that it is developing laser systems for the treatment of presbyopia. Generally, SurgiLight intends to use a laser to perform the ACS procedure, which weakens the sclera. We believe that this procedure structurally weakens the globe of the eye, subjecting it to risk of rupture via a severe blow to the eye or head. We believe that, while SurgiLight's approach is based on our scientific theory, the use of a laser to weaken the sclera will provide only a modest benefit, which will regress with healing. In March 2000, we filed a patent infringement suit against SurgiLight (see "*Item 3. Legal Proceedings*").

Glaucoma medications remain the predominant "standard of care" in many countries, including the United States, for the treatment of primary open angle glaucoma and ocular hypertension. While no glaucoma medication can cure or restore vision loss due to glaucoma, most of these medications are generally effective in the temporary reduction of intraocular pressure ("IOP"). It is generally believed that the primary cause of these conditions is elevated IOP over time. Glaucoma medications are believed to help maintain a patient's current vision by avoiding or reducing the likelihood of additional vision loss due to high IOP. Merck's *Timoptic*, Alcon Laboratories' *Betoptic*, Allergan's *Betagan* and Pharmacia's *Xalatan* are four of the leading glaucoma medications worldwide. While generally effective, selection of a patient drug regimen and therapy remains highly individualized and based on a number of factors such as:

- efficacy,
- ocular or systemic safety and tolerance,
- availability in health plans,
- cost, and
- side effects.

Many of these medications have to be taken several times each day on a strict schedule for the rest of the patient's life, are not continuous in their action and are not fully effective due to the patient's lack of compliance with proper use of the medication. In a study conducted in 2002, approximately 21% of once daily users of a particular

glaucoma medication did not refill their subscription after one year. In another study, approximately 12% of glaucoma patients on once or twice daily medication regimes reported missing a significant number of doses of their medication and 15% did not properly administer their medication.

Glaucoma medications represent approximately 40% of all ophthalmic medications and 16% of all ophthalmology revenues worldwide, according to a recent study by SG Cowen. As such, they represent the single largest competition to SSP for the treatment of ocular hypertension and primary open angle glaucoma. However, we believe that the SSP will prove to have several significant advantages over glaucoma medications:

- maintenance of lower IOP versus the temporary reduction from medications,
- a one-time surgery as compared to a lifetime of daily drug use,
- less expensive over time,
- fewer side effects,
- no daily drug compliance issues,
- avoidance of drug effectiveness/intolerance issues, and
- at the same time, a reduction or elimination of presbyopia along with IOP reduction.

While a variety of surgical techniques and medical devices exist for the treatment of ocular hypertension and primary open angle glaucoma, we believe that none of these surgical treatments work in the same manner as the SSP and do not offer stable, continuous therapy with the added benefit of an improvement in near vision:

- *Argon Laser Trabeculoplasty (ALT)* is the most common procedure for glaucoma and involves using a laser to increase the drainage of aqueous through the trabecular meshwork. However, the IOP lowering effect is not lasting and, thus, requires multiple treatments. A new procedure similar to ALT is selective laser trabeculoplasty, which may hold more promise than ALT but actually requires more treatments than ALT.

- *Trabeculectomy or filtering surgery* is the most common surgical procedure performed for uncontrolled glaucoma. It essentially involves making a drainage hole in the eye. The procedure has significant potential adverse reactions with a relatively high failure rate.

- *Glaucoma valves* involve making a drainage site in the eye whose rate of outflow is controlled by a valve. This procedure is usually only performed for very severe cases of glaucoma and where trabeculectomy has failed. Glaucoma valves have high failure rates and can cause significant adverse reactions. A newer drainage valve, the Optonol, consists of a miniature stainless steel pipe to drain fluid from the eye. This device is used for uncontrolled glaucoma. Since it is new to the market, the long-term failure rates and potential complications are unknown.

Manufacturing

CIBA had sole responsibility for manufacturing our products and the selection of manufacturing contractors subsequent to the March 2002 CIBA Agreement and until the January 2004 Transfer Agreement. Historically, the PSI had been manufactured to our specifications by an independent contractor using a standard injection molding process. The customized surgical instruments and other equipment previously sold by us were manufactured by independent contractors that specialize in the production of these types of instruments and equipment. As a result of the Transfer Agreement, we will have to reestablish our own manufacturing capabilities. However, we believe we have sufficient quantities of PSIs on hand to meet expected demand for the next 12 to 24 months.

Government Regulation

Our primary products are subject to regulation by governmental authorities in the United States and most other countries. The PSI received European Union CE Mark certification, which was issued to us, and other regulatory approvals were subsequently obtained in a variety of countries around the world. As contemplated by the CIBA Agreement, CIBA assumed responsibility for manufacturing and marketing the PSI. As a result of the transition of

our manufacturing responsibilities to CIBA, the modifications in the packaging of the PSI and the resultant changes to those processes, the CE Mark certification we had obtained in 2000 on the PSI no long applies.

Under the Transfer Agreement, CIBA will provide certain transition support until December 31, 2004, including continuing assistance to obtain CE Mark certification of the PSI for sale in the European Union. If CIBA obtains CE Mark certification, CIBA and we will enter into a technical agreement, which will permit us to directly sell our products in CIBA packaging during 2004 in the European Union. However, by the end of 2004, we will have to establish our own CE Mark certification on the PSI in order to continue any sales in the European Union.

United States

The PSI and the PresVIEW Incision System are not currently approved for sale in the U.S.

In the United States, medical devices are subject to regulation by the FDA under the Food, Drug, and Cosmetic Act (the "FD&C Act"). The FDA regulates, among other things, the manufacture, distribution, study, and marketing of medical devices sold in the United States. Under the FD&C Act, the FDA classifies medical devices into one of several classes depending on the risks that the FDA believes are associated with the device and the types of controls necessary to assure safety and effectiveness. The PSI is a Class III device and subject to the FDA's most rigorous review. The hand piece, as well as the blade, that are part of the PresVIEW Incision System are also subject to the same review as part of the FDA approval process.

Before the PSI can be sold in the United States, FDA approval must be obtained through a Pre-Market Approval ("PMA") application. A PMA must be supported by extensive data, including preclinical and clinical trial data, that demonstrates the safety and effectiveness of the device. Among other requirements, we or our contractors are required to manufacture and test our products in accordance with Good Manufacturing Practices as specified in the regulations for such devices. Both the manufacturer's facilities and the facilities used for packaging and testing of the PSI will be subject to periodic inspections by the FDA.

Prior to conducting the clinical trials in the United States, we were required to apply to the FDA for an Investigational Device Exemption ("IDE"). The IDE application must include, among other things, a complete report of prior investigations, copies of all labeling, copies of all forms and informational materials used as a basis for obtaining informed consent, a description of the methods of manufacture, and a detailed description of the proposed clinical trial, including by way of example, the protocol, a risk analysis, monitoring procedures and sites where the device will be tested.

We received approval from the FDA in 2000 to conduct feasibility clinical trials of the PSI in the United States for the treatment of presbyopia. The feasibility clinical trials were conducted at the Barnes-Jewish Hospital at Washington University School of Medicine in St. Louis, Missouri, the Dean A. McGee Eye Institute at the University of Oklahoma in Oklahoma City, Oklahoma, the New York Eye and Ear Infirmary in New York City, New York, the Jules Stein Eye Institute at UCLA in Los Angeles, California, the Stanford University School of Medicine in Stanford, California and the Storm Eye Institute at the Medical University of South Carolina in Charleston, South Carolina.

The Phase I clinical surgeries were performed during 2000 on 29 eyes at these six sites. We believe that the results continue to demonstrate the safety of the SSP, since no significant complications were observed at any of the six clinical sites. Patient data from three of the sites generally demonstrated a good effect in improving near vision, while patient data from the other three sites generally demonstrated much less of an effect or no effect. The Phase I surgical protocol required the surgeons to make the incisions to create the scleral pockets using manual diamond blades. The surgeons also attempted to place the incision at a predetermined standard distance behind the limbus (the line between the colored cornea and the white of the eye). While skilled surgeons were selected to perform the clinical trials, subsequent observation determined that the location of the implant on the sclera and the depth of the scleral pockets varied from patient to patient. Early during the study, we determined that a more consistent means of making the scleral incision would be required to provide consistently good surgical results. As discussed, we have developed an automated incision device, the PresVIEW Incision System, which more consistently determines the placement of the implant and automatically makes an incision of the correct depth in the sclera.

Of the 29 patients, 14 patients had an increase in accommodative amplitude of 1.5 diopters or more with a mean increase for these patients of more than 3.0 diopters. These results include 24 month data for most of the 14 patients, but a minimum of 12 month follow-up on all 14 patients. The remaining 15 patients had a lesser effect or no effect. The range of accommodative improvement for the 14 successful patients was from 1.5 to 5.0 diopters. A diopter is a measurement of the ability of the eye to accommodate or focus on close objects. Generally, for a patient with normal distance vision, a 1.5 diopter increase in the amplitude of accommodation will allow the patient to comfortably read newspaper size print in good light. An increase of more than 1.5 diopters will increase the patient's comfort, and a higher increase in diopters of accommodation will allow the patient to read progressively smaller print in less than ideal lighting conditions. Published investigational studies of "accommodating intraocular lenses" have generally reported improvements in accommodation limited to about 1.5 diopters. We believe that the 14 successful cases demonstrate the potential for our surgical treatment. The next phase of the FDA clinical trials will include the use of the PresVIEW Incision System to try to improve the outcomes of the SSP.

The second-year annual IDE progress report relaying the 18-month patient results from the feasibility phase was submitted to the FDA in March 2002. Modifications to the Phase II clinical trial protocol and indications for use were proposed to the FDA in July 2002. An IDE application was submitted to the FDA in March 2003 followed by amendments later in 2003. The IDE protocol changes incorporated requests for a Phase II clinical study population of 150 patients with a two-year follow-up period. In December 2003, the FDA approved the start of Phase II clinical trials conditioned on the submittal of certain final documentation. In this prospective, multi-center, randomized study, 100 patients will receive the SSP with the PSI and 50 patients will be designated as control patients. Phase II clinical trials began in the first quarter of 2004. The initial clinical data from the trials is expected to be submitted to the FDA within three to six months after commencement. Upon submission of the initial Phase II data to the FDA, and assuming successful outcomes, we anticipate that we will request FDA approval to start Phase III of the trials, resulting in a total of 330 eyes in the study. Depending on the timing of the Phase II surgeries and the surgical results, the Phase III trial could begin in late 2004 and would run concurrent with the initial stage of 150 patients.

The Phase III clinical results would be submitted to the FDA as soon as all patients in the trial reach the one-year point. At this point, it is anticipated that we will also have two-year follow-up results from our Phase II clinical trial. All patients would continue to be followed for a required two-year period. After submission of the final PMA, including the clinical results, the FDA generally takes one year or longer to review and approve a Class III device for sale in the United States. For equivalent medical devices, the clinical and regulatory process to FDA approval and commercialization can take three to five years from the initiation of Phase II clinical trials.

We will also be required to submit an IDE, conduct separate clinical trials and submit a final PMA to obtain approval of the PSI for the treatment of ocular hypertension and primary open angle glaucoma. If adequate funding is available, we will submit an IDE to the FDA during 2004 requesting approval to begin a clinical trial of the SSP for the treatment of primary open angle glaucoma and ocular hypertension.

Europe

The regulatory environment in Europe for medical devices differs significantly from that in the United States. A total of 15 European countries are grouped in a union with the objective of establishing a single market without internal borders among the member countries and eliminating divergent national requirements. The members of the European Union (the "EU") include Austria, Belgium, Denmark, Finland, France, Germany, Greece, Ireland, Italy, Luxembourg, The Netherlands, Portugal, Spain, Sweden, and the United Kingdom. In May 2004, Cyprus, the Czech Republic, Estonia, Hungary, Latvia, Lithuania, Malta, Poland, Slovakia and Slovenia will join the current 15 members. Iceland, Liechtenstein, Norway and Switzerland are members of the European Free Trade Association. Iceland, Norway and Liechtenstein are also members of the European Economic Area.

Products that comply with the requirements of a specified EU medical directive are entitled to bear the CE Mark. All commercial medical device products are required to bear CE Mark certification. It is illegal to market these products in the EU without CE Mark certification. To obtain a CE Mark, the product must be assessed and found to conform to the applicable directive. This assessment is carried out by the manufacturer, in most cases with the assistance of a third-party certification organization known as a "notified body." The notified body assessment may consist of an audit of the manufacturer's quality system or specific testing of the product. A manufacturer can sell a product throughout the EU once it secures an assessment by a notified body in one of the EU countries.

The EU has adopted several directives to regulate medical devices such as the PSI. A manufacturer may affix the CE Mark after a determination that the product complies with the essential requirements of the applicable directives and completion of the appropriate conformity assessment procedures as specified by the directives. The conformity assessment requirements are based upon a given product's classification within the directive. Products within the scope of the directive are grouped within four classes: Class I, IIA, IIB and III. A product with a higher classification is considered to have higher risk and will, therefore, be subject to more controls in order to obtain the CE Mark. The PSI has been designated as a Class III device.

Essential requirements under the directives for the most stringent device, the Class III PSI, include substantiating that the device meets the manufacturer's performance claims and that any undesirable side effects of the device constitute an acceptable medical risk when weighed against the intended benefits of the device. Certification under the ISO 9000 series of standards for quality assurance and manufacturing processes is one of the CE Mark requirements.

There are two basic options for assessing conformity of devices designated as Class III. The first option allows a manufacturer to seek a decision from the notified body that the processes employed in the design and manufacture of a device qualify as a full quality system. Alternatively, manufacturers can seek product certification based on various control schemes. The full quality system encompasses the organizational structure, responsibilities, procedures, processes and resources necessary to assure quality assurance in design, development, production, installation and servicing of its medical devices. Once a manufacturer has satisfactorily completed the regulatory compliance tasks required by the directive and received a favorable decision from the notified body, it may affix the CE Mark to its product.

Manufacturers are required to report serious adverse incidents concerning CE Marked devices to the authorities of the countries where the incidents take place. If such incidents occur, the manufacturer may have to take remedial action, perhaps even withdrawal of the product from the European market.

Our EU distributor obtained "Own Brander" CE Mark certification for the PSI in November 1997. This certification involved a limited amount of clinical testing and review of the distributor's quality system. The significance of the Own Brander CE Mark is that the EU distributor is responsible for certain quality control issues and record keeping. For regulatory purposes, the product is considered to "originate" from the EU distributor, and we, in the United States, served as a manufacturing subcontractor.

We were awarded ISO 9001 and E46001 certification and our own CE Mark certification for the PSI in January 2000. We obtained qualification of our processes as a full quality system. During 2001, we formed a wholly-owned subsidiary, Presby Corp – Europe SPRL, organized under the laws of Belgium. The purpose of Presby Corp – Europe SPRL was to obtain and maintain "Own Brander" CE Mark certification on our products. Presby Corp - Europe SPRL was awarded the Own Brander CE Mark certification for the PSI in 2001. Presby Corp - Europe SPRL was awarded CE Mark certification for an early prototype of the PresVIEW Incision System and the disposable blades in 2002. We sold our products in the EU from late 1997, based on the EU distributor's CE Mark certification, until termination of the distributor agreement in late 2000. Product sales in 2000 and 2001 were based on our own certifications. We ceased direct sales of our products in 2001. As a result of the transition of those manufacturing responsibilities to CIBA, the modifications in the packaging of the PSI and the resultant changes to those processes, the CE Mark certification we obtained on the PSI no longer applies.

CIBA has been seeking CE Mark certification of the PSI for planned marketing in the EU by CIBA in early 2004. The CE Mark certification of the PSI is still pending. The Transfer Agreement includes CIBA's continuing efforts to obtain CE Mark certification of the PSI, and if obtained, CIBA and we will enter into a technical agreement whereby we can directly sell our products in CIBA packaging during 2004 in the EU. We cannot be assured that all regulatory requirements will be finalized and that CIBA can finalize issuance of the CE Mark certification for our current PSI inventory since the certification process requires extensive documentation of the manufacturing, packaging and other processes.

The PresVIEW Incision System is comprised of several components, which include the custom designed snap-on drive unit and disposable blade that are covered by patents held by us. The remaining components of the Pres-

VIEW Incision System include a power box, cable, hand held base drive assembly and footplate. In late 2003, the manufacturers of these components received CE Mark certification for ophthalmic applications.

Canada

The PSI is not currently approved for sale in Canada by Health Canada, the applicable Canadian regulatory agency. Clinical trials of the PSI for the treatment of ocular hypertension and/or primary open angle glaucoma have been conducted at one Canadian facility. The study of 27 patients was conducted by Aaron Rifkind, M.D., Associate Clinical Professor of Ophthalmology at McMaster University in Hamilton, Ontario. The study indication was "the reduction of IOP in patients with ocular hypertension and primary open angle glaucoma." The summary two-year results were presented at the April 2003 meeting of the American Society of Cataract and Refractive Surgery in San Francisco, California.

All 27 patients were receiving one or more glaucoma medications prior to entering into the study and at the time the pre-surgery IOP was measured. All patients completed a three-week wash-out period of glaucoma medication to establish an unmedicated baseline IOP for the study. The SSP was then performed on 27 dominant eyes. At six months post-operative, 16 subjects elected to have the SSP performed on their non-dominant eye as permitted by the protocol. After the SSP, if the IOP was greater than 25 mmHg, or there appeared to be a change in the optic nerve, the eye was treated with glaucoma medication.

At the 18-month follow-up exam, the study data indicated a mean IOP decrease of 6.8 mmHg. overall in the dominant eyes, which was 0.4 mmHg. lower than the pre-surgery IOP values. The number of glaucoma medications decreased from a mean of 1.7 to 0.7 medications per eye. In the two-year follow-up exam, data was available for 23 dominant eyes, which had a mean IOP decrease of 7.1 mmHg overall, which was 0.7 mmHg lower than the pre-surgery mean IOP value. At the two-year point, 56% of the study patients were receiving no glaucoma medication. Of the 44% of the patients receiving medication, either for the non-operated eye or both eyes, a large majority were receiving substantially less medication than prior to the study. Near vision was also evaluated in those patients and it was found that there was an overall improvement in the patients' near visual acuity at 20 centimeters. There were no significant surgical complications.

In November 2002, CIBA and we submitted to Health Canada an application for approval to commercialize the PSI in surgery for the treatment of ocular hypertension, primary open angle glaucoma and presbyopia applications. On June 13, 2003, Health Canada informed us that it had determined that the sample size submitted in our Class III submittal for the surgical treatment of glaucoma and other ocular disorders was insufficient for approval, and denied the application. Based on further discussions with Health Canada in October 2003, we will need to perform further clinical trials at more sites and with significantly more patients in order to receive approval for commercial sales. We are uncertain, at this time, as to when we may receive Health Canada's approval, but we believe it will not be until at least 2005 before results of these additional clinical trials can be resubmitted. Our immediate focus, however, is currently on the FDA clinical trials and not those in Canada.

Research and Development

Research and development expenditures were approximately $109,000, $167,000 and $339,000 during the years ended December 31, 2003, 2002 and 2001, respectively. The expenditures for all three years were related primarily to the development of the PresVIEW Incision System. These expenditures for the PresVIEW Incision System will decrease in the future as development of the system has been completed, subject to modifications or improvements that might be made based on feedback from the use of the system in the FDA clinical trials.

Additional expenditures for research on a treatment for ARMD will be conducted by us primarily on a consulting basis, and expenditures for this research are not expected to be significant in the near term. We will also need to expend additional amounts for research to develop the SEVFL. We believe that these research and development costs will be very limited until we have adequate cash flow or other significant funding is obtained. Therefore, we believe that our research and development activities will not result in a new revenue source in the near future.

Other Material Agreements

Dr. Schachar's Separation and Consulting Agreement

On February 25, 2003, Dr. Ronald A. Schachar, our founder and former Chief Scientist, and we entered into a Severance, Release and Consulting Agreement (the "Consulting Agreement"). In accordance with the Consulting Agreement, Dr. Schachar resigned as an officer, director and employee of us at the Merger Closing Date. We agreed to retain Dr. Schachar as a consultant for a period of up to five years, and he agreed not to compete with us during that time. Dr. Schachar will assist us in conducting research and development on our products for the treatment of ARMD for the initial two years of the Consulting Agreement and will assist in the maintenance of our patent portfolio and other matters for the entire term of the Consulting Agreement.

Subject to certain conditions, Dr. Schachar will be paid $1,750,000 over the consulting period, of which $950,000 will be paid in the first two years. The timing of the remaining $800,000 due in years three through five is partially dependent on our profitability in those years; however, Dr. Schachar is guaranteed to receive a minimum of $250,000, but not more than $400,000, for each of the third and fourth years, with the remainder, if any, to be paid in the fifth year.

As security for the payment of his consulting fees, we granted Dr. Schachar a non-exclusive security interest in our patent rights relating to the ARMD device and the SEVFL. Dr. Schachar also received an assignment of our patents for the ARMD device outside the United States, which is revocable under certain conditions.

Verus Support Services Inc.

On March 3, 2003, we entered into an agreement with Verus Support Services Inc. ("Verus"), which was an advisor of ours involved in the March 6, 2003 private placement. Pursuant to this agreement, Verus was to provide strategic advisory services to us for a period of one year for a monthly fee of $15,000. In conjunction with Merger Agreement, Verus agreed that in the event that we did not successfully raise at least $1.0 million of additional capital within six months of March 6, 2003, upon terms that were at least as favorable as the March 2003 private placement, that they would subscribe for and purchase, or cause to be subscribed for and purchased, that number of units at a price of $2.00 per unit in order to satisfy the deficiency between the amount of additional capital we successfully raised and $1.0 million. Each unit purchased by Verus upon the occurrence of this event would consist of a share of common stock and a detachable warrant to purchase one-half of a share of our common stock at an exercise price of $2.50 per share that expires three years from the date of issuance. In light of events since March 2003, we reached agreements with Verus to allow the deferral of the $1.0 million contingent investment until January 6, 2004, in return for their forgiveness of $60,000 in advisory fees for the same period.

In January 2004, a dispute arose as to the continuing obligation of Verus under this agreement. As a means of deferring and ultimately resolving this dispute, we entered into an amendment to our agreement to further extend to June 30, 2004, Verus' obligation to raise up to $1.0 million. Verus has advised us that its ability to provide the original subscription amount at a stock price well above current market is limited, and it indicated that current market conditions should be considered. Therefore, we have agreed to amend the funding obligation to permit Verus to reduce its funding obligation by:

- the surrender and cancellation of shares of our common stock and warrants to purchase shares of our common that were issued to Verus or its affiliates, assigns or designees, or investors in the March 2003 private placement, based on the current market price of our common stock,
- the waiver of the remaining $20,000 in advisory fees due to it under its existing agreement,
- the waiver of up to $60,000 in advisory fees that might become due to it during the extension period, and
- an amount of $25,000 that was received from an investor in a December 2003 private placement, since that investor was introduced to us by Verus.

Further, after the credit of these amounts to the funding obligation, Verus has agreed to subscribe for and purchase, or cause to be subscribed for and purchased, an amount that will raise, at prevailing market prices, an amount equal to 1.25 times the remaining funding obligation. We believe that this agreement is in our best interest and may result

in funding during this extension period; however, we cannot be assured that Verus will not continue to dispute this obligation.

Kingsdale Capital Corp.

On March 4, 2003, we entered into an agreement with Kingsdale Capital Corp ("Kingsdale") which was an advisor of ours involved in both a March 2003 and a December 2003 private placement. Pursuant to this agreement, Kingsdale was to provide strategic advisory services to us in Canada for a period of one year for a monthly fee of $15,000. Kingsdale has agreed to allow us to defer the payment of its fees for services rendered since August 2003.

Employees

We currently have four employees, including one person who oversees our FDA clinical trials and three persons who perform executive and administrative functions. We are not a party to any collective bargaining agreement with a labor union, and we consider relations with our employees to be good.

CAUTIONARY STATEMENTS

If any of the following material risks occur, our business, financial condition and/or results of operations would likely suffer.

Risks Related to Our Business and Industry

As a result of the CIBA Transfer Agreement, we must reestablish our own marketing and other operational functions, which will substantially increase our costs and potentially cause delays. In March 2002, CIBA and we entered into the CIBA Agreement pursuant to which we granted CIBA, among other things, the right to use our patent rights and other intellectual property rights in connection with the manufacture, marketing and sale of ophthalmic medical devices used in the treatment of presbyopia, ocular hypertension and primary open angle glaucoma. In January 2004, CIBA and we terminated the CIBA Agreement and CIBA transferred all of its rights under that agreement back to us. Prior to the termination of the CIBA Agreement, we were dependent on CIBA for the commercialization of our products, part of our future capital needs and other license obligations. As a result of the Transfer Agreement, we now need to reestablish our own manufacturing, marketing, distribution, regulatory, and other operational activities. We may determine that we prefer to establish strategic agreements with various third parties for some operations and perform other of these operations internally. We can provide no assurances, however, that we will be able to establish agreements with third parties or successfully perform the transition of such operations within a reasonable time. Nor can we be sure of our ability to finance such operations. Consequently, our business, financial condition and results of operations may be adversely affected.

As a result of the Transfer Agreement, we will assume full management responsibility for the FDA clinical trials, and we have less experience and resources in those matters than CIBA, which could result in delays or problems. Prior to the CIBA Agreement executed in March 2002, we managed the feasibility phase of the FDA clinical trials in the United States. That phase of the clinical trials required a much longer period of time than we had anticipated. Under the CIBA Agreement, a joint technical committee of CIBA and our personnel would have managed the FDA clinical trials going forward. CIBA retained a qualified consultant to assist in those matters. As a result of the Transfer Agreement, we have again assumed full responsibility for the FDA clinical trials and have already retained the same consultant that was retained by CIBA. However, our management personnel have significantly less experience in the management of FDA matters than CIBA. We can provide no assurances that we can successfully assume the management of the FDA clinical trials without incurring significant delays or substantial additional expense.

The Transfer Agreement provides that CIBA will continue its efforts to obtain CE Mark certification on the PSI inventory, but if that certification is not issued, European Union sales will be delayed. CIBA has been seeking CE Mark certification of the PSI for its planned marketing efforts in the European Union in early 2004. The

CE Mark certification of the PSI is still pending. The Transfer Agreement requires CIBA to continue its efforts to obtain CE Mark certification of the PSI. If the CE Mark certification for the PSI is obtained, CIBA and we will enter into a technical agreement, which will allow us to directly sell our products in CIBA packaging during 2004 in the European Union. We cannot assure you, however, that all regulatory requirements will be finalized and that CIBA can finalize the issuance of the CE Mark certification for our current PSI inventory. The certification process requires extensive documentation of the manufacturing, packaging, and other processes. If we are unable to provide all of the documentation required in order to meet the regulatory requirements, if such documentation requires substantial expenditures by us, or if such documentation results in significant delays, CIBA may be unable to obtain the CE Mark certification in order for us to market the PSI during 2004 in the European Union.

As a result of the Transfer Agreement, we will need to reestablish our own international regulatory processes, which will require management time and significant expense. Prior to the CIBA Agreement executed in March 2002, we obtained CE Mark certification of the PSI, which permits sales of the device in the European Union and certain other international locations. Under the CIBA Agreement, CIBA was responsible for regulatory matters outside the United States. In accordance with the CIBA Agreement, we ceased all direct manufacturing and marketing of the PSI and related products. As a result of the transition of those manufacturing responsibilities to CIBA, the modifications in the packaging of the PSI and the resultant changes to those processes, the CE Mark certification we had obtained in 2000 on the PSI is no longer applicable. As a result of the Transfer Agreement, we will need to reestablish our own CE Mark certification on the PSI. In addition, we will be required to manage the process of obtaining regulatory approval for our products in other international markets. We have retained consultants to assist us in that effort; however, this process is time consuming, requires considerable management effort and will be expensive. Our failure to reestablish our own CE Mark certification for the PSI would prevent us from marketing our products in the European Union after December 31, 2004. Further, failure to establish regulatory approvals in other international markets on a timely basis will have a material adverse effect on our financial condition as well.

As a result of the Transfer Agreement, we will need to reestablish manufacturing arrangements for the production of the PSI to support future sales, or we will be unable to supply the PSI after our current inventory is exhausted. Prior to the CIBA Agreement, we manufactured a significant quantity of the PSI for future use. We no longer have those manufacturing arrangements in place because CIBA assumed responsibility for manufacturing under the CIBA Agreement. Due to the sufficiency of the available PSI inventory, CIBA did not establish an injection molding manufacturing arrangement during the term of the CIBA Agreement. We believe that we have adequate inventory of the PSI for our expected requirements over the next 12 to 24 months. Consequently, we must reestablish an injection molding manufacturing source for production of the PSI before our current inventory is exhausted. The PSI is a precisely designed micro-engineered part that requires special manufacturing expertise, especially to meet the regulatory requirements for use as a medical implant. The process of establishing manufacturing sources will be time consuming, require considerable management effort and will be expensive. In addition, the costs of producing the associated injection molds may be high. There can be no assurances, however, that we will be able to reestablish these arrangements in a timely and cost-effective manner prior to our need for additional PSI inventory. An inability to establish these arrangements could have a material adverse effect on our future sales.

As a result of the Transfer Agreement, we will need to reestablish our own marketing and distribution arrangements, which will take time and increase our costs. Prior to the CIBA Agreement, we marketed our products through distribution agreements in various countries outside the United States. Those distribution agreements provided the distributor with a commission based upon a percentage of the sales price. Under the CIBA Agreement, CIBA was responsible for worldwide marketing and distribution of our products and, thus, all of our previous distribution arrangements were terminated. As a result of the Transfer Agreement, we will be required to reestablish distribution agreements for the international marketing and distribution of our products. We may, however, seek to market our products directly, especially in the European Union, during 2004. We may also establish other distribution, license or strategic arrangements on a global or regional basis. We can provide no assurances, however, that we will be able to reestablish new distribution and marketing arrangements in a timely and cost effective manner, and our failure to do so would have a material adverse effect on our business.

As a result of the Transfer Agreement, we may need to reestablish our own product development efforts, which will take time and increase our costs. During the term of the CIBA Agreement, CIBA devoted substantial internal resources and manpower, including hiring several consultants, to resolve problems with, and substantially finalize the development of, the PresVIEW Incision System. Although we believe development of the PresVIEW

Incision System is complete, additional development or enhancements may be identified as the PresVIEW Incision System is further used in the SSP. We are in the process of retaining several of the consultants used by CIBA to finalize the development of the system, but have not completed all of those arrangements. If significant development issues are later identified that require material financial resources, or if the consultants are not available to us on terms acceptable to us, or at all, to resolve any issues, it would have a material adverse effect on our business.

If we do not receive and maintain regulatory approvals for our products, we will not be able to market and sell our products. We cannot market and sell our products or surgical procedure in the United States until the products receive approval from the FDA, and there can be no assurance that we will receive the necessary approvals. Before receiving FDA clearance to market and sell a product, we must demonstrate that the product is safe and effective in the patient population that will be treated for specific indications. Negative or inconclusive results or adverse medical events during a clinical trial could cause a clinical trial to be repeated, a program to be terminated or delays in receiving approval. We have limited experience in conducting or managing the clinical trials necessary to obtain regulatory approval. Instead, we rely on third-party clinical investigators to conduct our clinical trials and other third-party organizations to perform certain other tasks. As a result, we may face additional delaying factors outside our control. In addition, delays or rejections may be encountered based upon additional governmental regulation from future legislation, administrative action or changes in FDA policies or interpretations during the period of product development, clinical trials or FDA regulatory review. Therefore, the actual time and expenditures required to pursue FDA approval are beyond our control and cannot be predicted.

We received approval for, and have conducted, feasibility clinical trials in the United States on the PSI for the treatment of presbyopia. We submitted the clinical trial data to the FDA and filed an investigational device exemption application with the FDA in March 2003 to obtain approval for initiating Phase II clinical trials. We subsequently filed amendments to that application and received approval to start our Phase II clinical trials in December 2003, subject to certain final documentation. The FDA may decline to authorize additional clinical trials after the Phase II trials or may substantially delay those trials for a variety of reasons. We also plan to submit an application to the FDA to conduct clinical trials on the PSI for the treatment of ocular hypertension and primary open angle glaucoma. The FDA may not approve the proposed study or may significantly delay the study, if approved.

Sales of medical devices outside the United States are subject to regulatory requirements that vary by country. The time required to obtain approval may be shorter or longer than the time required for FDA consideration and involve complexities of dealing with a variety of international governmental regulations. We have limited experience in dealing with the specific regulations that must be met to sell our medical devices in certain international markets. The failure to obtain the necessary regulatory approvals on a timely basis may have a material adverse effect on our business, financial condition and results of operations.

We will require additional financing to conduct our operations and fund our FDA clinical trials. We do not currently have sufficient financial resources to fund our operations for the next twelve months. In addition, we will require substantial additional capital to fund our future operations and conduct our FDA clinical trials over the next several years. Therefore, we may be required to seek additional funding through collaborative arrangements with corporate partners and through public or private debt or equity financings. Any additional equity financing may be dilutive to stockholders. Any debt financing, if available, may involve restrictions on our ability to pay dividends on our capital stock, be dilutive due to possible conversion features or attached warrants, or restrict the manner in which we conduct our business. We can give you no assurances, however, that additional funding will be available in sufficient amounts, on terms acceptable to us, or at all, when needed. Our ability to obtain additional financing depends on many factors, some of which are beyond our control, including the state of the capital markets, the market price of our common stock and the prospects for our business. The inability to obtain sufficient funds may require us to delay, scale back or eliminate some or all of our research and product development programs, clinical studies and/or regulatory activities or may cause us to cease our operations.

We rely on third-party sales, marketing, manufacturing, training and customer service, which may have a material adverse effect on our business. We have a limited staff of four full-time persons and rely on a number of independent consultants. We have no sales, manufacturing, training or customer service staff. We have marketed and sold only a relatively small number of PSIs. As a result of the Transfer Agreement, we will have to develop new arrangements with third parties or hire a significant number of new staff, either of which may result in substantially

higher costs or lower revenues to us. We may be unable to hire qualified staff or may be unable to retain qualified consultants to perform these functions, which could result in a material adverse effect to our business.

We have a limited operating history, a single unproven product to date, a history of net losses, and our business may never become profitable. We have spent the past nine years concentrating our efforts on the development of the PSI and the related surgical procedure for the correction of presbyopia and, more recently, for the treatment of ocular hypertension and primary open angle glaucoma. Sales of the PSI are pending approval of the product by the FDA in the United States and by other regulatory authorities in other countries.

Our limited history may not be adequate to enable you to fully assess our ability to achieve market acceptance of our products or our ability to respond to competition. Accordingly, we are subject to the same uncertainties and risks associated with any company developing new products and beginning operations. If we are unsuccessful in addressing the risks and uncertainties frequently encountered by early stage companies in a new and evolving market, our business will be seriously harmed.

We have incurred losses every year since we began operations. As of December 31, 2003, our accumulated deficit was $22.6 million, including a net loss of $5.7 million for the year ended December 31, 2003. These losses have resulted primarily from expenses associated with research and development activities, pre-clinical and clinical trials, obtaining regulatory approvals in international markets and general and administrative expenses. We anticipate our operating expenses will increase substantially for the foreseeable future as we expand our FDA clinical trials in the United States and assume functions formerly performed by CIBA.

To become profitable, we must be able to generate revenues from product sales. We have not had any significant revenues since 2000. For the next several years, our revenues will be dependent on the SSP for the treatment of presbyopia, ocular hypertension and primary open angle glaucoma utilizing our patented PSI and the PresVIEW Incision System. There can be no assurance that the PresVIEW technology will be proven safe and effective or that, if proven safe and effective, the technology will be successfully commercialized. To improve the surgical outcomes of the SSP, we developed the PresVIEW Incision System, which we believe consistently produces incisions of accurate length and depth for the placement of the PSI. We believe that the development of this device has been completed, subject to continued enhancements as surgeons use the PresVIEW Incision System in the SSP. Any unexpected problems with the PresVIEW Incision System would cause additional delays in our ability to market our primary product, the PSI.

If substantial growth in our revenues does not occur, we may not be able to achieve or maintain profitability in the future. The amount of losses we will incur before achieving profitability, and the time required to reach profitability, are each highly uncertain. No assurances can be given that we will ever achieve profitability.

The components of the PresVIEW Incision System and the related disposable blade are available only from single sources, and other sources may not be available or they may not properly provide products. Under the CIBA Agreement, these items were provided through suppliers established by CIBA. Although CIBA will provide transition services under the Transfer Agreement, we have not yet entered into supply contracts with these sources. If one or more of these vendors are lost, delivery of our products could be delayed or prevented and our business would suffer. If we are unable to produce our products in a cost-effective or timely manner, or if the manufacturing of our products is interrupted, our business, financial condition and results of operations could be materially adversely affected.

Many of the manufacturing processes require a significant degree of technical expertise. If these third-party vendors and manufacturers fail to produce to our specifications or inadvertently use defective materials in the manufacturing process, the reliability and performance of our products will be compromised.

We are dependent on our management, key personnel and consultants, and may be dependent on the recruitment of additional personnel to succeed; and the loss of personnel or consultants may damage our business. Our principal executive officers, consultants and key personnel have extensive knowledge of our PresVIEW technology, the PresVIEW Incision System and the research and development efforts needed to bring the products to market. The loss of the services of any of our executive officers or other key personnel or consultants could have a material adverse effect on our business and financial condition.

In light of the transition of certain operations from CIBA to us, our success and business strategy will likely depend in large part on our ability to attract and retain key management, scientific and operating personnel. We may need to develop expertise, add skilled personnel and/or retain consultants in the areas of research and development, clinical trials, government regulatory approvals, sales, marketing and manufacturing. These persons are in high demand and are often subject to competing employment offers. There can be no assurances that we will be able to attract and retain qualified personnel or develop the expertise needed for our business. We currently have a small management group with limited operating experience. The inability to hire additional personnel and develop expertise as needed could have a material adverse effect on us.

We face various international risks that may cause an increase in costs. We face risks due to our expected reliance on sales in international markets. Our future success will depend in part upon our ability to recommence our international marketing operations and our ability to expand international sales of the PSI. International sales may be our only source of revenue for the next several years while we seek FDA approval of our products in the United States. International operations expose us to risks, including:

- need for export licenses;
- unexpected regulatory requirements;
- tariffs and other potential trade barriers and restrictions;
- political, legal and economic instability in foreign markets;
- longer account receivable cycles;
- difficulties in managing operations across disparate geographic areas;
- foreign currency fluctuations;
- reduced or limited protection of our intellectual property rights in some countries;
- dependence on local distributors; and
- potential disruptions in sales or manufacturing due to military or terrorist acts.

If one or more of these risks materialize, our sales to international customers may be less than expected and costs may be more than expected, which could negatively impact our financial condition.

Due to our dependence on the PSI, failure to achieve market acceptance in a timely manner could harm our business. Even if regulatory authorities approve our products, the PSI and the PresVIEW Incision System may not be commercially successful. Acceptance of, and demand for, the PSI and the PresVIEW Incision System will depend largely on the following factors:

- safety and effectiveness for all targeted indications (i.e., presbyopia, primary open angle glaucoma and ocular hypertension);
- awareness and acceptance by ophthalmologists and patients of our product as safe and effective;
- safety, effectiveness and pricing of alternative products;
- prevalence and severity of side effects associated with our product;
- the possibility of unknown side effects;
- pricing of our product to both the ophthalmic community and the consumer;
- our ability to decrease the technical skill level of surgery required for outstanding outcomes via the standardization and automation steps provided by the PresVIEW Incision System;
- the amount of training required for the proper use of the PresVIEW Incision System and insertion of the PSI;
- the general resistance to implanting a foreign object in the eye;
- the lack of long-term follow-up data;
- the degree of usage by the ophthalmic community as a treatment alternative;
- how quickly competitors can develop and obtain FDA approval for competitive treatment methods;
- successful seeding efforts with noted physicians and commercialization in Europe and other international markets preceding FDA approval; and
- resolution and/or clarification of the various scientific theories of what causes presbyopia and the specific mechanism of action involved in the SSP.

Because all of our revenues over the next several years are projected to come from the sale of the PSI and related products, our financial performance will depend upon ophthalmologists' adoption and patient awareness of the SSP. If we are unable to convince ophthalmologists to use the PSI, we may not be able to generate revenues because our other product candidates are not ready, and may never be ready, for commercialization.

In order for us to sell our products, ophthalmologists must recommend and endorse them. We may not obtain the necessary recommendations or endorsements from ophthalmologists. Acceptance of our product is dependent upon educating the ophthalmic community as to the distinctive characteristics, perceived benefits, clinical efficacy and cost-effectiveness of our product compared to competitive products and on training ophthalmologists in the proper application of our product and the surgical techniques of the SSP. No assurances can be given that the medical community or the patients will accept the SSP over current conventional treatments.

If we fail to keep pace with advances in our industry or fail to persuade physicians to adopt new products that we introduce, customers may not buy our products and our revenues and profits may decline. The ophthalmic industry is characterized by the following: rapid product development, with a significant competitive advantage gained by companies that introduce products that are first to market; constant innovation in products and techniques; frequent new product introductions; and price competition.

Our future growth depends, in part, on our ability to develop products that are more effective in treating diseases and disorders of the eye or that incorporate the latest technologies. In addition, we must be able to manufacture and effectively market those products and persuade a sufficient number of eye care professionals to use the new products that we introduce. Many doctors are reluctant to switch a patient to a new treatment. For example, ophthalmologists may be reluctant to cease a patient's current treatment for glaucoma if the current treatment remains effective. Also, sales of our existing products may decline rapidly if a new product is introduced by one of our competitors or if we announce a new product that, in either case, represents a substantial improvement over our existing products. Similarly, if we fail to make sufficient investments in research and development programs or if we focus on technologies that do not lead to more effective products, our current and planned products could be surpassed by more effective or advanced products.

We are subject to extensive governmental regulation that increases our costs and could prevent us from, or delay us in, selling our products. Our products (including the PSI and the PresVIEW Incision System) are subject to extensive governmental regulation. Governmental regulation includes inspection of, and controls over, testing, manufacturing, safety and environmental controls, efficacy, labeling, advertising, promotion, record keeping and the sale and distribution of medical device products and samples. We are also subject to similar governmental regulation that affects the prices we will charge, the rebates we may offer to customers and the methods of our marketing. Governmental regulation substantially increases the cost of developing, manufacturing and selling our products.

We are required to obtain the approval of regulatory agencies worldwide before we can market and sell the PSI or other products and to undergo rigorous inspections by these agencies. In the United States, we must obtain FDA approval or clearance for each medical device before the devices can be marketed and sold. The FDA approval process is typically lengthy and expensive, and approval is never certain. In order to obtain these approvals, our products must be shown to be effective and safe for use in humans. In addition, products distributed outside of the United States are subject to governmental regulation, which may be equally or more demanding. Our products could take a significantly longer time than we expect to gain regulatory approval or may never gain approval. If a regulatory authority delays approval of a product, our market value and operating results may decline. Even if the FDA or another regulatory agency approves a product, the approval may limit the indicated uses for a product or may otherwise limit our ability to promote, sell and distribute a product. A regulatory agency may require post-marketing studies. If we are unable to obtain regulatory approval of our products, we will not be able to market these products, which would result in a significant shortfall in our sales. Currently, we are pursuing CE Mark certification of our products from regulatory authorities for sale of our products in the European Union. We are also seeking FDA and Health Canada approval for the sale of our products in the United States and Canada. Growth in our sales will depend on the timely and successful introduction and marketing of some or all of our products.

The clinical trials required to obtain regulatory approvals are complex and expensive, and their outcomes are uncertain. We have incurred, and will continue to incur, substantial expense for, and will continue to devote significant time to, clinical trials, but we cannot be certain that the trials will ever result in the commercial sale of a prod-

uct. Positive results from pre-clinical studies and early clinical trials do not ensure positive results in later clinical trials that form the basis of an application for regulatory approval. We may suffer significant setbacks in clinical trials, even after earlier clinical trials show promising results. Any of our products may produce undesirable side effects that could cause us or regulatory authorities to interrupt, delay or halt clinical trials. The FDA, another regulatory authority or we may suspend or terminate clinical trials at any time if they or we believe that the trial participants face unacceptable health risks.

We are also required to demonstrate compliance with the FDA's quality system regulations before we can receive FDA approval for the PSI and the PresVIEW Incision System. The FDA enforces its quality system regulations through pre-approval and periodic post-approval inspections. These regulations relate to product testing, vendor qualification, design control, product manufacturing and quality assurance, as well as the maintenance of records and documentation. If we are unable to conform to these regulations, we will be required to locate alternative manufacturers that do conform. Identifying and qualifying alternative manufacturers may be a long and difficult process and the delays could seriously harm our business.

Medical devices are also subject to post-market reporting requirements. If safety or efficacy problems occur after the product reaches the market, the FDA may take steps to prevent or limit further marketing and sales of the product. Additionally, the FDA actively enforces regulations prohibiting marketing of devices for indications or uses that have not been cleared or approved by the FDA.

Noncompliance with applicable United States requirements can result in fines, injunctions, penalties, disgorgement of profits, mandatory recalls or seizures, suspensions of production, denial or withdrawal of pre-marketing approvals, marketing restrictions, recommendations by the FDA against governmental contracts, criminal prosecution or clinical trial delays. The FDA also has the authority to request repair, replacement or refund of the cost of any device that we manufacture or distribute. Regulatory authorities outside of the United States may impose similar sanctions against us for noncompliance with applicable regulatory requirements. No assurances can be given that restrictions, sanctions or findings by one of the worldwide regulatory agencies will not result in similar or stronger actions by other regulatory agencies, including the FDA.

We currently lack long-term data regarding the safety and efficacy of our product and may find that long-term data does not support our short-term clinical results. The SSP is a new technology with only a relatively limited number of clinical cases to date. The long-term effects, if any, of the procedure have not been determined. The human eye may or may not tolerate the presence of the PSI. The PSI may ultimately result in undesirable side effects or medical complications. We are unaware of any patient who has suffered any significant damage to their vision or experienced any serious complications in the investigational surgeries conducted to date. The complications experienced to date appear to be minor and related to the evolution of the surgical technique. Further clinical testing of the PSI could reveal other complications and side effects, which could bear on the long-term safety and efficacy of the PSI, any of which could have a material adverse effect on our business. There can be no assurances, therefore, that the PSI and the related surgical procedure will not result in latent complications or that our belief that the SSP is fully reversible in all patients will be confirmed by clinical experience.

We face competition from alternative therapies, and sales of our products may be less than our expectations. We compete with many domestic and foreign competitors, who conduct business in various rapidly evolving and technologically advanced fields, including medical device, pharmaceutical and biopharmaceutical companies. For example, in the worldwide presbyopia market, the PSI will compete with reading glasses, bifocals, multifocal glasses, and the bifocal and multifocal contact lens industry, as well as alternative surgical techniques, such as the implant of "accommodating" intraocular lenses. There are world leaders in these markets, such as: Varilux, Bausch & Lomb, Vistakon (a subsidiary of Johnson & Johnson), Alcon, Allergan and VISX. For the treatment of ocular hypertension and primary open angle glaucoma, we will compete with major pharmaceutical companies, including Alcon, Allergan, Bausch & Lomb, Merck and Pfizer. These competitors may develop technologies and products that are more effective, easier to use or less costly than any of our current or future product candidates or that could render our technologies and product candidates obsolete or noncompetitive. Many of these competitors have substantially more resources, as well as more product development, manufacturing and marketing experience and capabilities, than we do. In addition, many of our competitors have significantly greater experience than we do in conducting pre-clinical testing, clinical trials and in obtaining FDA and other regulatory approvals of products and therapies.

The vision correction industry is intensely competitive. The significant competitive factors in the industry include price, convenience, acceptance of new technologies, patient satisfaction, and government approval. Our ability to compete successfully depends, in part, on our ability to respond quickly to medical and technological change and user preference through the development and introduction of new products that are of high quality and that address patient and surgeon requirements. We compete with many larger companies that enjoy several competitive advantages, including established distribution networks; established relationships with health care providers and payors; additional lines of products; the ability to bundle products to offer higher discounts or other incentives to gain a competitive advantage; and greater resources for product development, sales and marketing and patent litigation. If we are unable to compete effectively against existing or future competitors, sales of our products may be significantly less than our expectations.

Other companies are developing products based on the same or similar scientific theories used by us. Those products may be more effective than our products and may not infringe our intellectual property rights. These companies may be able to develop a surgical technique that does not require the use of any implant device to achieve the same or similar surgical result.

We may not successfully develop and launch replacements for our products that lose patent protection, which could significantly decrease our future sales and profits. Most of our products are covered by patents that give us a degree of market exclusivity during the term of the patent. Significant patents covering our products will expire within the next 8 to 14 years. Upon patent expiration, our competitors may introduce products using the same technology. As a result of this possible increase in competition, we may need to charge a lower price in order to maintain sales of our products, which could result in these products becoming less profitable. If we fail to develop and successfully launch, and receive regulatory approval for, more advanced replacement products prior to the expiration of patents for our existing products, our sales and profits with respect to those products could decline significantly. We may not be able to develop and successfully launch more advanced replacement products before these and other patents expire.

Resources devoted to research and development may not yield new products that achieve commercial success, and we would be dependent only on the PSI for sales. In the past, we have devoted substantial resources to research and development. In the foreseeable future, we plan to devote relatively less resources to research and development. The research and development process is expensive, prolonged and entails considerable uncertainty. Development of a new product, from discovery through testing and registration to initial product launch, typically takes between four and ten years for a medical device. These periods vary considerably from product to product and country to country. Because of the complexities and uncertainties associated with ophthalmic research and development, products we are currently developing may not complete the development process or obtain the regulatory approvals required for us to market these products successfully. None of the products currently in our development pipeline may be commercially successful. We are dependent on Dr. Ronald A. Schachar to conduct research and development on the ARMD product for us. He may be unsuccessful in his efforts or may not devote adequate time to that project resulting in our inability to commercialize that product.

Surgeon training and the ability of surgeons to routinely achieve a good surgical result for virtually all *patients is important to our success.* *Failure, for any reason, by surgeons to achieve good results will harm our* business. During the course of the development of the PSI, the PresVIEW Incision System and the related surgical procedure, the surgical technique and surgical instruments have evolved and changed as we attempted to make the surgical procedure easier for the surgeon to perform. The SSP, while using surgical skills similar to other ophthalmic surgical procedures, is a relatively new surgical technique that requires training and precise execution by the surgeon. Some surgeons were not able to successfully use earlier prototypes of the PresVIEW Incision System. Some surgeons have not been able to successfully place the PSI in the sclera of the eye to achieve the necessary effect. Certain of these surgeons have chosen to publish their unsuccessful clinical results.

It is critical to our sales effort to train a sufficient number of physicians to properly perform the SSP. We will need to educate ophthalmic surgeons through presentations at international conferences and through surgical training courses. If physicians are not properly trained, they may misuse or ineffectively use our products, resulting in unsatisfactory patient outcomes, patient injury and related liability or negative publicity. If we are not successful in ade-

quately training surgeons, or perhaps in further improving the technique and surgical instruments so that all surgeons with the requisite skills can routinely obtain good surgical results, our business will be significantly harmed.

We may be subject to future product liability litigation that could be expensive and may result in the inability to obtain insurance coverage. The manufacture, distribution and sale of medical devices is inherently subject to the risk of product liability claims. We use appropriate efforts to take reasonable precaution in the handling, testing, packaging and distribution of the product to minimize potential liability. Nonetheless, it is possible that we may become subject to litigation involving the PSI, both in domestic and international markets. We have provided, and may continue to provide, certain limited indemnities to academic or other institutions that are participating in the FDA clinical trials.

We have obtained $5.0 million in product liability insurance coverage. The coverage is on a claims made basis and has a retroactive effective date to the date of incorporation of Ocular in August 1994. Despite such coverage, we may be subject to claims that exceed the insurance coverage, and these claims may have a material adverse effect on us. In addition, we may require additional product liability coverage if sales of our products increase. Product liability insurance is expensive and may not be available to us in the future on acceptable terms, or at all. We have not been subject to any product liability litigation to date.

Although we are not currently subject to any product liability proceedings, we may incur material liabilities relating to product liability claims in the future, including product liability claims arising out of procedures performed using the PSI or our surgical equipment. The combination of our insurance coverage and cash flows may not be adequate to satisfy product liabilities we may incur in the future. Even claims without merit could subject us to adverse publicity, hinder us from securing insurance coverage in the future and require us to incur significant legal fees. Successful product liability claims could have a material adverse effect on our financial condition as well.

We may be subject to future claims from physicians who disagree with our return policy, and we may incur unexpected expenses to resolve the complaints. A number of ophthalmologists with practices based in the United States purchased surgical kits, including the PSI, at international locations. While certain of these physicians conducted investigational surgeries at international locations for the purpose of research, many of these physicians purchased our products with a desire to participate in the anticipated clinical trials of the PSI, which are regulated by the FDA. All of these physicians were aware that the PSI was not approved by the FDA for use in the United States at the time of their purchase. We did not sell the products with a right of refund. Nevertheless, several of these ophthalmologists have requested a refund or have informed us that if they are not selected to participate in the clinical trials, they plan to return the products with a request for a refund. We cannot ensure that all these physicians will be selected to participate in the clinical trials. We did not sell our products with a right of refund and do not believe that we have any liability to refund the cost of these products.

As a result of our continued suspension of sales, we have been notified by two of our foreign distributors that they are seeking refunds on unsold products remaining in their inventory. We did not sell our products with a right of refund and do not believe that we have any liability to refund the cost of these products.

As a result of the Transfer Agreement, we will be responsible for all future marketing. As part of future marketing programs in the United States and internationally, we may determine that it is in our best interest to provide some compensation in the form or product discounts or by other means to the surgeons who bought our kits, and did not get to participate in the FDA trials, or to foreign distributors of our products. At this time, we are currently unable to determine the amount of possible compensation, if any, that we may agree to pay in the future.

We established a reserve of $50,000 at December 31, 2001, as an estimate of the cost of providing replacement PSIs to physicians that might have PSI inventory on hand. We had encouraged these physicians not to perform any surgeries until the PresVIEW Incision System was available. The packaging of the PSI provided guaranteed sterility only for a limited period of time, and that sterility dating has expired. We may decide to replace the PSI inventory of these physicians with new PSIs when they are again able to perform the SSP, or, rather than replace all the expired inventory, we may instead grant special pricing on future purchases to these physicians. Actual claims may exceed, and/or the cost of replacing the PSIs may be higher than, our estimate and additional charges may have to be taken.

Failure by users of our products to obtain adequate reimbursement from third-party payors could limit market acceptance of our products, which could impact our sales and profits. The initiatives of managed care organizations and governments to contain healthcare costs in the United States and elsewhere are placing an increased emphasis on the delivery of more cost-effective medical therapies. This emphasis could adversely affect sales and prices of our products. For example:

- major third-party payors for hospital services, including government insurance plans, Medicare, Medicaid and private healthcare insurers, have substantially revised their payment methodologies during the last few years, resulting in stricter standards for reimbursement of hospital and outpatient charges for some medical procedures, including cataract and intraocular lens procedures. Because of increased transparency of prices following the adoption of the euro, member governments in some countries in the European Union are requesting price reductions to match prices charged in other countries in the European Union;
- numerous legislative proposals have been considered that, if enacted, would result in major reforms in the United States healthcare system;
- our competitors may reduce the prices of their products, which could result in our competitors being reimbursed for a larger number of procedures by third-party payors;
- there are proposed and existing laws and regulations governing product prices and the profitability of companies in the health care industry; and
- there have been recent initiatives by third-party payors to challenge the prices charged for medical products, which could affect our profitability.

Surgical procedures to improve vision that are currently available, such as laser refractive surgery, are generally not reimbursable by third-party payors. We believe that third-party payors will not provide reimbursement to patients for the SSP if the procedure is undergone for the treatment of presbyopia. Third-party payors or government insurance programs may provide some level of reimbursement to patients that undergo the SSP for the treatment of ocular hypertension or primary open angle glaucoma. In the United States, this reimbursement may not be available immediately at FDA approval or, if available, any reimbursement may be limited, thereby adversely affecting our ability to sell our medical devices on a profitable basis for the treatment of ocular hypertension or primary open angle glaucoma. Further, an adverse coverage decision by the Centers for Medicare and Medicaid Services, the United States government agency that oversees the Medicare and Medicaid programs, could adversely influence private insurers, as well as other public payors.

Reductions in the prices for our products in response to the trends noted above could reduce our profits. Moreover, the SSP for the treatment of ocular hypertension and primary open angle glaucoma may not be covered in the future by third-party payors. Consequently, ophthalmologists, out-patient surgical facilities, hospitals and other health care providers may be reluctant to purchase our products if they do not receive substantial reimbursement for the cost of our products and for procedures performed using our surgical medical device products from third-party payors, including Medicare and Medicaid in the United States and health insurance programs, both governmental and private. Therefore, the failure of our products to be so covered could cause our profits to decline.

Since the SSP treats presbyopia, as well as ocular hypertension and primary open angle glaucoma, a decline in the price of the PSI due to price pressures by third-party payors could result in a price decline for the PSI used in the treatment of the other indication.

Economic conditions and price competition may cause sales of our products used in elective surgical procedures to decline and reduce our profitability. Sales of our products used in elective surgical procedures may be adversely impacted by economic conditions. Generally, the costs of elective surgical procedures are borne by individuals without reimbursement from their medical insurance providers or government programs. Accordingly, individuals may be less willing to incur the costs of these procedures in weak or uncertain economic conditions and, therefore, there may be a decline in the number of these procedures. Sales of the PSI worldwide may come under pressure if weak economic conditions exist and, therefore, our revenues would likely be negatively impacted.

We may be required to bring litigation to enforce our intellectual property rights, which may result in substantial expense. We rely on patents to protect our intellectual property rights. We have 18 issued United States patents and 20 issued or published international patents. We have 14 pending United States patent applications and

56 pending international patent applications. Related only to the PresVIEW technology, we have 11 issued United States patents, 15 issued or published international patents, 9 pending United States patent applications and 51 pending international patent applications. The patents associated with the PresVIEW technology have expiration dates ranging from 2012 to 2020. The patents and patent applications related to our early stage products generally do not expire until after 2015. The strength of our patent portfolio, however, could be challenged. In particular, our competitors and others may allege that:

- our patents and pending patent applications use technology that we did not invent first, or
- we were not the first to file patent applications for these inventions.

Further, because of the uncertain nature of patent protection, we cannot be certain that:

- others will not independently develop similar or alternative technologies or duplicate our technologies;
- others will not develop enhancements to our technology that are beneficial to us, which we may not be able to utilize unless we license or pay compensation for those enhancements;
- any of our pending patent applications will result in further issued patents; or
- any patents issued to us will provide a basis for commercially viable products, will provide us with any competitive advantages or will not face third-party challenges or be subjected to further proceedings limiting their scope.

We may become involved in interference proceedings in the U.S. Patent and Trademark Office to determine the priority of our inventions. We could also become involved in opposition proceedings in foreign countries challenging the validity of our patents. In addition, costly litigation could be necessary to protect our patent position. In some jurisdictions, patent laws relating to the scope of claims in the technology fields in which we operate is still evolving and, consequently, patent positions in our industry are somewhat uncertain. We may not prevail in any lawsuit or, if we do prevail, we may not be awarded commercially valuable remedies. Further, it is possible that we will not have the resources required to pursue necessary litigation or to otherwise protect our patent rights. Failure to protect our patent rights could harm us.

We have been involved as plaintiffs in three lawsuits in the United States related to our patented technology for the SSP. For more information on these lawsuits, see "*Item 3. Legal Proceedings*".

Patent rights in jurisdictions outside of the United States are even more uncertain and difficult to protect. There may be patents in certain international jurisdictions that are not enforceable or, if enforceable, we may determine not to attempt to enforce these rights due to the expense, the likelihood of prevailing or for other reasons. Furthermore, the laws of foreign countries may not protect our intellectual property rights to the same extent as the laws of the United States.

We rely on trade secrets, unpatented proprietary know-how and continuing technological innovation, which we seek to protect with confidentiality agreements with employees, consultants and others with whom we discuss our business. We may not be able to prevent the unauthorized disclosure or use of our technical knowledge or other trade secrets by consultants, vendors, former employees and current employees, despite the existence of nondisclosure and confidentiality agreements and other contractual restrictions. These individuals may breach these confidentiality agreements and our remedies may not be adequate to enforce these agreements. Disputes may arise concerning the ownership of intellectual property or the applicability or enforceability of these agreements, and these disputes may not be resolved in our favor. Furthermore, our competitors may independently develop trade secrets and proprietary technology similar to ours. If we do not receive patents for products arising from our research, we may not be able to maintain the confidentiality of information relating to those products.

If our intellectual property rights are not adequately protected, we may be unable to keep other companies from competing directly with us, which could result in a decrease in our market share. Enforcement of our intellectual property rights to prevent or inhibit appropriation of our technology by competitors can be expensive and time-consuming to litigate, or otherwise dispose of, and can divert management's attention from carrying on with our core business.

Our products could infringe upon the intellectual property rights of others, which may cause us to engage in costly litigation and, if we are not successful, could cause us to pay substantial damages and prohibit us from selling our products. Third parties may assert infringement or other intellectual property claims against us based on their patents or other intellectual property claims. We may be required to pay substantial damages, including treble damages, for past infringement if it is ultimately determined that our products infringe a third-party's patents. Even if infringement claims against us are without merit, defending a lawsuit takes significant time, may be expensive and may divert management's attention from other business concerns. Further, we may be prohibited from selling our products before we obtain a license from the owner of the relevant technology. If such a license is available, it may require us to pay substantial royalties.

We may implement a product recall or voluntary market withdrawal due to product defects or product enhancements and modifications, which would significantly increase our costs. The manufacturing and marketing of medical devices and surgical equipment and instruments involves an inherent risk that our products may prove to be defective or cause a health risk. In that event, we may voluntarily implement a recall or market withdrawal or may be required to do so by a regulatory authority. We have recalled products in the past as explained later in this section and, based on this experience, believe that the occurrence of a recall could result in significant costs to us, potential disruptions in the supply of our products to our customers and potential adverse publicity, all of which could harm our ability to market our products. A recall of one of our products, or a similar product manufactured by another manufacturer, could impair sales of the products we market as a result of confusion concerning the scope of the recall.

We have devoted substantial financial and management resources to research and development and the enhancement and improvement of both the patented PSI and the SSP. In order to improve the results of the SSP, we have on several occasions replaced the inventory of the physician customers with a new release of the PSI. We have also provided to our paid customers, free of charge, all upgrades or modifications to the hand-held surgical instruments previously used to perform the SSP. We have written off the cost of the previous injection molding equipment, the discontinued PSI and instrument inventory and other costs associated with the upgrade of the PSI and instruments.

In 1999 and early 2000, Ocular conducted a voluntary recall of the PSI as a result of a redesign in the shape of the segments of the PSI. One or more of the segments of the PSI prototype sold in 1998 and early 1999 had a tendency to turn on its side in a small percentage of patients, presumably as a result of the patients rubbing their eyes. Although not posing any known safety risk to the patient, the patient would generally notice that their improvement in near vision as a result of the surgery would decrease after the segment rotated. Ocular redesigned the shape of the PSI segments by making the segment wider than it was tall with the intent of eliminating this rotation problem. Ocular replaced, at no cost to the physicians, the PSI inventory of physician customers worldwide with the newly designed PSI. We are not aware of any report of the rotation of the current PSI design. During the period of the recall, Ocular did not recognize sales pending shipment of the new release of the PSI. In addition, in early 2001, Ocular suspended sales of the PSI while it was developing the PresVIEW Incision System. There can be no assurances that expenses associated with product upgrades and the loss of revenues from the suspension of sales during similar future periods, if any, will not have a material impact on our results of operations and financial condition.

Future modifications to our products may require new clinical trials, FDA 510(k) clearances or pre-market approvals or may require us to recall the modified devices until clearances are obtained. Any modification to an FDA-cleared device that significantly affects its safety or effectiveness, or that would constitute a major change in its intended use, requires a new FDA 510(k) clearance or possibly pre-market approval. The FDA requires every manufacturer to make this determination in the first instance, but the FDA can review any decision. We may make additional modifications to our products and future products after they have received clearance or approval and, in appropriate circumstances, determine that a new submission is unnecessary. The FDA may not agree with our decision not to seek new clearance or approval. Also, in those circumstances, we could be subject to significant regulatory fines or penalties.

Acquisitions that we consummate could disrupt our business and harm our financial condition. In the future, we may evaluate potential strategic acquisitions of complementary businesses, products or technologies. We may not be able to identify appropriate acquisition candidates or successfully negotiate, finance or integrate any busi-

nesses, products or technologies that we acquire. Furthermore, the integration of any acquisition may divert management's time and resources from our core business. While we, from time to time, evaluate potential acquisitions of businesses, products and technologies, and anticipate continuing to make these evaluations, we have no present understandings, commitments or agreements with respect to any acquisitions.

We are subject to critical accounting policies and actual results may vary from our estimates. We follow accounting principles generally accepted in the United States of America in preparing our financial statements. In preparing the financial statements, we must make many estimates and judgments about future events. These affect the reported amounts of assets and liabilities, the disclosure of contingent assets and liabilities, and the reported amounts revenues and expenses. We believe that these estimates and judgments are reasonable, and we make them in accordance with our accounting policies based on information available to us at the time. Actual results, however, could differ from our estimates, and this could require us to record adjustments to the reported amounts of assets and liabilities, change the disclosures related to contingent assets and liabilities, and/or adjust the recorded amounts of revenues and expenses. These changes could be material to our financial condition and results of operations.

Risks Related to Our Common Stock

The liquidity of our common stock is affected by its limited trading market. Shares of our common stock are traded on the OTC Bulletin Board under the symbol "RFCG.OB." We expect them to continue to trade in that market. There is currently no broadly followed, established trading market for our common stock. An established trading market may never develop or be maintained. Active trading markets generally result in lower price volatility and more efficient execution of buy and sell orders. The absence of an active trading market reduces the liquidity of our shares. The trading volume of our common stock, historically, has been limited and sporadic. As a result of this trading activity, the quoted price for our common stock on the OTC Bulletin Board is not necessarily a reliable indicator of its fair market value. Further, if we cease to be quoted, holders would find it more difficult to dispose of, or to obtain accurate quotations as to the market value of, our common stock, and the market value of our common stock would likely decline.

Our common stock may be subject to regulations prescribed by the Securities and Exchange Commission relating to "penny stock." The Securities and Exchange Commission has adopted regulations that generally define a penny stock to be any equity security that has a market price (as defined in these regulations) of less than $5.00 per share, subject to certain exceptions. If our common stock meets the definition of a penny stock, it will be subject to these regulations, which impose additional sales practice requirements on broker-dealers who sell these securities to persons other than established customers and accredited investors, generally institutions with assets in excess of $5.0 million and individuals with a net worth in excess of $1.0 million or annual income exceeding $0.2 million (individually) or $0.3 million (jointly with their spouse).

We are required to file and maintain the effectiveness of registration statements for shares issued in our private placements. Pursuant to registration rights agreements with stockholders who purchased shares of our common stock in the March 2003 private placement, we agreed to use our reasonable best efforts to register the shares for resale and to maintain the effectiveness of the registration through March 6, 2004. While we filed a registration statement on a timely basis, it was not declared effective prior to March 6, 2004.

In addition, pursuant to registration rights agreements with stockholders who purchased shares of our common stock in the December 2003 private placement, we agreed to use our reasonable best efforts to register for resale that stock and to maintain the effectiveness of that registration statement through December 23, 2004. We have filed a registration statement that included the shares that these stockholders purchased in that private placement, but it has not yet been declared effective. Once the registration statement has been declared effective, we are required to maintain the effectiveness of the registration statement until December 23, 2004, except as permitted.

Our common stock will likely be subject to substantial price and volume fluctuations. The market price of our common stock has been volatile and could fluctuate widely in response to several factors, some of which are beyond our control, including:

- our quarterly operating results;

- additions or departures of key personnel;
- changes in the business, earnings estimates or market perceptions of our competitors;
- the introduction of new products by us or our competitors;
- future sales of our common stock by us or other selling stockholders;
- changes in general market or economic conditions; and
- announcements of legislative or regulatory changes.

The stock market has experienced extreme price and volume fluctuations in recent years that have significantly affected the quoted prices of the securities of many companies, including companies in our industry. The changes often appear to occur without regard to specific operating performance. In addition, there has been a limited public market for our common stock. We cannot predict the extent to which investor interest in us will be maintained. Interest in our common stock is necessary for an active, liquid trading market for our common stock. Active trading markets generally result in lower price volatility and more efficient execution of buy and sell orders for investors. The price and trading volumes of our common stock may fluctuate widely due to the limited public market for our stock.

Sales of a significant number of shares of our common stock in the public market could harm the market price of our common stock. At December 31, 2003, approximately 18% of our outstanding common stock was unrestricted and could be sold in the public market without registration under the Securities Act or compliance with Rule 144.

Approximately 9% of our outstanding common stock that was issued to former Ocular stockholders and in the March 2003 private placement became eligible for sale under Rule 144 beginning on March 6, 2004. In general, a person who has held restricted shares for a period of one year may, upon filing with the Securities and Exchange Commission a notification on Form 144, sell into the market shares of stock up to an amount equal to the greater of 1% of the outstanding shares or the average weekly number of shares sold in the last four weeks prior to that sale. These sales may be repeated once each three months, and any of the restricted shares may be sold by a non-affiliate without compliance with Rule 144 after such shares have been held two years. Another 8% of our common stock is also eligible for sale under Rule 144 starting March 6, 2004, but these shares are subject to lock-up agreements that generally limit the number of shares that can be sold each month to 9% of a stockholder's holdings from the March 2003 private placement. Under the lock-up arrangement, a maximum of approximately 163,000 shares of our outstanding common stock could be sold by these stockholders in the first month following March 6, 2004.

In addition, 19% of our outstanding common stock will become eligible for sale the earlier of the effective date of a registration statement we have filed covering these shares or December 23, 2004. Another 46% of our outstanding common stock will also be eligible for sale the earlier of the effective date of that registration statement or March 6, 2005, but these shares are subject to various lock-up agreements that subject stockholders to limitations on the number of shares that can be sold each month. A maximum of approximately 158,000 shares of our outstanding common stock that are subject to lock-up agreements could be sold in the first month following the effective date of a registration statement under the terms of those lock-up agreements. In subsequent months, additional shares will also be released from lock-up arrangements according to various agreements.

All of the lock-up agreements expire March 6, 2005, thus releasing any remaining unsold shares from these limitations. The release of shares from lock-up arrangements may have a negative impact on our stock price if such released shares are sold by the holders.

After giving effect to the merger, certain of our principal stockholders continue to have significant voting power and may take actions that may not be in the best interest of other stockholders. Certain of our directors and principal stockholders continue to control a significant percentage of our outstanding common stock. If these stockholders act together, they may be able to exert significant control over our management and affairs requiring stockholder approval, including approval of significant corporate transactions. This concentration of ownership may have the effect of delaying or preventing a change in control and might adversely affect the market price of our common stock. This concentration of ownership may not be in the best interests of all our stockholders.

We do not anticipate paying dividends in the foreseeable future, and the lack of dividends may have a negative effect on the stock price. While there are no restrictions on the payment of dividends, we have not declared or paid any cash dividends or distributions on our common stock in the last two fiscal years. We currently

intend to retain our future earnings to support operations and to finance expansion and, therefore, do not anticipate paying any cash dividends on our common stock in the foreseeable future.

Our certificate of incorporation and Delaware law contain certain anti-takeover provisions that may inhibit a takeover, and we may adopt other measures to discourage a takeover. Delaware law and provisions in our certificate of incorporation, including those related to a classified board of directors, may have the effect of not only discouraging attempts by others to buy us, but also of making it more difficult or impossible for existing stockholders to make management changes. Our board of directors is divided into three classes. Directors in each class are elected for terms of three years. As a result, the ability of stockholders to effect a change in control of us through the election of new directors is limited by the inability of stockholders to elect a majority of our board of directors at any particular annual meeting. Our board may consider and adopt additional measures that would prevent us from being subject to a takeover.

ITEM 2. DESCRIPTION OF PROPERTIES

Our corporate headquarters are located at 10300 North Central Expressway, Suite 104, Dallas, Texas, in approximately 1,274 square feet of space occupied under a lease with a monthly rental rate of $1,433.25 that expires in June 2004. Prior to September 2003, we occupied additional space in a freestanding 4,000 square foot building on 4.5 acres in Denison, Texas under a month-to-month lease. The Denison facility housed our clean room and is owned by Dr. Ronald A. Schachar, the former chairman and Chief Scientist of Ocular. The rent for the Denison facility was $4,000 per month. We terminated the lease for the Denison facility effective August 31, 2003. Mr. Walts, a director and our Chief Executive Officer and President, is based in Atlanta, Georgia.

ITEM 3. LEGAL PROCEEDINGS

From time to time we may become subject to proceedings, lawsuits and other claims in the ordinary course of business, including proceedings related to our products and other matters. Such matters are subject to many uncertainties, and outcomes are not predictable with assurance.

In March 2000, we filed suit against Surgilight for patent infringement in the United States District Court for the Middle District of Florida, Orlando Division. We own multiple domestic and international patents. Certain of these patents are directed to methods, devices and systems for the treatment of presbyopia and other eye disorders. One of these patented methodologies is directed to the use of lasers to weaken the sclera (the white of the eye), and thereby manipulate the ciliary muscle to treat presbyopia. Our international patent portfolio is directed to, and includes within its scope, various means and methodologies that increase the effective working distance of the ciliary muscle in a presbyopic eye. By using lasers to ablate the sclera, we asserted that Surgilight infringed upon one or more of our patents.

In December 2001, we accepted a cash settlement from Surgilight. In conjunction with that settlement, Surgilight acknowledged the validity and enforceability of our patents. The settlement did not include a license of any of our technology to Surgilight.

In May 2000, we filed a patent infringement suit against Howard N. Straub, D.O., the Colorado Eye Institute, Restorvision, Inc. and LensTec, in the United States District Court for the District of Colorado. We alleged that Straub had performed, or arranged for the performance of, surgical procedures on United States citizens and in foreign countries in which unauthorized copies of our patented PSI were used. We and our patent counsel believe that the copies of the PSI created by the defendants are covered under existing patents issued to us. In June 2002, the Court granted a motion jointly proposed by both parties that stayed the litigation for a period of twelve months. The Court granted an additional twelve month stay in 2003. During this period, the United States Patent and Trademark Office will continue its investigation into the validity of Restorvision's patent applications.

If the Patent Office issues a patent on Restorvision's modification, our patent counsel and we believe that Restorvision would still be required to obtain a license to our underlying patents prior to marketing the Restorvision modification in the United States and in many countries around the world.

To encourage medical and scientific research that might otherwise constitute patent infringement in the United States, Congress has provided a limited patent infringement exemption. This exemption, found at 35 U.S.C. § 271(e)(1), provides that a person does not commit an act of infringement by using patented technology "solely for uses reasonably related to the development and submission of information" to the FDA. This exemption applies equally to patented drugs and medical devices. In the Surgilight and Straub suits, the defendants attempted to rely upon this exemption as part of their defense. We disputed that the defendants' activities are protected by the exemption. We contend, among other things, that in order for activities to be undertaken solely for the purposes of submitting information to the FDA, the activities must comply with the regulations of the FDA. We believe that the defendants have violated FDA regulations and are not protected by the exemption. We further believe that any activities not permitted under this exemption, such as commercial activities in the United States, are violations of our patents.

In May 2001, we also filed suit against Douglas Steel, M.D. We alleged in the suit that Dr. Steel copied, manufactured and sold in the United States a scleral prosthesis developed and patented by us. We further alleged that Dr. Steel performed numerous commercial surgeries in the United States to treat presbyopia in accordance with procedures developed and patented by us. The United States District Court for the Central District of California issued a preliminary injunction in late May 2001 against Dr. Steel, as requested by us. In October 2001, we accepted a cash settlement from Dr. Steel. The settlement did not include a license of any of our technology to Dr. Steel.

We have notified certain other potential infringers of potential litigation, but are not currently engaged in other litigation.

ITEM 4. SUBMISSION OF MATTERS TO A VOTE OF SECURITY HOLDERS

None

PART II

ITEM 5. MARKET FOR CORPORATION'S COMMON EQUITY AND RELATED STOCKHOLDER MATTERS

On April 16, 2002, shares of common stock of VeryBestoftheInternet.com became eligible for quotation on the NASD Electronic Bulletin Board under the symbol "VYIB.OB". On February 25, 2003, the symbol was changed to "RFCG.OB". No trades, however, were ever made with respect to shares of Refocus common stock prior to the merger, which was effective March 6, 2003. As a result, the range of high and low bid information for shares of Refocus common stock for each full quarterly period within the two most recent fiscal years is not available. The range of high and low bids for shares of Refocus common stock by quarter since the closing of the merger through December 31, 2003 are as follows, based on bids that represent prices quoted by broker-dealers on the OTC Bulletin Board System (these quotations reflect inter-dealer prices, without retail mark-up, mark-down or commissions, and may not represent actual transactions):

Year 2003:	High	Low	Dividends Paid
First Quarter since March 6, 2003	$ 5.50	$ 3.50	$ 0.00
Second Quarter	3.70	1.50	0.00
Third Quarter	2.25	1.05	0.00
Fourth Quarter	1.80	0.36	0.00

Ocular stock, prior to the merger, was not traded on a public trading market, and Ocular had no registered securities outstanding.

As of March 26, 2004, there were 23,382,182 shares of Refocus common stock outstanding with approximately 377 stockholders of record.

Dividend Policy

While there are no restrictions on the payment of dividends, we have not declared or paid any cash or other dividends on shares of Refocus common stock in the last two fiscal years and presently have no intention of paying any cash dividends in the foreseeable future.

Equity Compensation Plan Information

Information relating to Refocus' equity compensation plans will be set forth in our 2004 Proxy Statement for the Annual Meeting of Stockholders.

Transactions and Sales of Unregistered Securities:

We consummated a private placement on December 23, 2003 resulting in the issuance of 4,425,000 units at $.50 per unit. Each unit consisted of a share of our common stock with a detachable warrant to purchase one-half share of our common stock at an exercise price of $2.00 per share. We issued a total of 4,425,000 shares of our common stock and warrants to purchase an aggregate of 2,212,500 shares of our common stock. We received gross proceeds of $2,212,500. We paid $185,000 in agent fees and $81,348 for legal, audit, and other private placement costs. As consideration for services provided to us, we issued warrants to purchase an aggregate of 170,000 shares of our common stock at an exercise price of $2.00 per share to the agent. All the $2.00 warrants issued in connection with the private placement expire in December 2006. In addition, a warrant that had been issued to that agent in March 2003 to purchase 200,000 shares of our common stock at an exercise price of $2.50 per share was cancelled and re-issued at the same exercise price but with an expiration date of December 23, 2006.

The shares of our common stock and warrants to purchase shares of our common stock that were issued in the private placement were not registered under the Securities Act of 1933 and, as a result, are "restricted securities" and may not be offered or sold in the United States absent registration or an applicable exemption from registration requirements. Certificates and agreements representing these shares and warrants, respectively, contain a legend stating the same. These securities were issued by us in reliance upon an exemption from registration set forth in Section 4(2) of the Securities Act of 1933 and Rule 506 promulgated under that act. The issuance of the shares of our common stock to the investors in the private placement was undertaken without general solicitation or advertising. The investors represented to us that, among other items, they were acquiring these securities for investment purposes only and not with a view toward public distribution and that they were accredited investors within the meaning of Rule 506. Moreover, we filed with the Securities and Exchange Commission a Form D pursuant to Rule 506 with respect to this transaction.

The participants in this private placement who invested in our March 6, 2003 private placement, which was previously disclosed in our Annual Report on Form 10-KSB for the year ended December 31, 2002, and who invested an amount equal to their second tranche commitment under the terms of the March 2003 private placement, were relieved of that second tranche commitment. In addition, the shares issued to these investors in the first tranche of the private placement were released from any trading restrictions imposed by a lock-up agreement agreed to by those participants.

Pursuant to the terms of the private placement, we agreed to register for resale under the Securities Act of 1933 the shares of our common stock and shares of our common stock acquirable upon exercise of the warrants issued in the private placement. Such shares were included in a registration statement filed with the Securities and Exchange Commission, but that registration statement has not yet been declared effective as discussed below.

As a result of the Transfer Agreement with CIBA entered into in January 2004, one of the conditions precedent to the closing of the second tranche of the March 2003 private placement, previously disclosed in Item 5 of our Annual Report on Form 10-KSB for the year ended December 31, 2002, cannot be fulfilled. Therefore, we can no longer compel the investors in the first tranche of the private placement to fund the second tranche and the closing of the second tranche will not occur.

We originally filed with the Securities and Exchange Commission a Registration Statement on Form SB-2 (File Number 333-108440) in September 2003. We filed an amendment in February 2004. The registration statement has

not yet been declared effective. The registration statement seeks to register the resale of shares of our common stock and shares of our common stock underlying warrants already held by certain stockholders. We will not receive any proceeds from the sale of those securities, except to the extent amounts are received for the exercise of warrants into our common stock.

ITEM 6. MANAGEMENT'S DISCUSSION AND ANALYSIS OR PLAN OF OPERATIONS

REFOCUS GROUP, INC. AND SUBSIDIARIES
MANAGEMENT'S DISCUSSION AND ANALYSIS OR PLAN OF OPERATIONS
DECEMBER 31, 2003

The following discussion and analysis of the financial condition and results of operations of Refocus Group, Inc. and its subsidiaries should be read in conjunction with the financial statements and related footnotes included in Item 7. All dollar amounts presented in this section have been rounded to the nearest thousand, except per share amounts.

The following discussion and analysis contains "forward-looking statements" that are based on the assumptions, beliefs and opinions of management. Such statements reflect our current views with respect to future events and involve known and unknown risks, uncertainties and other factors that may cause our actual results, levels of activity, performance or achievements to be materially different from what management currently believes. See a more detailed discussion about such statements prior to "*Item 1. Description of Business*". Also see those risks described in "*Cautionary Statements*" above.

Overview

On March 6, 2003, Refocus Group, Inc. ("Refocus") and Refocus Ocular, Inc. ("Ocular"), formerly known as Presby Corp ("Presby"), entered into a merger agreement (the "Merger Agreement"). On March 6, 2003 (the "Merger Closing Date"), a newly created, wholly-owned subsidiary of Refocus was merged with and into Ocular, with Ocular surviving as a wholly-owned subsidiary of Refocus. In addition, on the Merger Closing Date, Refocus completed the first tranche of a private placement of its shares of common stock.

After the merger, Refocus discontinued its previous business as an internet website ranking service, the founders of Refocus resigned their positions, and Refocus succeeded to the business of Ocular. For accounting purposes, the merger was accounted for as a reverse merger, whereby Ocular was deemed to be the accounting acquirer of Refocus since the former stockholders of Ocular owned a majority of the issued and outstanding shares of common stock of Refocus on the Merger Closing Date, including those shares issued in the first tranche of the private placement that closed on that date. Therefore, all financial information included in this report prior to the Merger Closing Date is that of Ocular as if Ocular had been the reporting entity. The audited financial information in this report is also that of Ocular, as it provides the most relevant information for Refocus on a continuing basis.

All references to "Refocus", "Presby", "Ocular", "we", "us", "our", or the "Company" mean Refocus or Ocular, as the former Presby, separately prior to the Merger Closing Date and Refocus, as successor to the business of Ocular, after giving effect to the merger.

We are a medical device company based in Dallas, Texas, engaged in the research and development of surgical treatments for human vision disorders. We may also use our research and understanding of the human eye to develop and patent technology for use with commercial optical lens applications.

Our principal products are the patented PresVIEW Scleral Implant (the "PSI") and the PresVIEW Incision System, which consists of the surgical instruments used to implant the PSI in the human eye. The PSI and the PresVIEW Incision System are utilized in our surgical technique, the Scleral Spacing Procedure (the "SSP"), for the treatment of presbyopia, ocular hypertension and primary open angle glaucoma in the human eye. Presbyopia, the Greek word for "old eye", is the primary reason that a substantial portion of the population beginning in their early 40s uses bifocals, reading glasses or removes their distance glasses in order to read at a comfortable distance. We believe that the SSP treats presbyopia by reducing the crowding of the underlying tissues surrounding the crystalline lens, which allows the muscles to once again reshape the lens to restore the eye's ability to accommodate or focus. In the case of ocular hypertension and primary open angle glaucoma, we believe that the SSP restores the natural base-line tension of the muscle inside the eye, which permits the eye to drain naturally and, thus, lower the intraocular pressure.

We have additional products in early-stage research, including a medical device for the treatment of dry age-related macular degeneration ("ARMD") and a single element variable focus lens ("SEVFL") for use in commercial optical applications.

In addition, you should be aware that we may not be able to continue as a going concern over the next twelve months if additional funding is not obtained. See the discussion in "*Liquidity and Capital Resources*" below.

The Merger and March 2003 Private Placement

As a result of the March 2003 private placement discussed below and immediately prior to the merger, the holders of Ocular's Series B preferred stock and Series C preferred stock converted their shares into common stock of Ocular. At the same time, Ocular completed a 2.14-to-1 reverse split, resulting in 11,940,144 shares of Ocular common stock outstanding, including the shares of common stock issued upon conversion of the preferred stock.

Each share of Ocular common stock outstanding on the Merger Closing Date was converted into common stock of Refocus on a one-for-one basis. Therefore, Refocus issued 11,940,144 shares of common stock to the stockholders of Ocular, representing approximately 63% of Refocus' outstanding common stock following the merger and the funding of the initial tranche of the March 2003 private placement, in exchange for 100% of the outstanding capital stock of Ocular. Following the merger, all of Refocus' business operations are conducted through its wholly-owned subsidiary, Ocular. Because Refocus did not have any significant business prior to the merger and its former operations were discontinued after the merger, there was no goodwill or other intangibles that arose from the merger.

As part of the Merger Agreement, Refocus assumed the Amended and Restated Presby Corp 1997 Stock Option Plan and all outstanding options (after they were adjusted for the 2.14-to-1 reverse split) to purchase Ocular common stock were converted into options to purchase 719,486 shares of Refocus common stock.

In connection with the merger, we completed a private placement of shares of our common stock that was to be consummated in two tranches, with 50% of the total subscribed paid with each tranche. The first tranche closed on the Merger Closing Date and consisted of 2,875,000 units at $2.00 per unit. Each unit was comprised of a share of our common stock and a detachable three-year warrant to purchase one-half of a share of our common stock at an exercise price of $2.50 per share. As a result, the investors in the first tranche of the private placement were issued 2,875,000 shares of our common stock and warrants to purchase 1,437,500 shares of our common stock. In addition, 12,500 shares of our common stock, three-year warrants to purchase 1,250,000 shares of our common stock at an exercise price of $2.50 per share and five-year warrants to purchase 50,000 shares of our common stock at an exercise price of $2.00 per share were issued to agents and others involved in the private placement.

We paid certain agent and advisory fees and legal, audit and other private placement costs from the proceeds received from the offering as follows:

Proceeds from the offering: 2,875,000 units at $2.00 per unit	$5,750,000
Amounts paid to placement agent and advisors	(577,000)
Legal and audit fees incurred	(620,000)
Expenses incurred by advisors	(147,000)
Expenses incurred by us	(90,000)
Payment to founders of Refocus for their stock	(25,000)
Cash received from the offering	$4,291,000

Investors who participated in the first tranche of the March 2003 private placement were required to irrevocably commit to the second tranche, with the remaining 50% of the funds from the private placement to be paid at the closing of the second tranche. The closing of the second tranche was contingent on certain conditions precedent. One of the conditions, an additional investment by CIBA Vision AG ("CIBA"), will not be met as a result of an agreement reached between CIBA and us in January 2004 (see "*CIBA Agreements*" below) and, therefore, the second tranche will never be funded.

The shares issued in the first tranche are subject to lock-up agreements. Only 9% of the shares held by a first tranche investor can be sold each month starting on the earlier of the effective date of a registration statement cover-

ing those shares or March 6, 2004. These lock-up agreements expire March 6, 2005. Those first tranche investors who participated in the December 2003 private placement (see discussion below) had their lock-up agreements waived. Therefore, of the 2,875,000 shares issued in the first tranche, 1,806,250 are still subject to lock-up agreements.

In April 2003, we engaged an agent to conduct a post-closing private placement. The post-closing private placement offering expired September 6, 2003, without being funded. We wrote off $192,000 of deferred offering expenses in connection with the offering. These expenses are included in "Selling, general and administrative" expenses for the year ended December 31, 2003. In the event that at least $1,000,000 was not raised in a post-closing private placement within six months of March 6, 2003, on terms no less favorable than the private placement consummated in March 2003, another party, Verus Support Services, Inc. ("Verus"), subscribed to purchase that number of units at $2.00 per unit in order to satisfy the deficiency between the amount of additional capital successfully raised and $1,000,000. Each unit would have consisted of a share of our common stock and a detachable warrant to purchase one-half of a share of our common stock at an exercise price of $2.50 per share. Since no funds were received from a post-closing private placement, Verus is required to fund the entire $1,000,000. We previously gave Verus an 120-day extension to their funding requirement in exchange for their forgiveness of $60,000 in consulting fees we owned them.

In January 2004, a dispute arose as to the continuing obligation of Verus under this agreement. As a means of deferring and ultimately resolving this dispute, we entered into an amendment to our agreement to further extend to June 30, 2004, Verus' obligation to purchase up to $1,000,000 of units and to make certain other amendments. Verus has advised us that its ability to provide the original subscription amount at a stock price well above current market is limited, and it indicated that current market conditions should be considered. Therefore, we have agreed to amend the funding obligation to permit Verus to reduce its funding obligation by:

- the surrender and cancellation of shares of our common stock and warrants to purchase shares of our common that were issued to Verus or its affiliates, assigns or designees, or investors in the March 2003 private placement, based on the current market price of our common stock,
- the waiver of the remaining $20,000 in advisory fees due to it under an existing consulting agreement,
- the waiver of up to $60,000 in advisory fees that might become due to it during the extension period, and
- an amount of $25,000 that was received from an investor in a December 2003 private placement since that investor was introduced to us by Verus.

Further, after the credit of these amounts to the funding obligation, Verus has agreed to subscribe for and purchase, or cause to be subscribed for and purchased, an amount of our common stock at prevailing market prices equal to 1.25 times the remaining funding obligation. We believe that this agreement is in our best interest and may result in funding during this extension period; however, we cannot be assured that Verus will not continue to dispute this obligation.

CIBA Agreements

In March 2002, we entered into a license agreement with CIBA (the "CIBA Agreement") pursuant to which CIBA obtained an exclusive license to our patents related to the treatment of presbyopia, ocular hypertension and primary open angle glaucoma in international markets. CIBA also had the right in the CIBA Agreement to acquire a license for our products in the United States. We were entitled to receive a percentage royalty on CIBA's worldwide sales of the PSI and related products under the CIBA Agreement. Upon entering into the CIBA Agreement, CIBA paid us $2,000,000 in advance royalties and was committed to purchase equity interests in us if we obtained certain other investments from third-parties. Simultaneously with our receipt of third-party investments in the first tranche of the March 2003 private placement, CIBA purchased 625,000 shares of our common stock and a warrant to purchase 312,500 shares of our common stock at an exercise price of $2.50 per share for an aggregate purchase price of $1,250,000. In addition, CIBA was committed to make an additional $1,250,000 investment at the closing of the second tranche of the March 2003 private placement.

Under the CIBA Agreement, CIBA was responsible for manufacturing, marketing and distributing our products worldwide at its expense. CIBA was also responsible for regulatory matters outside the United States and was com-

mitted to jointly manage the United States Food and Drug Administration (the "FDA") clinical trials with us. In accordance with the CIBA Agreement, we ceased all direct manufacturing and marketing of the PSI and related products. As a result of the transition of those manufacturing responsibilities to CIBA, the modifications in the packaging of the PSI and the resultant changes to those processes, the CE Mark certification we had obtained in 2000 on the PSI is no longer applicable. CIBA has been seeking CE Mark certification of the PSI for its planned marketing efforts in the European Union in early 2004. That CE Mark certification of the PSI is still pending. Late in 2003, a CE Mark certification of the components of the PresVIEW Incision System was obtained by the suppliers of those components.

In August 2003, CIBA announced that it was seeking strategic alternatives for its surgical business unit, including the sale of that unit. CIBA's surgical business unit marketed a variety of ophthalmic products and was primarily responsible for performing the CIBA Agreement. On December 29, 2003, CIBA informed us that it was exiting the surgical business and expected to complete the sale of the surgical business unit's various product lines to a variety of parties by early 2004. In conjunction with that sale, CIBA received an offer from a third-party to purchase CIBA's rights under the CIBA Agreement. Pursuant to the CIBA Agreement, the transfer of the license required our consent. As a condition to the assumption of CIBA's duties associated with that proposed license assignment, the third-party requested the renegotiation of certain key terms of the license agreement. After deliberation, we declined to renegotiate the license and did not permit the assignment of the license to the third-party. As a result, we began negotiations with CIBA for the transfer of CIBA's rights under the CIBA Agreement back to us and the termination of the license.

In January 2004, we entered into an agreement with CIBA, the License Transfer and Transition Services Agreement (the "Transfer Agreement"). Pursuant to the Transfer Agreement, we reacquired all worldwide license rights to our patents that were granted to CIBA under the CIBA Agreement, and CIBA was released from all future financial commitments, including its commitment to fund $1,250,000 at the closing of the second tranche of the March 2003 private placement and its obligations associated with manufacturing, marketing, distribution and regulatory matters. Under the Transfer Agreement, CIBA has agreed to provide us with certain transition services during 2004, including efforts to finalize the CE Mark certification of the PSI. These transition services will help us transfer the manufacturing, distribution and marketing functions back to us from CIBA. If CIBA obtains CE Mark certification of the PSI, CIBA and we will enter into a technical agreement, which will permit us to directly sell our products in CIBA packaging during 2004 in the European Union while we seek our own CE Mark certification. As consideration for the acquisition of CIBA's license rights, the forgiveness of the $2,000,000 in prepaid royalties we received under the CIBA Agreement and the transition services to be performed by CIBA under the Transfer Agreement, we agreed to pay CIBA an aggregate of $3,000,000 in twelve quarterly installments commencing in the first calendar quarter of 2006. We, however, are entitled to prepay and extinguish our payment obligations by paying an aggregate amount of $2,000,000 to CIBA prior to January 1, 2006.

Under the Transfer Agreement, CIBA has also agreed to return the warrant to purchase 312,500 shares of our common stock that it acquired in the March 2003 private placement. While it will retain the 625,000 shares of common stock acquired at the same time, these shares will be subject to certain restrictions on their transfer.

We expect that the transition from CIBA will result in a significant increase in costs for us related to performing functions that CIBA had assumed under the CIBA Agreement. Conversely, however, we will be entitled to all gross proceeds from the sale of our products instead of a royalty based on a percentage of sales as previously specified in the CIBA Agreement. Even assuming that CIBA obtains the CE Mark certification of the PSI, our ability to directly market our products in the European Union is currently limited. The anticipated date of the initial sale of our products in the European Union is likely to be delayed, and the number of PresVIEW Incision System and PSI units sold is likely to be reduced, in the short term and especially in 2004, relative to the number of unit sales that could have been achieved by CIBA. We may seek to market the PSI and PresVIEW Incision System in the European Union and elsewhere directly or through other distribution, license or strategic arrangements. Therefore, as a result of the increased expenses and potential for delayed revenues, we believe that the Transfer Agreement may have a material adverse impact on our financial condition in the short term. We believe that the reacquisition of our license will be in the best long-term interest of our stockholders.

Dr. Schachar's Separation and Consulting Agreement

On February 25, 2003, Dr. Ronald A. Schachar, our founder and former Chief Scientist, and we entered into a Severance, Release and Consulting Agreement (the "Consulting Agreement"). In accordance with the Consulting Agreement, Dr. Schachar resigned as an officer, director and employee of us at the Merger Closing Date. We agreed to retain Dr. Schachar as a consultant for a period of up to five years, and he agreed not to compete with us during that time. Dr. Schachar will assist us in conducting research and development on our products for the treatment of ARMD for the initial two years of the Consulting Agreement and will assist in the maintenance of our patent portfolio and other matters for the entire term of the Consulting Agreement.

Subject to certain conditions, Dr. Schachar will be paid $1,750,000 over the consulting period, of which $950,000 will be paid in the first two years. The timing of the remaining $800,000 due in years three through five is partially dependent on our profitability in those years; however, Dr. Schachar is guaranteed to receive a minimum of $250,000, but not more than $400,000, for each of the third and fourth years, with the remainder, if any, to be paid in the fifth year.

As security for the payment of his consulting fees, we granted Dr. Schachar a non-exclusive security interest in our patent rights relating to the ARMD device and the SEVFL. Dr. Schachar also received an assignment of our patents for the ARMD device outside the United States, which is revocable under certain conditions.

We recorded the present value of the future payments under the Consulting Agreement as a liability on the balance sheet at March 31, 2003. We allocated the liability and the value of the ARMD patents assigned to Dr. Schachar to prepaid consulting and research and development expenses, to a non-compete agreement and to severance expense.

December 2003 Private Placement

On December 23, 2003, we successfully completed a private placement of 4,425,000 units at a purchase price of $0.50 per unit. Each unit consisted of a share of our common stock and a three-year warrant to purchase one-half of a share of our common stock at an exercise price of $2.00 per share. An agent involved in the private placement received a three-year warrant to purchase 170,000 shares of our common stock at an exercise price of $2.00 per share. In addition, a warrant that had been issued to that agent in March 2003 to purchase 200,000 shares of our common stock at an exercise price of $2.50 per share was cancelled and reissued at the same exercise price but with an expiration date of December 23, 2006.

We paid certain agent fees and legal, audit and other private placement costs from the proceeds received from the offering as follows:

Proceeds from the offering: 4,425,000 units at $.50 per unit	$2,212,000
Amount paid to agent	(185,000)
Legal and audit fees incurred	(69,000)
Expenses incurred by agent	(7,000)
Expenses incurred by us	(5,000)
Cash received from the offering	$1,946,000

The funds received will be primarily used to fund our Phase II clinical trials for the surgical treatment of presbyopia (see below). For an investor who participated in this private placement in an amount equal to or greater than that investor's investment in the initial tranche of the March 2003 private placement, we waived that investor's lock-up arrangement on their common stock and warrants acquired in the March 2003 private placement.

Other

In November 2002, we, along with CIBA, submitted to Health Canada an application for approval to commercialize the PSI in surgery for the treatment of ocular hypertension, primary open angle glaucoma and presbyopia. On June 13, 2003, Health Canada informed us that it had determined that the sample size submitted in our application was insufficient for approval, and denied the application. Based on further discussions with Health Canada in Octo-

ber 2003, we will need to perform further clinical trials at more sites and with significantly more patients in order to receive approval for commercial sales. We are uncertain, at this time, as to when we may receive Health Canada's approval, but we believe it will not be until at least 2005 before the results of these additional clinical trials can be resubmitted. Our immediate focus, however, is currently on the FDA clinical trials and not those in Canada.

In March 2003, an investigational device exemption application was submitted to the FDA to obtain approval for initiating our Phase II clinical trials for the surgical treatment of presbyopia utilizing the PSI and SSP. This application was followed by later amendments. In December 2003, we received approval to begin our Phase II clinical trials of the PSI and SSP for the treatment of presbyopia. The FDA approval was conditioned on our submittal of certain final documentation concurrent with the initiation of the clinical study. We started these clinical trials in the first quarter of 2004.

See "Liquidity and Capital Resources" below for a discussion of our expected cash inflows, cash requirements and operating plan.

Application of Critical Accounting Policies

The process of preparing financial statements in conformity with accounting principles generally accepted in the United States of America requires the use of estimates and assumptions that affect the reported amounts of assets, liabilities, revenues and expenses. These estimates and assumptions are based upon the best information available at the time. These estimates and assumptions could change materially as conditions within and beyond our control change. Accordingly, actual results could differ materially from these estimates. The following are the most significant accounts affected by these estimates.

Revenue recognition – Sales will be recognized when product has been shipped. We do not sell our products with a right of return. Any amounts received for training or seminars will be recognized at the time the training or seminar takes place.

As a result of the suspension of sales of our products in 2001, while we were developing the PresVIEW Incision System, and the continued suspension of sales as a result of CIBA Agreement, pursuant to which CIBA was supposed to exclusively handle our future sales and marketing, we have encouraged customers not to perform the SSP using the PSI until the PresVIEW Incision System is available, and we and/or CIBA were ready to begin sales of the PSI again. The packaging of the PSI provided guaranteed sterility only for a limited time, and the sterility date on the PSIs still held by our customers has expired. An estimated liability of $50,000 was recorded for the possible replacement of these PSIs at our historical manufacturing cost. The estimate was based on the total number of PSIs that had been sold by us less an estimate of the number already used. Rather than replace all the expired inventory, we may instead grant special pricing on future purchases to these surgeons. Actual claims by customers may exceed, and/or the cost of replacing the PSIs may be higher than, our estimates and additional charges may have to be taken.

In addition, certain physicians may have purchased surgical kits in anticipation of taking part in the FDA clinical trials. The physicians were aware that the product was not yet approved for use in the United States, and we did not sell the surgical kit with a right of return. Several of these physicians have requested a refund or have informed us that if they are not selected to participate in the clinical trials, they will be seeking a refund. Since we did not sell our products with a right of return, we do not believe we have any liability to repurchase these products.

As a result of our continued suspension of sales, we have been informed by two of our former foreign distributors that they are seeking refunds on unsold products remaining in their inventory. We did not sell our products with a right of return and do not believe we have any liability to repurchase these products.

As a result of the Transfer Agreement, we will be responsible for all future marketing. As part of future marketing programs in the United States or internationally, we may determine that it is in our best interest to provide some compensation in the form of product discounts or by other means to the surgeons who bought our kits, and did not get to participate in the FDA trials, or to foreign distributors of our products. At this time, we are currently unable to determine the amount of possible compensation, if any, that we may agree to pay in the future.

Income taxes – Deferred income taxes are provided for temporary differences between the basis of assets and liabilities for tax and financial reporting purposes. A valuation allowance is established for any portion of the deferred tax assets for which realization is not likely. We maintain a 100% valuation allowance against our deferred tax assets. The valuation allowance is subject to periodic review, and we may determine that a portion of our deferred tax assets may be realizable in the future.

Patent costs, trademarks, non-compete agreement and property and equipment – These assets are subject to periodic review to determine our ability to recover their cost. We must make estimates about their recovery based on future cash flows and other subjective data. We, in the future, may determine that some of these costs may not be recoverable, which may require us to adjust their capitalized value by writing off all or a portion of the value of these assets. The patents for the SEVFL have a carrying value of $173,000 and the patents for ARMD have a carrying value of $27,000 at December 31, 2003. Since these patents involve new technologies that have not been proven, we cannot yet determine whether these costs are recoverable. We believe that these technologies can be developed and will continue to carry these patents at their amortized value. At some future point, if we believe that we cannot develop these technologies or these technologies cannot be profitability developed, we will reduce the carrying value of these assets at that time to their estimated fair value.

Results of Operations

The Year Ended December 31, 2003 Compared to the Year Ended December 31, 2002

Revenues. There were no revenues for the years ended December 31, 2003 or December 31, 2002. The lack of sales resulted from (i) our suspension of sales in 2001 while we developed the PresVIEW Incision System and (ii) the CIBA Agreement in March 2002, pursuant to which CIBA assumed responsibility for all marketing and sales of the PSI and related surgical instruments. We had previously anticipated that future revenues would be generated from royalties on product sales and from milestone payments made under the CIBA Agreement. As a result of the Transfer Agreement that was effective in January 2004, future revenues are instead expected to be generated by sales of the product by us directly or through other distributors. No distribution contracts are in place at this time. Our immediate focus is on our FDA clinical trials and, because of the lack of funds, most of our available capital will be expended on these clinical trials. Therefore, we do not expect to be able to devote much management time or funds to international markets where we may receive approval to sell our products during the next year.

We had expected CIBA to start sales in European Union in the first quarter of 2004; however, as a result of the transition of marketing responsibilities under the Transfer Agreement, we will not begin sales as expected. CIBA is in the process of obtaining their CE Mark on the PSI. Assuming they are successful, CIBA and we will enter into a technical agreement, which will permit us to directly sell our products in CIBA packaging during 2004 in the European Union. Depending on the timing of their obtaining the CE Mark certification for the PSI and on our ability to supply products and training, sales in Europe may be delayed for several months, or possibly longer. In addition, we will have to obtain our own CE Mark by the end of 2004 in order to continue sales in the European Union after 2004.

Cost of Sales. There were no cost of sales for the years ended December 31, 2003 or 2002, as there were no revenues, as discussed above. Until we fully assume manufacturing operations from CIBA under the Transfer Agreement, and determine how we are going to distribute our products in international markets where we may receive approval to sell, we cannot accurately estimate what profit margins are to be expected from future sales.

Selling, General and Administrative Expenses. For the year ended December 31, 2003, selling, general and administrative ("SG&A") expenses were $1,172,000 compared to $889,000 for the year ended December 31, 2002, an increase of $283,000. The increase was due to increased costs for public relations of $266,000, director fees of $132,000 and other public company expenses of $68,000. In addition, insurance costs increased $158,000 as compared to the prior year. These increases were partially offset by decreased costs for leases of $156,000, for the write off of excess property and equipment of $61,000 and for other SG&A expenses of $124,000 compared to the prior year.

Public relations, director fees and other costs associated with being a public company increased as a result of our merger with Refocus in March 2003. Insurance costs increased primarily as a result of higher premiums for coverage for directors and officers as a result of our becoming a public company with the merger with Refocus. Lease costs decreased as a result of our moving to a smaller office in connection with the downsizing of our operations and the termination of our lease on our facility in Denison, Texas in the current year. The decrease in the write off of our property and equipment was also related to our downsizing, as was the decrease in other SG&A expenses. Both the downsizing and closing of our Denison facility were the result of the CIBA Agreement, whereby CIBA had assumed manufacturing, distribution, marketing and other operations from us starting in March 2002.

We expect additional costs related to being a public company to continue to negatively impact the comparison to the prior year through the first quarter of the next fiscal year. However, as a result of our liquidity concerns discussed below, we have temporarily eliminated most of our public relation costs since September 2003. We are currently unable to estimate the impact of the Transfer Agreement on our SG&A expenses going forward. It is likely that our SG&A expenses will increase as a result of the Transfer Agreement. However, due to our lack of funds and our immediate focus on our FDA clinical trials, we will try to minimize the impact the Transfer Agreement will have on our SG&A expenses.

Salary and Related Expenses. For the year ended December 31, 2003, these expenses were $1,224,000 compared to $1,170,000 for the year ended December 31, 2002. The increase of $54,000 was principally due to (i) a severance charge of $595,000 related to employee terminations, including Dr. Schachar's Consulting Agreement, as described above and (ii) bonus payments of $103,000. The increases were offset by a $644,000 decrease in salaries and related employee expenses.

The decrease in salaries and related expenses was due to the reduction in the number of employees reflecting the downsizing that took place as a result of the CIBA Agreement that was entered into in March 2002. The bonus payments were primarily required to maintain our key staff during the downsizing. We were able to significantly reduce staff because CIBA assumed responsibility for the manufacturing, distribution, and marketing of our PresVIEW products. The decrease also reflected an allocation to research and development of $89,000 for the year ended December 31, 2003 of salaries of certain personnel in 2003 involved full-time in research and development work.

Our salary and related expenses may increase in the future as we may hire additional personnel in connection with reestablishing our manufacturing, distribution, marketing and regulatory operations as a result of the Transfer Agreement. We cannot, at this time, determine to what extent our salary and benefits costs will increase.

Stock-based Compensation: Stock-based compensation was $792,000 for the year ended December 31, 2003 compared to $8,000 for the year ended December 31, 2002. The increase was primarily due to options issued to officers and directors in connection with our merger with Refocus and the completion of the private placement in March 2003.

Professional Services. Professional service fees were $1,337,000 for the year ended December 31, 2003 compared to $534,000 for the year ended December 31, 2002. The $803,000 increase in professional services was the result of an increase of $38,000 in auditing fees, $539,000 in consulting fees and $226,000 in legal fees.

Higher auditing fees are associated with being a public company. We expect that audit fees will probably not change significantly over the next year. The higher consulting fees are almost entirely related to investment advisors and bankers that provided services related to long-range financial planning and investor relations. We currently expect costs related to these consulting agreements with investment advisors and bankers will be the same or lower in the next twelve months as a result of the expiration of certain of these contracts. While legal fees increased between the two periods, the prior year costs related primarily to litigation expense associated with defending our patents, while the current year costs related primarily to the negotiation and drafting of the Consulting Agreement and to our being a public company.

Future costs related to defending our patents, hiring consultants for regulatory matters in various countries and hiring consultants to assist in the transition and management of operations assumed from CIBA under the Transfer Agreement will cause an increase in our consulting costs. The amount of that increase cannot be determined at this time. Legal costs related to our being a public company will continue to be significant.

Clinical Trials: The cost incurred for our FDA and other clinical trials increased $295,000 to $358,000 for the year ended December 31, 2003 compared to $63,000 for the year ended December 31, 2002. The increase in clinical trial costs consisted of an increase of $109,000 in consulting fees, $75,000 in salary expense associated with clinical trials, $77,000 in equipment purchased for doctors participating in the clinical trials, $20,000 in travel expenses and $14,000 in other expenses. The increase in consulting fees primarily relates to our contract with Promedica International ("Promedica") who will be managing our Phase II FDA clinical trials and had already started preliminary work for those trials in 2003. The increase in salaries and travel expenses reflects our hiring of a full time director of clinical affairs to oversee the trials and work with Promedica and the physicians performing the clinical surgeries. Equipment purchases increased as we bought equipment for doctors participating in our Phase II clinical trials. Expenses have increased in the current year because we did not incur any material clinical trial expenses in the prior year while we continued development of the PresVIEW Incision System.

As a result of the funds obtained through the initial tranche of the private placement in March 2003 and the private placement in December 2003, we will be able to fund the start our Phase II FDA clinical trials now that we have obtained FDA approval. We expect that costs in the coming months will be materially higher than comparable periods of the prior year as we ramp up these clinical trials. Contingent on the availability of funding, we had projected spending approximately $2,406,000 related to these clinical trials during 2004. However, the actual cost is subject to many variables, some of which are beyond our control. Therefore, the actual amount that will be spent and when such funds will be needed may be materially different than this projection. We currently do not have adequate resources to complete the FDA clinical trials in the United States. Additional funding will be needed to complete these trials.

Research and Development Expense. Research and development expense decreased $58,000 to $109,000 for the year ended December 31, 2003 compared to $167,000 for the year ended December 31, 2002. The decrease was the result of incurring $162,000 less in expenses, which was partially offset by (i) a charge of $89,000 for salaries in 2003 for certain personnel devoting full time to research and development and (ii) a charge of $15,000 for the settlement of a dispute with a manufacturer of prototypes of the PresVIEW Incision System in 2003. Of the $162,000 decrease, $161,000 related to a decrease in costs incurred for the production and testing of the prototypes of the PresVIEW Incision device. Other research and development expenses decreased $1,000. The increase in salaries was the result of the allocation of salaries for employees who were working full-time in this area in 2003. These employees were terminated during the quarter ended June 30, 2003. Most of our expenditures related to the development of the PresVIEW Incision System were incurred prior to 2003.

Research and development expenses are not expected to increase materially in the near term. Most of our future research and development on the ARMD device will be done by Dr. Schachar as part of his Consulting Agreement. We do not expect to spend any additional funds on research for the SEVFL during the next year. However, as a result of the Transition Agreement, we may spend additional funds on the further enhancement of the PresVIEW Incision device over the next year.

Depreciation and Amortization Expense. Depreciation and amortization expense was $604,000 for the year ended December 31, 2003 compared to $123,000 for the year ended December 31, 2002. Of the $481,000 increase, amortization of patents and trademarks increased approximately $345,000, amortization of the non-compete agreement was $163,000, and depreciation decreased approximately $27,000.

The increase in patent and trademark amortization primarily reflects (i) the $253,000 write-off of certain of our PSI and SEVFL patents and (ii) the write-off of Presby and related device trademarks of $95,000, partially offset by a $3,000 decrease in amortization of patents. The write-off of the patents was related to a cost-benefit analysis performed by us and our patent attorney, whereby we decided not to maintain or pursue patents in countries where the cost of obtaining or defending those patents appeared to outweigh the potential return from sales of our products. We have continued to maintain or pursue patents in all major economic areas. The write-off of the trademarks related to the change in the Presby name to Refocus Ocular. Amortization decreased primarily as a result of the write-offs during the year. The amortization of the non-compete agreement began in March 2003 as a result of the capitalization of the non-compete component of the Consulting Agreement. Depreciation decreased primarily due to the write-off of surplus furniture and equipment in 2002, due to the reduction in their value in connection with the downsizing of our operations after the CIBA Agreement.

Other Income (Expense), Net. Other expense of $98,000 for the year ended December 31, 2003 consisted primarily of interest expense of $122,000 which was partially offset by $24,000 in interest income on our cash balances. Interest expense consisted of $1,000 paid on a bridge loan received in February 2003 to fund operations until the completion of the merger and private placement and $121,000 that represented the accretion of discount on the liability for the Consulting Agreement. Other income of $20,000 for the year ended December 31, 2002 was primarily interest income earned on cash balances held by us.

Income Taxes. We recorded no income tax benefit for either period. Any benefit related to the current or prior year's loss was offset by a corresponding increase in the deferred tax asset valuation allowance.

Preferred Dividends. Preferred dividends and the accretion of discount on the preferred stock were $4,000 for the year ended December 31, 2003. Preferred dividends and accretion of discount were $2,801,000 for the year ended December 31, 2002. The decrease from 2002 to 2003 was due to the July 2002 agreement with the Series B preferred stockholders, whereby the Series B preferred stockholders received approximately 1,199,837 additional shares of Series B preferred stock in 2002 in lieu of any future dividends on their shares, and the subsequent conversion of the Series B preferred stock to common stock in conjunction with the merger, which was consummated in March 2003.

The Year Ended December 31, 2002 Compared to the Year Ended December 31, 2001

Revenues. There were no revenues for the year ended December 31, 2002. Revenues for the year ended December 31, 2001 of $230,000 consisted of seminar revenues of $67,000 and $163,000 in sales of PSIs and surgical kits.

The decrease in product sales resulted from our decision to suspend sales of PSIs and surgical kits in early 2001 in order to develop an automated incision making tool, the PresVIEW Incision System, for use in the SSP. Since seminars were used by us to promote the sale of the PresVIEW technology, these were also suspended in 2001. In addition, as a result of the CIBA Agreement in March 2002, CIBA was to be responsible for all PSI and surgical kit sales and seminars in the future. As a result, we had anticipated generating future revenues from royalties from CIBA on product sales and from milestone payments CIBA would make under the CIBA Agreement and not from either seminars or from direct product sales for the PSI and related products. See the above discussion of the Transfer Agreement and its expected impact on revenues.

Cost of Sales. There were no cost of sales for the year ended December 31, 2002, as there were no revenues. Cost of sales were $223,000 for the year ended December 31, 2001 of which $182,000 related to seminar fees and $41,000 to sales of PSIs and surgical kits.

Selling, General and Administrative Expenses. For the year ended December 31, 2002, SG&A expenses were $889,000 compared to $1,036,000 for the same period in 2001. SG&A expenses decreased as a result of the CIBA Agreement, which allowed us to reduce the size of our operations as we would no longer be responsible for distribution, marketing and manufacturing.

Future SG&A expenses will reflect a full year of our decreased size. In addition, costs related to public relations, board of director fees, insurance and other public company costs will increase substantially after the merger discussed in the *"Overview"* above.

Salary and Related Expenses. For the year ended December 31, 2002, these expenses were $1,170,000 compared to $1,286,000 for the year ended December 31, 2001. Salaries in 2001 reflected the additional staff hired in association with the FDA feasibility clinical trials and the development of the PresVIEW Incision System in 2001. As a result of the CIBA Agreement, staffing was reduced during the year for marketing, administration, FDA clinical trials and engineering functions. The full impact of these reductions will not be recognized until future periods.

Stock-based Compensation: Stock-based compensation was $8,000 for the year ended December 31, 2002 compared to $160,000 for the year ended December 31, 2001. These amounts represent the value of options issued to a former president of ours under his employment contract.

Instrument Upgrade Costs. Instrument upgrade costs were $365,000 for the year ended December 31, 2001. The expenses primarily related to additions and modifications made to the associated hand-held instruments provided in a surgical kit. Instrument modifications or additions made to the surgical kit were generally provided at no charge to physicians that had previously purchased the surgical kit. We wanted to ensure that physicians were using the latest instrumentation in performing the SSP.

Inventory Adjustment Costs. Inventory adjustment costs were $128,000 for the year ended December 31, 2002. The costs primarily represented inventory write-downs related to the transfer of distribution and marketing to CIBA under the CIBA Agreement. Since the PSIs were to be manufactured by CIBA and packaged under the PresVIEW brand name, and since the surgical instruments in our inventory were to be replaced by the PresVIEW Incision System or by instruments branded by CIBA, we wrote off our remaining inventory less any expected recoveries.

Professional Services. Professional service fees were $534,000 in 2002 and $1,231,000 in 2001. The decrease in professional service fees related primarily to decreased costs of litigation initiated by us against companies and individuals allegedly infringing upon our patent rights partially offset by higher accounting and consulting fees. In the future, we expect public company costs related to consulting fees, legal fees and audit fees will increase substantially after the merger.

Clinical Trials. Clinical trial costs were $63,000 for the year ended December 31, 2002 compared to $194,000 for the year ended December 31, 2001. The prior year expense reflected primarily the costs related to the completion of FDA Phase I clinical trials, while the expense for 2002 primarily reflected certain costs related to obtaining FDA Phase II clinical trial approval. The low level of expenditures during 2002 reflected the delay in trying to start our Phase II clinical trials until the PresVIEW Incision System was ready. We expect a significant increase in expenditures related to the FDA clinical trials in the next fiscal year after the PresVIEW Incision System is ready.

Research and Development Expense. Research and development expense decreased to $167,000 for the year ended December 31, 2002 compared to $339,000 for the year ended December 31, 2001. The decrease was primarily related to the design, development and production of prototypes of the PresVIEW Incision System that started in 2001. The level of spending in 2002 decreased as most of the engineering had been done in 2001. In the future, research and development expenses are expected to decrease even further as testing and engineering on the PresVIEW Incision System is nearing completion.

Depreciation and Amortization Expense. Depreciation and amortization expense was $123,000 for the year ended December 31, 2002 compared to $119,000 for the year ended December 31, 2001. Of the $4,000 increase for the year ended December 31, 2002, amortization of patents and trademarks increased approximately $18,000 due to patent and trademark additions during 2002, while depreciation decreased approximately $14,000 primarily due to the write-off of surplus furniture and equipment.

Other Income (Expense), Net. Other income decreased to $20,000 for the year ended December 31, 2002, compared to $273,000 for the year ended December 31, 2001. Interest income decreased to $21,000 from $171,000 due to the decrease in interest rates and in cash available for investment. We have had to use our cash reserves for operations due to the lack of revenue after we suspended product sales. Other income includes a legal settlement of $115,000 in 2001, which also contributed to the decrease.

Income Taxes. We recorded no income tax benefit for either period. Any benefit related to the current or prior year's loss was offset by a corresponding increase in the deferred tax asset valuation allowance.

Preferred Dividends. Preferred dividends and the accretion of discount on the preferred stock were $2,801,000 for the year ended December 31, 2002 compared to $618,000 for the year ended December 31, 2001. The increase was due to the July 2002 agreement with the Series B preferred stockholders whereby the Series B preferred stockholders received approximately 1,199,837 shares of Series B preferred stock, valued at $2,455,000, in 2002 in lieu of any future dividends on their shares.

LIQUIDITY AND CAPITAL RESOURCES

Cash and cash equivalents were $3,000,000 at December 31, 2003. This represents an increase of $2,733,000 since December 31, 2002. The increase was primarily funded from the $6,431,000 in funds received from private placements of common stock during the year, which was partially offset by $3,468,000 in funds used for operations, additions to patents and trademarks of $225,000, and additions to property and equipment of $13,000. In order to fund operating expenses until the Merger Closing Date, we borrowed $250,000 in late February 2003, of which a majority was converted into our common stock at the closing of the March 2003 private placement. We paid interest of approximately $1,000 on this loan at the closing of that private placement.

With the funds received from the private placements in March 2003 and December 2003, we began our Phase II FDA clinical trials in the United States during the first quarter of 2004. We retained Promedica to assist in the management of these FDA clinical trials. We have five sites participating in this early phase of the clinical trials. We have incurred significant costs in preparation for the start of the clinical trials, which costs will continue to increase as the trials progress. We expect to spend an additional $1,228,000 by August 2004 related to the FDA clinical trials, subject to the availability of funds. The actual costs to be incurred are subject to many variables, some of which are beyond our control. Therefore, the actual amount that will be spent and when such funds will be needed may be materially different than our current projection. We currently do not have adequate resources to complete the FDA trials, which may continue for several years. Additional funding will be needed to complete these FDA clinical trials.

We cannot sell our products in the United States until they receive approval from the FDA, and there can be no assurance, even if we have adequate funding, that we will receive the necessary approvals. Clinical trials required to obtain regulatory approvals are complex and expensive, and their outcomes are uncertain. Negative or adverse results during a clinical trial could cause substantial delays in receiving approval. Delays may also arise from additional government regulations from future legislation, administrative actions or changes in FDA policies. Therefore, the actual time and expenditures required to pursue FDA approval cannot be predicted with certainty, and the amounts of additional funding needed for these clinical trials may not be available when needed.

We will not generate any significant revenue in 2004, as the expected re-introduction of the procedure in the European Union during 2004 will be delayed due to the Transfer Agreement with CIBA, remaining issues associated with the CE Mark certification of the PSI, and the lack of adequate funding. Even if the SSP is marketed in the European market during 2004, our marketing efforts may involve only a few physicians. These initial physicians would later train other physicians as well as generate surgical data that can be published to encourage other physicians to adopt our procedure. We do not presently have any plans to start the procedure in any other international markets during 2004.

As a result of the Transfer Agreement, we need to reestablish our own manufacturing, marketing, distribution, regulatory and other operational functions. If we decide to perform these functions directly, our expenses will increase substantially before any revenues from international sales could be achieved. We cannot be sure of our ability to finance these tasks due to their cost and our limited amount of funding. We may also determine that we prefer to establish strategic, license or distribution agreements with various regional partners for some operations. We can provide no assurance, however, that we will be able to establish agreements with third parties within a reasonable time frame. Therefore, as a result of increased expenses and the potential for delayed revenues, we believe that the Transfer Agreement will have a material adverse impact on our financial condition in the short term.

We have taken steps to preserve our cash to give us time to complete the first group of surgeries under the Phase II clinical trials, which results we anticipate will indicate the success of the SSP in treating presbyopia. In order to preserve our funds, we operate with only four full-time employees, have taken steps to significantly reduce our public relation costs and have deferred payments of consulting fees to financial advisors, with their concurrence. In addition, several of our directors have agreed to accept a portion of their director fees in stock rather than cash. However, in addition to our planned FDA clinical trial expenditures noted above, we also will pay approximately $433,000 to Dr. Schachar in 2004 in connection with his Consulting Agreement, will pay a former employee approximately $32,000 in 2004 under his severance agreement, and will continue to incur significant expenditures for costs related to being a public company, especially audit, legal, insurance and director fees. As noted above, the cost

of assuming the operating functions previously performed by CIBA under the CIBA Agreement may be very significant relative to our available funds. At this time, we cannot estimate the amount of, and when, funds will be required to reestablish the functions formerly performed by CIBA. We will concentrate our immediate efforts on our FDA clinical trials, and any operations or matters not directly connected with those clinical trials will probably be managed on a minimum funding basis.

We believe that the funds currently on hand will fund operations until approximately the first month of the 3rd quarter of 2004. Therefore, we do not have sufficient financial resources to fund our operations for the next twelve months. In addition, we will require substantial additional capital to fund our future operations and conduct our FDA clinical trials over the next several years. We may be required to seek additional funding through collaborative arrangements with corporate partners and through public or private debt or equity financings. Any equity financing may be dilutive to stockholders. Any debt financing may involve restrictions on our ability to pay dividends on our capital stock, may also be dilutive to stockholders if it involves conversion features or warrants, or may affect the manner in which we can conduct our business. We cannot give any assurances that additional equity or debt funding will be available in sufficient amounts, on terms acceptable to us, or at all, when needed. Our ability to raise additional capital depends on many factors, some of which are beyond our control, including the state of capital markets, the market price of our common stock and the prospects for our business. The inability to obtain sufficient funds may require us to delay, scale back or eliminate some or all of our research, clinical studies and/or regulatory activities or may cause us to cease operations. We may seek a merger partner or the sale of our assets if additional financing is not available. Our inability to obtain additional financing could have a material adverse effect on us.

We will be seeking additional equity funds as soon as possible, most probably after the initial results of our Phase II FDA trials are known. We anticipate that those results will indicate to prospective investors or corporate partners that the SSP is a successful treatment for presbyopia. We cannot assure you that the results will be available before funds are needed or that they will enable us to attract new funding.

OTHER

THIS ANNUAL REPORT ON FORM 10-KSB DOES NOT CONSTITUTE AN OFFER TO SELL OR SOLICITATION OF AN OFFER TO PURCHASE SECURITIES OF THE COMPANY. ANY OFFER OF SECURITIES MADE BY THE COMPANY OR OTHER PERSON ON BEHALF OF THE COMPANY MAY BE MADE ONLY PURSUANT TO MATERIALS AND OTHER OFFERING DOCUMENTS PREPARED BY THE COMPANY AND DELIVERED TO QUALIFIED PURCHASERS EXPRESSLY FOR USE IN CONNECTION WITH, OR PURSUANT TO AN EXEMPTION FROM, SECTION 5 OF THE SECURITIES ACT OF 1933. THE SECURITIES OFFERED WILL NOT BE REGISTERED UNDER THE SECURITIES ACT OF 1933 AND MAY NOT BE OFFERED OR SOLD IN THE UNITED STATES ABSENT REGISTRATION OR AN APPLICABLE EXEMPTION FROM REGISTRATION REQUIREMENTS.

Recently Issued Accounting Pronouncements: In April 2002, the Financial Accounting Standards Board ("FASB") issued Statement of Financial Accounting Standards ("SFAS") No. 145 "Rescission of FASB Statements No. 4, 44 and 64, Amendment of FASB Statement No. 13, and Technical Corrections". SFAS No. 13 is amended to eliminate any inconsistency between the required accounting for sale leaseback transactions and the required accounting for certain lease modifications that have economic effects that are similar to leaseback transactions. This statement also amends other existing authoritative pronouncements to make various technical corrections, clarify meanings, or describe their applicability under changed conditions. We adopted this standard in our fiscal year beginning January 1, 2003. There was no impact on our results of operations or financial condition as a result of the adoption of the standard.

In June 2002, the FASB issued SFAS No. 146 "Accounting for Costs Associated with Exit or Disposal Activities". This statement requires recording costs associated with exit or disposal activities at their fair value when a liability has been incurred. Under previous guidance, certain exit costs were accrued upon management's commitment to an exit plan, which is generally before an actual liability has been incurred. The provisions of this statement are effective for exit or disposal activities that are initiated after December 31, 2002. This standard did not have any impact on our results of operations or financial condition.

In November 2002, the FASB issued Interpretation No. 45 ("FIN 45") "Guarantor's Accounting and Disclosure Requirements for Guarantees, Including Indirect Guarantees of Indebtedness of Others". This interpretation elaborates on the disclosures to be made by a guarantor in its interim and annual financial statements about its obligations under certain guarantees that it has issued. It also clarifies that a guarantor is required to recognize, at the inception of a guarantee, a liability for the fair value of the obligation undertaken in issuing the guarantee. The disclosure requirements and initial measurement requirements of FIN 45 are effective prospectively for guarantees issued or modified after December 31, 2002. We are not a party to any agreement in which we are a guarantor of indebtedness of others. Accordingly, the pronouncement is currently not applicable to us.

In April 2003, the FASB issued SFAS No. 149 "Amendment of Statement 133 on Derivative Instruments and Hedging Activities". This statement amends SFAS No. 133 "Accounting for Derivative Instruments and Hedging Activities" for certain decisions made by the FASB. This statement is effective for most contracts entered into or modified, and for most hedging relationships designated, after June 30, 2003. Because we do not currently have any derivative instruments or hedging relationships, the adoption of this standard did not have any impact on our results of operations or financial condition.

In May 2003, the FASB issued SFAS No. 150 "Accounting for Certain Financial Instruments with Characteristics of both Liabilities and Equity". This statement establishes standards for how an issuer classifies and measures certain financial instruments with characteristics of both liabilities and equity. It requires that many instruments formerly classified as equity will be classified as liabilities. The statement does not apply to features that are embedded in a financial instrument that is not a derivative in its entirety. It also does not affect the classification or measurement of convertible bonds or other outstanding shares that are conditionally redeemable. Generally, these liabilities should initially be measured at fair value. The statement is effective for financial instruments entered into or modified after May 31, 2003 and, otherwise, shall be effective at the first interim period beginning after June 15, 2003. Restatement of financial statements issued for earlier periods is not permitted. Our former Series B redeemable preferred stock, which was exchanged for common stock in March 2003, was redeemable at the option of the holder. Therefore, this statement does not change the prior accounting for that preferred stock. We do not currently have any instruments affected by this statement and, therefore, the standard will not have any impact on our results of operations or financial condition.

In December 2003, the FASB issued SFAS No. 132 (revised 2003) "Employers' Disclosures about Pensions and Other Postretirement Benefits". This statement retains the disclosures provided in the original SFAS No. 132 but adds disclosures describing the type of plan assets, investment strategy, measurement dates, plan obligations, cash flows and components of net periodic benefit cost recognized during interim periods. The revised statement is generally effective for fiscal years ending after December 15, 2003. We do not currently have any contributory plans that would require the additional disclosures.

ITEM 7. FINANCIAL STATEMENTS

The audited financial statements and related footnotes of Refocus Group, Inc. and Subsidiaries can be found beginning with the Index to Consolidated Financial Statements following Part III of this Annual Report on page F-1.

ITEM 8. CHANGES IN AND DISAGREEMENTS WITH ACCOUNTANTS ON ACCOUNTING AND FINANCIAL DISCLOSURE

The information required by this item has been previously disclosed by the registrant.

ITEM 8A. CONTROLS AND PROCEDURES.

At the end of the period covered by this report, an evaluation was performed under the supervision and with the participation of Company's management, including the principal executive officer and principal financial officer, of the effectiveness of the design and operation of the Company's disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)). Based on that evaluation, our principal executive officer and principal financial officer concluded that the Company's disclosure controls and procedures were effective in timely accumulating, processing, recording and communicating to them material information related to the Company and its consolidated subsidiaries that are required to be disclosed by the Company in reports that it files or submits under the Exchange Act. There have not been any changes in the Company's internal controls over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) during the quarter ended December 31, 2003 that have materially affected, or are reasonably likely to materially affect, the Company's internal control over financial reporting.

PART III

The information called for by Part III Items 9, 10, 11, 12 and 14 is incorporated herein by reference to our definitive Proxy Statement for our Annual Meeting of Stockholders which is expected to be filed with the Securities and Exchange Commission within 120 days of December 31, 2003.

ITEM 13. EXHIBITS AND REPORTS ON FORM 8-K

(a) Exhibits

Exhibit No.	Description
2.1	Agreement of Merger and Plan of Reorganization, dated as of March 6, 2003, by and among the Registrant, Refocus Acquisition Corp. and Presby Corp (Filed as Exhibit 2.1 to the registrant's Current Report on Form 8-K filed March 12, 2003 and incorporated herein by reference.)
3.1	Certificate of Incorporation of the Registrant, dated as of January 10, 2003. (Filed as Exhibit 3.1 to the registrant's Current Report on Form 8-K filed March 12, 2003 and incorporated herein by reference.)
3.1.1	Certificate of Amendment of Incorporation of the Registrant, dated as of July 3, 2003. (Filed as Exhibit 3.1.1 to the registrant's Form SB-2 filed September 2, 2003 and incorporated herein by reference.)
3.2	Bylaws of the Registrant. (Filed as Exhibit 3.2 to the registrant's Current Report on Form 8-K filed March 12, 2003 and incorporated herein by reference.)
3.2.1	First Amendment to Bylaws of the Registrant. (Filed as Exhibit 3.2.1 to the registrant's Form SB-2 filed September 2, 2003 and incorporated herein by reference.)
4.1	Form of common stock certificate. (Filed as Exhibit 4.1 to the registrant's Current Report on Form 8-K filed March 12, 2003 and incorporated herein by reference.)
4.2	Form of Warrant to Purchase Common Stock, issued to certain investors, at $2.50 per share, expiring March 6, 2006. (Filed as Exhibit 4.2 to the registrant's Current Report on Form 8-K filed March 12, 2003 and incorporated herein by reference.)
4.3	Form of Warrant to Purchase Common Stock, issued to certain advisors, at $2.50 per share, expiring March 6, 2006. (Filed as Exhibit 4.3 to the registrant's Annual Report on Form 10-KSB for the year ended December 31, 2002 and incorporated herein by reference.)
4.4	Form of Warrant to Purchase Common Stock, issued to certain advisors, at $2.50 per share, expiring March 6, 2006. (Files as Exhibit 4.4 to the registrant's Annual Report on Form 10-KSB for the year ended December 31, 2002 and incorporated herein by reference.)
4.5	Form of Warrant to Purchase Common Stock, issued to an advisor, at $2.00 per share, expiring March 6, 2008. (Filed as Exhibit 4.5 to the registrant's Annual Report on Form 10-KSB for the year ended December 31, 2002 and incorporated herein by reference.)
4.6	Form of Warrant to Purchase Common Stock, issued to certain investors, at $2.00 per share, expiring December 23, 2006. (Filed as Exhibit 4.6 to the registrant's Form SB-2 Amendment No. 1 filed February 2, 2004 and incorporated herein by reference.)
4.7	Form of Warrant to Purchase Common Stock, issued to an agent, at $2.00 per share, expiring December 23, 2006. (Filed as Exhibit 4.7 to the registrant's Form SB-2 Amendment No. 1 filed February 2, 2004 and incorporated herein by reference.)
10.1	Amended and Restated Presby Corp 1997 Stock Option Plan. (Filed as Exhibit 10.1 to the registrant's Current Report on Form 8-K filed March 12, 2003 and incorporated herein by reference.)
10.2	Presby Corp Employees Savings Plan. (Filed as Exhibit 10.2 to the registrant's Current Report on Form 8-K filed March 12, 2003 and incorporated herein by reference.)

10.3	Confidentiality Letter Agreement, dated as of May 5, 1999, by and between RAS Holding Corp. and CIBA Vision Corporation. (Filed as Exhibit 10.3 to the registrant's Current Report on Form 8-K filed March 12, 2003 and incorporated herein by reference.)
10.4	Secrecy Agreement, dated as of August 21, 2001, by and among CIBA Vision Corporation, RAS Holding Corp. and Presby Corp (Filed as Exhibit 10.4 to the registrant's Current Report on Form 8-K filed March 12, 2003 and incorporated herein by reference.)
10.5.1	License Agreement, dated as of March 6, 2002, by and between Presby Corp and CIBA Vision AG. (Filed as Exhibit 10.5.1 to the registrant's Current Report on Form 8-K filed March 12, 2003 and incorporated herein by reference.)
10.5.2	First Amendment to License Agreement, dated as of March 11, 2003, by and between Presby Corp and CIBA Vision AG. (Filed as Exhibit 10.5.2 to the registrant's Current Report on Form 8-K filed March 12, 2003 and incorporated herein by reference.)
10.6	Employment Agreement, dated as of April 24, 1998, by and between RAS Holding Corp. and Mark A. Cox, and as amended December 1, 2002. (Filed as Exhibit 10.6 to the registrant's Current Report on Form 8-K filed March 12, 2003 and incorporated herein by reference.)
10.7	Employee Confidentiality and IP Rights Agreement, dated July 1997, by and between Presby Corp. and Mark A. Cox. (Filed as Exhibit 10.7 to the registrant's Current Report on Form 8-K filed March 12, 2003 and incorporated herein by reference.)
10.8	Employment Agreement, dated as of September 5, 2002, by and between Presby Corp and Terence A. Walts. (Filed as Exhibit 10.8 to the registrant's Current Report on Form 8-K filed March 12, 2003 and incorporated herein by reference.)
10.8.1	First Amendment to Employment Agreement, dated as of May 29, 2003, by and between Presby Corp and Terence A. Walts. (Filed as Exhibit 10.8.1 to the registrant's Form SB-2 filed September 2, 2003 and incorporated herein by reference.)
10.9	Non-Qualified Stock Option Agreement with Terence A. Walts, dated as of September 1, 2002. (Filed as Exhibit 10.9 to the registrant's Current Report on Form 8-K filed March 12, 2003 and incorporated herein by reference.)
10.10	Severance, Release and Consulting Agreement, dated as of February 25, 2003, by and between Presby Corp and Ronald A. Schachar, M.D., Ph.D. (Filed as Exhibit 10.10 to the registrant's Current Report on Form 8-K filed March 12, 2003 and incorporated herein by reference.)
10.11	Amended and Restated Registration Rights Agreement, dated as of June 22, 2000, by and among RAS Holding Corp. and the parties named therein. (Filed as Exhibit 10.11 to the registrant's Current Report on Form 8-K filed March 12, 2003 and incorporated herein by reference.)
10.12	Form of Promissory Note, dated as of February 26, 2003, made by Presby Corp in favor of six lenders for $250,000 aggregate principal amount. (Filed as Exhibit 10.12 to the registrant's Current Report on Form 8-K filed March 12, 2003 and incorporated herein by reference.)
10.13	Advisory Agreement, dated as of March 3, 2003, by and between the Registrant and Verus Support Services Inc. (Filed as Exhibit 10.13 to the registrant's Current Report on Form 8-K filed March 12, 2003 and incorporated herein by reference.)
10.14	Advisory Agreement, dated as of March 4, 2003, by and among the Registrant and Kingsdale Capital Corporation and its affiliates. (Filed as Exhibit 10.14 to the registrant's Current Report on Form 8-K filed March 12, 2003 and incorporated herein by reference.)

10.15	Indemnification Agreement, dated as of March 6, 2003, by and among the Registrant, Daniel Gunter and Adrienne Beam. (Filed as Exhibit 10.15 to the registrant's Current Report on Form 8-K filed March 12, 2003 and incorporated herein by reference.)
10.16	Form of Lock-Up Letter by and between the Registrant and holders of Presby Corp common stock. (Filed as Exhibit 10.16 to the registrant's Current Report on Form 8-K filed March 12, 2003 and incorporated herein by reference.)
10.17	Form of Lock-Up Letter by and between the Registrant and holders of Presby Corp Series B preferred stock. (Filed as Exhibit 10.17 to the registrant's Current Report on Form 8-K filed March 12, 2003 and incorporated herein by reference.)
10.18	Form of Lock-Up Letter by and between the Registrant and holders of Presby Corp Series C preferred stock. (Filed as Exhibit 10.18 to the registrant's Current Report on Form 8-K filed March 12, 2003 and incorporated herein by reference.)
10.19	Form of Subscription Agreement. (Filed as Exhibit 10.19 to the registrant's Current Report on Form 8-K filed March 12, 2003 and incorporated herein by reference.)
10.20	Letter Agreement, dated as of March 6, 2003, by Verus Support Services Inc. and acknowledged by the Registrant relating to Verus's contingent subscription. (Filed as Exhibit 10.20 to the registrant's Current Report on Form 8-K filed March 12, 2003 and incorporated herein by reference.)
10.20.1	Letter Agreement, dated as of August 28, 2003, between the Registrant and Verus Support Services Inc. relating to the deferral of Verus's contingent subscription. (Filed as Exhibit 10.1 to the registrant's Quarterly Report on Form 10-QSB for the quarter ended September 30, 2003 and incorporated herein by reference.)
10.20.2	Letter Agreement dated as of December 4, 2003 between the Registrant and Verus Support Services Inc. relating to the deferral of Verus's contingent subscription. (Filed as Exhibit 10.20.2 to the registrant's Form SB-2 Amendment No. 1 filed February 2, 2004 and incorporated herein by reference.)
10.20.3	Letter Agreement dated as of January 6, 2004 between the Registrant and Verus Support Services Inc. relating to the deferral of Verus's contingent subscription and other items. (Filed as Exhibit 10.20.3 to the registrant's Form SB-2 Amendment No. 1 filed February 2, 2004 and incorporated herein by reference.)
10.21	Letter Agreement, dated as of March 4, 2003, by and between Registrant and Insite Productions, LLC. (Filed as Exhibit 10.21 to the registrant's Current Report on Form 8-K filed March 12, 2003 and incorporated herein by reference.)
10.22	Agreement between the registrant and Promedica International. (Filed as Exhibit 10.2 to the registrant's Quarterly Report on Form 10-QSB for the quarter ended September 30, 2003 and incorporated herein by reference.)
10.23	Form of Amended and Restated Subscription Agreement. (Filed as Exhibit 10.23 to the registrant's Form SB-2 Amendment No. 1 filed on February 2, 2004 and incorporated herein by reference.)
10.24	License Transfer and Transition Services Agreement, dated as of January 30, 2004, by and among the registrant, Refocus Ocular, Inc., CIBA Vision AG and CIBA Vision Corporation. (Filed as Exhibit 10.24 to the registrant's Current Report on Form 8-K filed on February 2, 2004 and incorporated herein by reference.)
14.1	Refocus Group, Inc. Code of Conduct and Ethics. *

21.1	Subsidiaries of the Registrant. *
31.1	Certification of Chief Executive Officer pursuant to Rule 13a-14(a) of the Securities Exchange Act. *
31.2	Certification of Chief Financial Officer pursuant to Rule 13a-14(a) of the Securities Exchange Act. *
32.1	Certification Required by 18 U.S.C. Section 1350 (as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002).*

* Filed herewith.

(b) Reports on Form 8-K

During the three months ended December 31, 2003, we did not file any Current Reports on Form 8-K.

The following Current Report on Form 8-K was filed after December 31, 2003:

Current Report on Form 8-K dated January 30, 2004, filed February 2, 2004, which disclosed the License Transfer and Transition Services Agreement between the registrant, its wholly-owned subsidiary, Refocus Ocular, Inc., CIBA Vision AG and CIBA Vision Corporation, that was entered into on January 30, 2004.

SIGNATURES

In accordance with Section 13 or 15(d) of the Exchange Act, the registrant caused this report to be signed on its behalf by the undersigned, thereunto duly authorized.

Refocus Group, Inc.

By /s/ Mark A. Cox
Mark A. Cox
Vice President, Secretary and Chief Financial Officer
(Principal Financial and Accounting Officer)

March 30, 2004

In accordance with the Exchange Act, this report has been signed below by the following persons on behalf of the registrant and in the capacities and on the dates indicated.

Principal Executive Officers:

/s/ Terence A. Walts Terence A. Walts	Director, Chief Executive Officer and President (Principal Executive Officer)	March 30, 2004
/s/Mark A. Cox Mark A. Cox	Vice President, Secretary and Chief Financial Officer (Principal Financial and Accounting Officer)	March 30, 2004

Additional Directors:

/s/ C. Glenn Bradley C. Glenn Bradley, Ph.D.	Director	March 30, 2004
/s/Abbey J. Butler Abbey J. Butler	Director	March 30, 2004
/s/ Melvyn J. Estrin Melvyn J. Estrin	Director	March 30, 2004
/s/ Peter C. Hobbins Peter C. Hobbins, Ph.D.	Director	March 30, 2004
/s/ Grady E. Schleier Grady E. Schleier	Director	March 30, 2004
/s/ David A. Williams David A. Williams	Director	March 30, 2004

REFOCUS GROUP, INC. AND SUBSIDIARIES

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INDEPENDENT AUDITORS' REPORT

Board of Directors
Refocus Group, Inc.

We have audited the accompanying consolidated balance sheets of Refocus Group, Inc. ("Refocus") and subsidiaries as of December 31, 2003 and Refocus Ocular, Inc. ("Ocular"), formerly known as Presby Corp, and subsidiaries (collectively, the "Company"), as of December 31, 2002 and the related consolidated statements of operations, shareholders' equity (deficiency), and cash flows for each of the three years in the period ended December 31, 2003. These financial statements are the responsibility of the Company's management. Our responsibility is to express an opinion on these financial statements based on our audits.

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

In our opinion, such consolidated financial statements present fairly, in all material respects, the consolidated financial position of the Company as of December 31, 2003 and 2002 and the results of its operations and its cash flows for each of the three years in the period ended December 31, 2003, in conformity with accounting principles generally accepted in the United States of America.

The accompanying 2003 consolidated financial statements have been prepared assuming that the Company will continue as a going concern. As described in Notes 1 and 4 to the consolidated financial statements, the Company believes that it will be unable to continue as a going concern through December 31, 2004 without obtaining additional debt or equity financing. The Company's uncertainty of obtaining sufficient additional debt or equity financing raises substantial doubt about its ability to continue as a going concern. Management's plans concerning these matters are also described in Note 4. The financial statements do not include any adjustments that might result from the outcome of this uncertainty.

As discussed in Note 1 to the financial statements, on March 6, 2003, a newly created wholly-owned subsidiary of Refocus was merged with and into Ocular, with Ocular surviving as a wholly-owned subsidiary of Refocus.

Deloitte & Touche LLP
Ft. Worth, Texas
March 29, 2004

REFOCUS GROUP, INC. AND SUBSIDIARIES
CONSOLIDATED STATEMENTS OF OPERATIONS

	Years ended December 31,		
	2003	2002	2001
REVENUES	$ -	$ -	$ 230,250
COST OF SALES	-	-	223,575
GROSS PROFIT	-	-	6,675
OPERATING EXPENSES:			
Selling, general and administrative	1,172,124	889,147	1,036,404
Salary and related expenses	1,224,248	1,170,438	1,285,907
Stock-based employee compensation	791,697	7,650	160,250
Instrument upgrade costs	-	-	364,695
Inventory adjustment costs	-	128,059	-
Professional services	1,337,445	534,432	1,231,176
Clinical trials	357,739	63,275	194,137
Research and development	108,918	166,949	339,289
Depreciation and amortization	604,028	123,403	118,789
LOSS FROM OPERATIONS	(5,596,199)	(3,083,353)	(4,723,972)
OTHER INCOME (EXPENSE):			
Interest income	23,805	20,577	171,367
Interest expense	(121,947)	-	-
Other income (expense)	15	(325)	101,494
Total	(98,127)	20,252	272,861
NET LOSS	(5,694,326)	(3,063,101)	(4,451,111)
Accretion of discount on preferred stock	(4,306)	(23,482)	(23,501)
Accrued dividends on preferred stock	-	(2,777,062)	(594,106)
NET LOSS APPLICABLE TO COMMON SHARES	$ (5,698,632)	$ (5,863,645)	$ (5,068,718)
NET LOSS PER SHARE APPLICABLE TO COMMON SHARES - BASIC AND DILUTED	$ (0.34)	$ (0.91)	$ (0.79)
AVERAGE NUMBER OF COMMON SHARES OUTSTANDING - BASIC AND DILUTED	16,862,075	6,450,878	6,447,164

See notes to the consolidated financial statements.

REFOCUS GROUP, INC. AND SUBSIDIARIES
CONSOLIDATED BALANCE SHEETS

	December 31, 2003	2002
ASSETS		
Current Assets		
Cash and cash equivalents	$ 2,999,784	$ 267,180
Accounts receivable	10,000	27,068
Prepaid expenses (Note 9)	230,464	83,733
Total current assets	3,240,248	377,981
Property and Equipment - net	12,252	22,595
Patent Costs and Trademarks - net (Note 1)	957,227	1,277,198
Non-Compete Agreement - net (Notes 1 and 6)	618,397	-
Other Long-Term Assets (Note 9)	138,412	194,447
Total Assets	$ 4,966,536	$ 1,872,221
LIABILITIES & SHAREHOLDERS' EQUITY (DEFICIENCY)		
Current Liabilities		
Accounts payable	$ 419,968	$ 104,194
Accrued expenses (Note 9)	277,312	190,983
Current portion of separation and consulting agreement (Note 6)	407,384	-
Current portion of CIBA obligation (Note 5)	375,000	-
Customer deposits	23,000	23,000
Total current liabilities	1,502,664	318,177
Long-Term Liabilities		
Separation and consulting agreement (Note 6)	688,421	-
CIBA obligation (Note 5)	1,625,000	2,000,000
Total long-term liabilities	2,313,421	2,000,000
Commitments and Contingencies (Note 10)	-	-
Redeemable Series B Preferred Stock - 4,500,000 shares of $.001 par value authorized, 4,481,396 shares issued and outstanding in 2002 - Refocus Ocular, Inc. (Note 7)	-	9,114,144
Shareholders' Equity (Deficiency) (Note 7)		
Preferred stock: 10,000,000 shares of $.0001 par value authorized, no shares issued and outstanding in 2003	-	
Series C preferred stock: 65,000 shares of $.001 par value authorized, 21,614 shares issued and outstanding in 2002 - Refocus Ocular, Inc.	-	1,049,104
Warrants for the purchase of Refocus Group, Inc. common stock	2,047,350	
Common stock: 60,000,000 shares of $.0001 par value authorized, 23,368,887 shares issued and outstanding in 2003	2,337	
Common stock: 30,000,000 shares of $.001 par value authorized, 6,450,878 shares issued and outstanding in 2002 - Refocus Ocular, Inc.	-	6,451
Paid-in capital	21,660,056	6,245,005
Accumulated deficit	(22,559,292)	(16,860,660)
Total shareholders' equity (deficiency)	1,150,451	(9,560,100)
Total Liabilities and Shareholders' Equity (Deficiency)	$ 4,966,536	$ 1,872,221

See notes to the consolidated financial statements.

REFOCUS GROUP, INC. AND SUBSIDIARIES
CONSOLIDATED STATEMENTS OF SHAREHOLDERS' EQUITY (DEFICIENCY)
FOR THE THREE YEARS ENDED DECEMBER 31, 2003

	Shares	Amount
Series C Preferred Stock of Refocus Ocular, Inc.:		
Balance at December 31, 2000	21,400	$ 1,025,747
Exercise of Series C preferred stock warrants (net of $2,609 in expenses)	214	23,357
Balance at December 31, 2001 and 2002	21,614	1,049,104
Conversion of Series C preferred stock to common	(21,614)	(1,049,104)
Balance at December 31, 2003	-	$ -
Series C Preferred Stock Warrants of Refocus Ocular, Inc.:		
Balance at December 31, 2000		$ 913,386
Exercise of Series C preferred stock warrants		(4,566)
Expiration of Series C preferred stock warrants		(904,254)
Balance at December 31, 2001		4,566
Expiration of Series C preferred stock warrants		(4,566)
Balance at December 31, 2002 and 2003		$ -
Warrants of Refocus Group, Inc.:		
Balance at December 31, 2000, 2001 and 2002		$ -
Warrants issued in private placement March 6, 2003		1,430,500
Warrant issued to agent		130,000
Warrant issued to consultant		130,000
Warrants issued in private placement December 23, 2003		460,850
Warrant issued March 6, 2003 cancelled		(104,000)
Balance at December 31, 2003		$ 2,047,350
PC Lens Corp Common Stock:		
Balance at December 31, 2000 and 2001	8,830,546	$ 1,286
Acquisition of common stock of PC Lens Corp	(8,830,546)	(1,286)
Balance at December 31, 2002 and 2003	-	$ -
Refocus Ocular, Inc. Common Stock:		
Balance at December 31, 2000	13,787,949	$ 13,788
Effect of 2.14-to-1 reverse split (see Note 2)	(7,344,898)	(7,345)
	6,443,051	6,443
Sale of common stock	5,374	5
Exercise of stock options	2,453	3
Balance at December 31, 2001 and 2002	6,450,878	6,451
Conversion of Refocus Ocular, Inc. Series B preferred stock to common	5,277,164	5,277
Conversion of Refocus Ocular, Inc. Series C preferred stock to common	212,102	212
Exchange of Refocus Ocular, Inc. common stock for Refocus Group, Inc. common stock	(11,940,144)	(11,940)
Balance at December 31, 2003	-	$ -
Refocus Group, Inc. Common Stock:		
Balance at December 31, 2000, 2001 and 2002	-	$ -
Common stock outstanding when Refocus Ocular, Inc. was merged into a subsidiary of Refocus Group, Inc. (Note 1)	4,097,107	410
Common stock issued to former stockholders of Refocus Ocular, Inc.	11,940,144	1,194
Common stock issued in private placement on March 6, 2003	2,887,500	288
Common stock issued in private placement on December 23, 2003	4,425,000	443
Stock options exercised	19,136	2
Balance at December 31, 2003	23,368,887	$ 2,337

See notes to the consolidated financial statements.

REFOCUS GROUP, INC. AND SUBSIDIARIES
CONSOLIDATED STATEMENTS OF SHAREHOLDERS' EQUITY (DEFICIENCY)
FOR THE THREE YEARS ENDED DECEMBER 31, 2003
(Continued)

	Amount
Paid-in Capital:	
Balance at December 31, 2000	$ 5,036,522
Effect of 2.14-to-1 reverse split (see Note 2)	7,345
	5,043,867
Expiration of Refocus Ocular, Inc. Series C preferred stock warrants	904,254
Sale of Refocus Ocular, Inc. common stock (net of $11,595 in expenses)	63,150
Exercise of Refocus Ocular, Inc. stock options	222
Stock-based employee compensation	160,250
Balance at December 31, 2001	6,171,743
Refocus Ocular, Inc. Series B preferred stock issued in lieu of service fee due to RAS Service LP	60,642
Expiration of Refocus Ocular, Inc. Series C preferred stock warrants	4,566
Acquisition of common stock of PC Lens Corp	404
Stock-based employee compensation	7,650
Balance at December 31, 2002	6,245,005
Conversion of Refocus Ocular, Inc. Series B preferred stock to common	9,113,173
Conversion of Refocus Ocular, Inc. Series C preferred stock to common	1,048,892
Exchange of Refocus Ocular, Inc. common stock for Refocus Group, Inc. common stock	10,746
Effect of Refocus Group, Inc. acquisition by Refocus Ocular, Inc. for accounting purposes	(42)
Refocus Group, Inc. common stock issued in private placement on March 6, 2003 (net of $1,459,259 in expenses)	2,859,953
Refocus Group, Inc. common stock issued in private placement on December 23, 2003 (net of $266,348 in expenses)	1,484,859
Refocus Group, Inc. warrant issued March 6, 2003 cancelled	104,000
Refocus Group, Inc. stock options exercised	1,773
Stock-based employee compensation	791,697
Balance at December 31, 2003	$ 21,660,056
Accumulated Deficit:	
Balance at December 31, 2000	$ (5,928,297)
Accretion of discount on Refocus Ocular, Inc. Series B preferred stock	(23,501)
Accrued dividends on Refocus Ocular, Inc. Series B preferred stock	(594,106)
Net loss	(4,451,111)
Balance at December 31, 2001	(10,997,015)
Accretion of discount on Refocus Ocular, Inc. Series B preferred stock	(23,482)
Accrued dividends on Refocus Ocular, Inc. Series B preferred stock	(322,195)
Refocus Ocular, Inc. Series B preferred stock issued in lieu of accrued dividends and in lieu of payment of dividends	(2,454,867)
Net loss	(3,063,101)
Balance at December 31, 2002	(16,860,660)
Accretion of discount on Refocus Ocular, Inc. Series B preferred stock	(4,306)
Net loss	(5,694,326)
Balance at December 31, 2003	$ (22,559,292)

See notes to the consolidated financial statements.

REFOCUS GROUP, INC AND SUBSIDIARIES
CONSOLIDATED STATEMENTS OF CASH FLOWS

	Years ended December 31,		
	2003	2002	2001
Cash Flows from Operating Activities:			
Net loss	$ (5,694,326)	$ (3,063,101)	$ (4,451,111)
Adjustments to reconcile net loss to net cash provided (used) by operating activities:			
Depreciation and amortization	604,028	123,403	118,789
Loss on disposal of equipment	6,091	66,951	600
Loss on write-down of inventory	-	128,059	-
Compensation cost due to stock options granted	791,697	7,650	160,250
Warrants issued in lieu of cash payments	260,000	-	-
Interest accreted on discounted liability	121,280	-	-
Cash provided (used) by working capital items:			
Accounts receivable	17,068	123,765	(101,544)
Inventories	-	4,532	307,878
Other assets	19,088	99,020	(150,417)
Accounts payable, accrued expenses and other liabilities	406,685	(96,522)	125,662
CIBA obligation	-	2,000,000	-
Net Cash Used by Operating Activities	(3,468,389)	(606,243)	(3,989,893)
Cash Flows from Investing Activities:			
Additions to property and equipment	(13,025)	(16,155)	(99,802)
Additions to patents and trademarks	(225,476)	(365,805)	(269,558)
Purchase of Refocus Group, Inc. by Refocus Ocular, Inc.	5,102	-	-
Other	1,277	(882)	-
Net Cash Used by Investing Activities	(232,122)	(382,842)	(369,360)
Cash Flows from Financing Activities:			
Borrowings	250,000	-	-
Borrowings repaid	(250,000)	-	-
Exercise of Series C preferred stock warrants	-	-	18,791
Proceeds from private placements, net of expenses	6,431,340	-	63,155
Exercise of common stock options	1,775	-	225
Offering expenses	-	(194,447)	-
Net Cash Provided (Used) by Financing Activities	6,433,115	(194,447)	82,171
Net Increase (Decrease) in Cash and Cash Equivalents	2,732,604	(1,183,532)	(4,277,082)
Cash and Cash Equivalents, beginning of year	267,180	1,450,712	5,727,794
Cash and Cash Equivalents, end of year	$ 2,999,784	$ 267,180	$ 1,450,712

See notes to the consolidated financial statements.

NOTE 1 – SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES

Going Concern: These financial statements have been prepared on a going concern basis, which contemplates the realization of the assets of Refocus Group, Inc. ("Refocus") and the satisfaction of its liabilities and commitments in the normal course of business. However, Refocus believes that it will be unable to continue as a going concern for the next twelve months without obtaining additional debt or equity financing. See Note 4 for a discussion of the Company's ability to continue as a going concern and its plans for addressing those issues. The inability to obtain additional financing could have a material adverse effect on Refocus.

Merger: On March 6, 2003, Refocus and Refocus Ocular, Inc. ("Ocular"), formerly known as Presby Corp ("Presby"), entered into a merger agreement (the "Merger Agreement"). On March 6, 2003 (the "Merger Closing Date"), a newly created, wholly-owned subsidiary of Refocus was merged with and into Ocular, with Ocular surviving as a wholly-owned subsidiary of Refocus. In addition, on the Merger Closing Date, Refocus completed the first tranche of a private placement of shares of its common stock and warrants to purchase shares of its common stock.

Since the former stockholders of Ocular owned a majority of the issued and outstanding shares of common stock of Refocus on the Merger Closing Date after the merger and the funding of the first tranche of the March 2003 private placement, this transaction was accounted for as a reverse merger, whereby Ocular was deemed to be the accounting acquirer of Refocus. Therefore, all financial information included in this report on Form 10-KSB prior to the Merger Closing Date is that of Ocular, as if Ocular had been the registrant. The financial information since the Merger Closing Date is that of Refocus and Ocular consolidated.

All references to "Refocus", "Presby", "Ocular", or the "Company" mean Refocus or Ocular, as the former Presby, separately prior to the Merger Closing Date and Refocus, as successor to the business of Ocular, after giving effect to the merger.

Basis of Presentation: The consolidated financial statements include the accounts of all wholly-owned subsidiaries. All significant intercompany accounts and transactions have been eliminated in the consolidated financial statements. All the outstanding stock of one of the subsidiaries, PC Lens Corp ("PCL"), was acquired in August 2002. This acquisition was accounted for as if pooled since the acquisition was of an entity under common control.

Description of Business: The Company's primary business has been the development of a patented medical device, the PresVIEW Scleral Implant (the "PSI"), and the related surgical technique, the Scleral Spacing Procedure (the "SSP"), for the treatment of presbyopia, primary open angle glaucoma and ocular hypertension in the human eye. Sale of this medical device is currently restricted while the Company seeks approval for the device in the United States, from the Food and Drug Administration (the "FDA"), and in other international markets. The Company has conducted research into, and has developed, a prototype device to treat dry age related macular degeneration ("ARMD"). Also, the Company conducted research into and may, at a later time, develop for commercial applications a single element variable focus lens ("SEVFL").

By 1998, the Company had obtained CE Mark approval for sales of its products in the European Union and subsequently in certain other international markets. In 2000, the Company received approval from the FDA to conduct Phase I clinical trials of the PSI for the treatment of presbyopia on humans. The Company decided to suspend international sales in 2001, however, in order to develop an automated surgical incision device to help simplify, standardize and automate the surgical procedure and to make the outcomes of the surgical procedure less dependent on each physician's surgical skill. Since that time, the Company has developed the PresVIEW Incision System, which consists of both automated and manual surgical instruments used to implant the PSI in the human eye. The Company believes the PresVIEW Incision System will improve the consistency of the results of the SSP.

In March 2002, the Company entered into a license agreement with CIBA Vision AG ("CIBA"), pursuant to which CIBA obtained an exclusive license to the Company's patents related to the treatment of presbyopia, ocular hypertension and primary open angle glaucoma in international markets. CIBA also had the right in the license agreement (the "CIBA Agreement") to acquire a license for the Company's products in the United States. Under the CIBA Agreement, CIBA was responsible for manufacturing, distribution and marketing of the Company's products, as well as for regulatory matters outside the United States. In accordance with the CIBA Agreement, the Company ceased all direct manufacturing, distribution and marketing of the PSI and related products. The CE Mark the Company had obtained was allowed to lapse because the product would be sold in the European Union by CIBA.

However, in August 2003, CIBA announced that it was seeking strategic alternatives for its surgical business unit, including the sale of that unit. CIBA's surgical unit marketed a variety of ophthalmic products and was primarily responsible for performing the CIBA Agreement. In January 2004, the Company entered into a License Transfer and Transition Services Agreement (the "Transfer Agreement") with CIBA. As a result of the Transfer Agreement, the Company has reacquired all worldwide license rights to its patents and will have to assume responsibility for marketing, manufacturing, distribution and regulatory functions. See Note 5 for a discussion of the CIBA Agreement and the Transfer Agreement.

The Company filed an investigational device exemption application with the FDA in March 2003 to obtain approval for initiating Phase II clinical trials. The Company subsequently filed amendments to that application and, in December 2003, received approval to start Phase II clinical trials, subject to certain final documentation. The Company started these trials during the first quarter of 2004.

The Company had also received permission from Health Canada (the Canadian equivalent of the FDA) in 2000 to begin clinical trials of the PSI for the treatment of ocular hypertension and primary open angle glaucoma. In November 2002, the Company submitted an application for approval to commercialize the PSI in Canada. On June 13, 2003, Canada denied the application due to the insufficient size of the clinical trial. In October 2003, Health Canada indicated the Company would have to increase the size of its clinical trials using more sites and significantly more patients before approval could be reconsidered.

PCL was formed primarily to develop the patented SEVFL technology. PCL has had no revenues for the three years ended December 31, 2003. In August 2002, a contract with a licensing agent to market the technology expired. At that time, Ocular determined that it should no longer continue to fund the operations of PCL on a promissory note basis and that it should repurchase the outstanding common stock of PCL. PCL had no source of funding other than Ocular. The holders of PCL common stock agreed to sell their common stock back to Ocular at a price per share less than par value. Ocular completed the purchase of all the outstanding common stock of PCL in August 2002 at a total cost of $882.

Business Segments: The Company has determined that it currently operates in one segment, development of optical technologies.

Management Estimates and Significant Risks and Uncertainties: The preparation of the consolidated financial statements, in conformity with accounting principles generally accepted in the United States of America, requires management of the Company to make estimates and assumptions that affect the reported amounts of assets and liabilities, and the disclosure of contingent assets and liabilities, at the dates of the financial statements and the reported amounts of revenues and expenses during such reporting periods. Actual results could differ from these estimates.

The Company is subject to a number of risks and can be affected by a variety of factors. For example, management of the Company believes that these following factors, as well as others, could have a significant negative effect on the Company's future financial position, results of operations and/or cash flows: failure to develop and commercialize existing and new products or product enhancements; failure to obtain or maintain necessary regulatory approvals; failure to maintain or obtain proprietary intellectual property rights; failure to obtain or maintain customer and physician acceptance or third party reimbursement; intense competition from companies with greater financial, technical and marketing resources; risks associated with the Company's assumption from CIBA of the marketing, distribution, regulatory and manufacturing operations formerly performed by CIBA; risks associated with product liability and product defects; and risks associated with general economic conditions.

Cash and Cash Equivalents: Cash and cash equivalents consist principally of amounts held in demand deposit accounts and amounts invested in financial instruments with initial maturities of three months or less at the time of purchase.

Inventories: Inventories were valued at the lower of cost (determined using an average cost method) or market. During 2002, as a result of the CIBA Agreement, the Company wrote off its remaining inventory at a cost of $128,059. Under that agreement, CIBA would be providing PSIs and surgical instruments under their brand name and, for the most part, would not be using the Company's inventory.

Property and Equipment: Property and equipment is stated at cost. Depreciation is computed once an asset is placed in service using a straight-line method at rates designed to distribute the cost of the asset over its estimated useful life of from 3 to 10 years for furniture and equipment. Amortization of leasehold improvements is included in depreciation and amortization expense and is based on the lesser of the asset's useful life or the projected term of the lease. The cost to maintain property and equipment is charged to expense as incurred. During 2002, the Company wrote off a substantial portion of its fixed assets as a result of the downsizing of its staff and office space in conjunction with CIBA assuming most of the responsibility for marketing, manufacturing and regulatory matters under the CIBA Agreement. The loss from disposal of excess fixed assets in 2002 was $66,951. Additional write-offs of $6,091, net of proceeds, were taken in 2003 from the disposal of additional equipment. Property and equipment consisted entirely of furniture and equipment at December 31, 2003 and 2002, respectively.

Intangible Assets: Costs incurred for patents and trademarks are capitalized and amortized over their actual or estimated life. If it is determined that a patent or trademark will not be issued or that the Company no longer wants to maintain or pursue a patent or trademark, the related costs are charged to expense at the time such determination is made. The cost of maintaining patents after they are issued is charged to expense and shown in "Depreciation and amortization".

As a result of the merger with Refocus, discussed in Note 2, and the subsequent change of the name of Presby to Refocus Ocular, Inc. in April 2003 as part of a rebranding of the Company's products that was implemented in late March 2003, the Company decided not to continue to defend or renew any of the Presby and related device trademarks. Therefore, these trademarks had no further value to the Company, and the remaining capitalized value of these trademarks was written off as of March 31, 2003. The charge of $94,592 was shown in "Depreciation and amortization" in the accompanying consolidated statement of operations for the year ended December 31, 2003.

In addition, under the separation and consulting agreement with the Company's former Chief Scientist (see Note 6), certain foreign patents related to a device for the treatment of ARMD were assigned to him. While the assignment is revocable under certain conditions, the value of these patents, for accounting purposes, of approximately $120,355 was considered transferred to him as part of his compensation under the separation and consulting agreement and was removed from the capitalized value of the patent portfolio.

The Company conducted a review of its entire patent portfolio after the Merger Closing Date. It is expensive to maintain and obtain patents, and the Company determined that it would reduce the number of countries in which it will continue to maintain or pursue PSI or SEVFL patents. The Company continues to pursue or maintain PSI and SEVFL patent protection in all major economic markets. The net book value of the patents written off for the year ended December 31, 2003 was $253,038. This amount was shown in "Depreciation and amortization" in the accompanying consolidated statements of operations.

The following tables show the capitalized value of patents and trademarks as of December 31, 2003 and December 31, 2002, respectively.

	Costs	Amortization	Net
PSI and related product patents	$ 925,718	$ 168,708	$ 757,010
Trademarks	-	-	-
ARMD patents	31,704	4,897	26,807
SEVFL Patents	222,756	49,346	173,410
Balance at December 31, 2003	$ 1,180,178	$ 222,951	$ 957,227
PSI and related product patents	$ 1,018,262	$ 175,981	$ 842,281
Trademarks	123,415	29,036	94,379
ARMD patents	149,452	13,000	136,452
SEVFL Patents	250,892	46,806	204,086
Balance at December 31, 2002	$ 1,542,021	$ 264,823	$ 1,277,198

Amortization expense for trademarks and patents was $425,092 (including the patents and Presby trademarks written off), $79,958 and $61,262 for the years ended December 31, 2003, 2002 and 2001, respectively. The estimated aggregate amortization expense for each of the succeeding five fiscal years will be approximately $31,350 each year based on the capitalized costs of patents granted at December 31, 2003.

A portion of the costs incurred in connection with the separation and consulting agreement with the Company's former Chief Scientist was allocated to a non-compete agreement and is being amortized over its life of 4 years on a straight-line basis. The $618,397 capitalized value of the non-compete agreement at December 31, 2003 was net of $162,737 of accumulated amortization. Amortization of the non-compete agreement was $162,737 for the year ended December 31, 2003. The estimated amortization expense during each of the remaining fiscal years of the non-compete agreement are as follows: for 2004 - $195,283; for 2005 - $195,283; for 2006 - $195,284; and for 2007 - $32,547.

Long-Lived Assets: The Company reviews long-lived assets and identifiable intangibles for impairment whenever events or circumstances indicate that the carrying value of an asset may not be recoverable. Recoverability of assets to be held and used is measured by a comparison of the carrying value of an asset to the undiscounted expected future cash flows generated by that asset. If the carrying value of that asset exceeds the expected future cash flows, an impairment exists and is measured by the amount the carrying value exceeds the estimated fair value of the asset. The SEVFL patents at December 31, 2003 had a carrying value of $173,410 and the ARMD patents had a carrying value of $26,807. Since these patents involve new technologies, it is not presently possible to accurately measure whether these costs are recoverable. However, management believes that these technologies can be developed at some future time and will continue to carry these patents at their amortized value until it is determined that they cannot be profitably developed. Therefore, management believes no impairment of its long-term assets existed at December 31, 2003 based on their current carrying value.

Fair Value of Financial Instruments: The fair value of financial instruments is determined by reference to various market data and other valuation techniques, as appropriate. Unless otherwise disclosed, the fair value of financial instruments approximate their recorded value due primarily to their short-term nature.

Revenue Recognition: Since March 2002, the Company has had one main source of potential revenue: royalty and milestone revenues earned under the CIBA Agreement. Prior to the CIBA Agreement, the Company's revenues consisted of products sales and seminar revenues. Revenue in each of these categories was recognized when the following four criteria were met:

- Persuasive evidence of an arrangement existed;
- Delivery had occurred or services had been rendered;
- The selling price was fixed or determinable; and
- Collectibility was reasonably assured.

No royalty or milestone revenues were earned under the CIBA Agreement in either 2002 or 2003. Prior to the CIBA Agreement, revenue was recognized when title passed to the buyer when goods were shipped or upon performance of the service for seminars. The Company's products were sold without warranty or the right to return. However, see Note 10 for claims being made by certain customers requesting refunds on products previously sold to them.

As a result of the Transfer Agreement executed in January 2004, the CIBA Agreement was terminated, and CIBA will not owe any royalty or milestone payments. Any future revenues will be primarily from product sales directly by the Company or, possibly, through other distributors (see Note 5).

The Company received $2,000,000 in advance royalties from CIBA in March 2002 that had been deferred and is shown in the consolidated balance sheets as the "CIBA obligation". None of the $2,000,000 advance royalty had been earned as of December 31, 2003. The advance royalty was forgiven in January 2004 as part of the Transfer Agreement.

Research and Development Costs: Research and development costs, including the costs of certain specialized equipment and the salaries of certain personnel devoting full time to research and development, are incurred to establish the feasibility of, and to develop, the Company's products and are charged to operations. As part of the separation and consulting agreement with the Company's former Chief Scientist (see Note 6), a portion of that contract has been designated as prepaid consulting expenses for research and development of the ARMD device. The original balance of the prepaid research and development costs was $57,557, which is being amortized over two years. The remaining balance included in current and long-term assets was $33,576 at December 31, 2003.

Stock-Based Compensation: In January 2002, the Company elected to adopt the fair value based method of accounting for stock-based compensation as defined in Statement of Financial Accounting Standards ("SFAS") No. 123 "Accounting for Stock-Based Compensation". The Company elected to report the change in accounting principle using the modified prospective method as outlined in SFAS No. 148 "Accounting for Stock-Based Compensation – Transition and Disclosure". Under this method, the stock-based employee compensation expense recognized for the years ended December 31, 2003 and 2002 is the same as would have been recognized had the fair value based recognition provisions of SFAS No. 123 been used to account for all employee awards granted, modified or settled after December 31, 1994.

For options issued during the three years ended December 31, 2003, the fair value of each option grant was estimated on the date of grant by using the Black-Scholes option-pricing model. The fair value of options issued during the year ended December 31, 2003 was approximately $1.14 per share, during the year ended December 31, 2002 was approximately $0.51 per share and during the year ended December 31, 2001 was approximately $13.78 per share. The following weighted average assumptions were used in valuing the options granted during these periods:

	2003	2002	2001
Expected dividend yield	0.00%	0.00%	0.00%
Expected volatility	60.50%	69.80%	49.90%
Risk-free interest rate	2.91%	4.88%	4.26%
Expected option lives	6 years	10 years	10 years

SFAS No. 123 requires disclosure of the pro forma effect on net income if a company continues to account for stock options under the provisions of Accounting Principles Board No. 25 "Accounting for Stock Issued to Employees" rather than the alternative fair value accounting provided under SFAS 123. As a result of adopting SFAS No. 123 in 2002 using the modified prospective method under the provisions of SFAS No. 148, the net loss for the years ended December 31, 2003 and 2002, which includes a charge of $791,697 and $7,650, respectively, related to stock-based compensation, is not different from the net loss that would have been recognized had SFAS No. 123 been adopted at its inception. The following table illustrates the effect on net loss and net loss per share for the three years ended December 31, 2003 as if compensation cost for the Company's stock options had been determined based upon the fair value at the date of grant for such awards consistent with using the provisions of SFAS No. 123.

	Year ended December 31,		
	2003	2002	2001
Net loss applicable to common shares as reported	$ (5,698,632)	$ (5,863,645)	$ (5,068,718)
Add: Stock-based employee compensation expense included in net loss applicable to common shares	791,697	7,650	160,250
Deduct: Stock-based employee compensation expense determined under a fair value based method	(791,697)	(7,650)	(161,000)
Pro forma net loss applicable to common shares	$ (5,698,632)	$ (5,863,645)	$ (5,069,468)
Net loss per share applicable to common shares – basic and diluted	$ (0.34)	$ (0.91)	$ (0.79)

Loss per share: The net loss applicable to common shares was used in the calculation of earnings per share for both basic and diluted loss per share. There was no adjustment to the calculation of diluted loss per share for dividends accrued on the shares of Series B convertible preferred stock outstanding, as they were anti-dilutive.

The weighted average number of shares of our common stock outstanding for calculation of both basic and diluted earnings per share was also the same. Options to purchase 1,111,051 shares of common stock and warrants to purchase 5,520,000 shares of common stock in 2003, options to purchase 161,851 shares of common stock in 2002, and options to purchase 189,922 shares of common stock in 2001 were not included in the computation of diluted earnings per share as the effect of including the options and warrants in the calculation would be anti-dilutive. Conversion of the Company's preferred stock was also not included in the calculation of diluted earnings per share as it would also have been anti-dilutive.

Comprehensive Loss: For all periods presented, comprehensive loss is equal to net loss.

Reclassifications: Certain previously reported amounts have been reclassified to conform to current year presentations.

Deferred Offering Expenses: The Company has deferred certain costs associated with common stock offerings until the offers are completed and the deferred expenses are offset against the proceeds received from the offerings. The balance of deferred offering expenses outstanding at December 31, 2001 was written off during the year ended December 31, 2002 as a result of the cancellation of the offering. Deferred offering expenses at December 31, 2002, which related to the March 2003 private placement discussed in Note 3, were offset against the proceeds of that offering. In addition, $192,123 of deferred offering expenses incurred during the year ended December 31, 2003 were written off as a result of the expiration of a post-closing private placement in September 2003 (see Note 3).

Income Taxes: Deferred tax assets and liabilities are established for temporary differences between financial statement carrying amounts and the taxable basis of assets and liabilities at rates currently in effect. A valuation allowance is established for any portion of a deferred tax asset for which realization is not likely. The deferred tax asset is reviewed periodically to determine the amount considered realizable.

Recently Issued Accounting Pronouncements: In April 2002, the Financial Accounting Standards Board ("FASB") issued SFAS No. 145 "Rescission of FASB Statements No. 4, 44 and 64, Amendment of FASB Statement No. 13, and Technical Corrections". SFAS No. 13 is amended to eliminate any inconsistency between the required accounting for sale leaseback transactions and the required accounting for certain lease modifications that have economic effects that are similar to leaseback transactions. This statement also amends other existing authoritative pronouncements to make various technical corrections, clarify meanings, or describe their applicability under changed conditions. The Company adopted this standard in its fiscal year beginning January 1, 2003. There was no impact on the Company's results of operations or financial condition as a result of the adoption of the standard.

In June 2002, the FASB issued SFAS No. 146 "Accounting for Costs Associated with Exit or Disposal Activities". This statement requires recording costs associated with exit or disposal activities at their fair value when a

liability has been incurred. Under previous guidance, certain exit costs were accrued upon management's commitment to an exit plan, which is generally before an actual liability has been incurred. The provisions of this statement are effective for exit or disposal activities that are initiated after December 31, 2002. This standard did not have any impact on the Company's results of operations or financial condition.

In November 2002, the FASB issued Interpretation No. 45 ("FIN 45") "Guarantor's Accounting and Disclosure Requirements for Guarantees, Including Indirect Guarantees of Indebtedness of Others". This interpretation elaborates on the disclosures to be made by a guarantor in its interim and annual financial statements about its obligations under certain guarantees that it has issued. It also clarifies that a guarantor is required to recognize, at the inception of a guarantee, a liability for the fair value of the obligation undertaken in issuing the guarantee. The disclosure requirements and initial measurement requirements of FIN 45 are effective prospectively for guarantees issued or modified after December 31, 2002. The Company is not a party to any agreement in which it is a guarantor of indebtedness of others. Accordingly, the pronouncement is currently not applicable to the Company.

In April 2003, the FASB issued SFAS No. 149 "Amendment of Statement 133 on Derivative Instruments and Hedging Activities". This statement amends SFAS No. 133 "Accounting for Derivative Instruments and Hedging Activities" for certain decisions made by the FASB. This statement is effective for most contracts entered into or modified, and for most hedging relationships designated, after June 30, 2003. Because the Company does not currently have any derivative instruments or hedging relationships, the adoption of this standard did not have any impact on the Company's results of operations or financial condition.

In May 2003, the FASB issued SFAS No. 150 "Accounting for Certain Financial Instruments with Characteristics of both Liabilities and Equity". This statement establishes standards for how an issuer classifies and measures certain financial instruments with characteristics of both liabilities and equity. It requires that many instruments formerly classified as equity will be classified as liabilities. The statement does not apply to features that are embedded in a financial instrument that is not a derivative in its entirety. It also does not affect the classification or measurement of convertible bonds or other outstanding shares that are conditionally redeemable. Generally, these liabilities should initially be measured at fair value. The statement is effective for financial instruments entered into or modified after May 31, 2003 and, otherwise, shall be effective at the first interim period beginning after June 15, 2003. Restatement of financial statements issued for earlier periods is not permitted. The Company's former Series B redeemable preferred stock, which was exchanged for common stock in March 2003, was redeemable at the option of the holder. Therefore, this statement does not change the prior accounting for that preferred stock. The Company does not currently have any instruments affected by this statement and, therefore, the standard will not have any impact on the Company's results of operations or financial condition.

In December 2003, the FASB issued SFAS No. 132 (revised 2003) "Employers' Disclosures about Pensions and Other Postretirement Benefits". This statement retains the disclosures provided in the original SFAS No. 132 but adds disclosures describing the type of plan assets, investment strategy, measurement dates, plan obligations, cash flows and components of net periodic benefit cost recognized during interim periods. The revised statement is generally effective for fiscal years ending after December 15, 2003. The Company does not currently have any contributory plans that would require the additional disclosures.

NOTE 2 – MERGER OF REFOCUS OCULAR, INC. AND REFOCUS GROUP, INC.

As a result of the March 2003 private placement discussed in Note 3, and immediately before the merger of Ocular into a wholly-owned subsidiary of Refocus, the holders of Ocular's Series B preferred stock and Series C preferred stock converted their shares into common stock of Ocular. At the same time, Ocular completed a 2.14-to-1 reverse split, resulting in 11,940,144 shares of Ocular common stock outstanding, including the common shares issued upon conversion of the preferred stock. All share and per share amounts prior to the Merger Closing Date shown in this report have been adjusted to reflect the reverse split.

Refocus was organized in November 2000 as VeryBestoftheInternet.com, Inc. ("VeryBest"). VeryBest was an internet website ranking service. In February 2003, VeryBest reincorporated in Delaware and changed its name to Refocus Group, Inc. Prior to the merger in March 2003, Refocus effected a forward split of its common stock on the basis of approximately six shares for each share issued and outstanding and also determined to change its busi-

ness operations. Following the forward-split and immediately prior to the March 2003 private placement and merger, the founders of Refocus sold substantially all of their shares back to the Company in exchange for $25,000. The amount paid for these shares has been deducted from paid-in capital. As a result, immediately before the merger, Refocus had 4,097,107 shares of common stock outstanding.

On the Merger Closing Date, a newly created, wholly-owned subsidiary of Refocus was merged into Ocular, with Ocular surviving as a wholly-owned subsidiary of Refocus. Each share of Ocular common stock outstanding on the Merger Closing Date was converted into common stock of Refocus on a one-for-one basis. Therefore, Refocus issued 11,940,144 shares of common stock to stockholders of Ocular, representing approximately 63% of Refocus' outstanding common stock following the merger and the funding of the initial tranche of the March 2003 private placement, in exchange for 100% of the outstanding capital stock of Ocular. Following the merger, all of Refocus' business operations are conducted through Ocular.

As part of the Merger Agreement, Refocus assumed the Amended and Restated Presby Corp 1997 Stock Option Plan, and all outstanding options (after they were adjusted for the 2.14-to-1 reverse split) were converted into the same number of options of Refocus. Ocular had stock options outstanding to acquire 719,486 shares of common stock at the Merger Closing Date. The exercise price of the assumed options was adjusted to reflect the 2.14-to-1 reverse split prior to the merger. See Note 8.

As a result of the merger and prior to the March 2003 private placement, the Company had 16,037,251 shares of common stock and options to purchase 719,486 shares of common stock outstanding.

Since the stockholders of Ocular owned a majority of the issued and outstanding shares of common stock of Refocus after the merger and the initial tranche of the March 2003 private placement, this transaction was accounted for as a reverse merger, whereby Ocular was deemed to be the accounting acquirer of Refocus. Because Refocus did not have any significant business prior to the merger and its former operations were discontinued after the merger, there was no goodwill or other intangibles that arose from the merger.

The assets and liabilities assumed from Refocus on the Merger Closing Date are as follows:

Cash	$ 5,102
Website technology	2,000
Accounts payable	(6,734)
Net credit to shareholders' equity	$ 368

The Company sold the website technology to another company associated with the founders of VeryBest in exchange for the forgiveness of $1,800 in debt due them and took a $200 charge for the remaining balance of the website technology, which is included in "Other income (expense)" in the consolidated statement of operations for the year ended December 31, 2003.

The following tables present the unaudited pro forma results of operations for the year ended December 31, 2003 and for the year ended December 31, 2002, assuming that the merger had occurred on January 1 of each year (in thousands, except per share amounts):

	For the year ended December 31,			
	As Reported		Pro Forma	
	2003	2002	2003	2002
Revenues	$ -	$ -	$ -	$ -
Loss from operations	(5,596)	(3,083)	(5,862)	(4,745)
Net loss	(5,694)	(3,063)	(5,960)	(4,759)
Net loss applicable to common shares	(5,699)	(5,864)	(5,960)	(4,759)
Net loss per share – basic and diluted	$ (0.34)	$ (0.91)	$ (0.32)	$ (0.25)
Average number of common shares outstanding – basic and diluted	16,862	6,451	18,473	18,925

The difference in the net loss for the Company as reported and the pro forma net loss is the result of the following:

- The net loss of Refocus from January 1, 2003 to the Merger Closing Date was $5,903. The net loss of Refocus was $60,640 for the year ended December 31, 2002. Refocus prior to the merger had no revenues and had no provision for income taxes in any of these periods.
- It was assumed that there would be no accrual of dividends or accretion of discount on the Series B preferred stock of Ocular, as the Series B preferred stock would be converted to common stock as part of the merger as actually occurred on the Merger Closing Date.
- There would be additional expenses for legal, audit, public relations and other expenses related to being a public company. The Company estimated that an additional $260,000 would have been incurred prior to the Merger Closing Date during the year ended December 31, 2003. The Company estimated that approximately $1,635,000 in additional expenses would have been incurred for the year ended December 31, 2002.

NOTE 3 – PRIVATE EQUITY TRANSACTIONS

In connection with the merger discussed above, and as a condition of that merger, Refocus completed a private placement of shares of its common stock and warrants to purchase common stock on March 6, 2003. The private placement was to be consummated in two tranches with gross proceeds of $5,750,000 due with each tranche. The funding of the second tranche was subject to the satisfaction of certain conditions precedent. In addition, at least $1,000,000 was expected to be raised from a post-closing private placement that was to close within six months of the Merger Closing Date.

The first tranche closed on the Merger Closing Date and consisted of 2,875,000 units at $2.00 per unit. Each unit was comprised of a share of Refocus common stock and a detachable warrant to purchase one-half share of Refocus common stock at an exercise price of $2.50 per share. As a result, the investors in the first tranche of the private placement were issued 2,875,000 shares of Refocus common stock and warrants to purchase 1,437,500 shares of Refocus common stock. In addition, 12,500 shares of Refocus common stock, warrants to purchase 1,250,000 shares of Refocus common stock at an exercise price of $2.50 per share and warrants to purchase 50,000 shares of Refocus common stock at an exercise price of $2.00 per share were issued to agents and others involved in the private placement. The $2.50 warrants expire in three years, and the $2.00 warrants expire in five years.

The warrants issued in connection with the initial tranche of the private placement were valued using the Black-Scholes option-pricing model. The Company assumed an expected volatility rate of 59.8%, an expected life of 2 years, a 1.38% risk-free interest rate and that no dividends would be paid. Based on these factors, the Company determined the value of the $2.00 warrants to be $.66, and the value of the $2.50 warrants to be $.52, for each share of common stock that could be acquired, for a total value of $1,430,500.

The Company paid certain agent and advisory fees and legal, audit and other private placement costs from the proceeds received from the offering as follows:

Proceeds from the offering: 2,875,000 units at $2.00 per unit	$5,750,000
Amounts paid to placement agent and advisors	(577,500)
Legal and audit fees incurred	(619,664)
Expenses incurred by advisors	(147,500)
Expenses incurred by the Company	(89,595)
Payment to founders of VeryBest for their stock	(25,000)
Cash received from the offering	$4,290,741

Investors who participated in the first tranche of the private placement were irrevocably committed to the second tranche, with the remaining gross proceeds of $5,750,000 from the private placement to be paid at the closing of the second tranche. The closing of the second tranche (and the funding of investor funds in connection with the second tranche) was contingent on:

(1) the initiation of the Company's Phase II FDA clinical trial for the treatment of presbyopia;
(2) the earlier of:
    (a) approval from Health Canada to commercialize the Company's treatment for primary open angle glaucoma and/or ocular hypertension; or
    (b) the completion, after the closing of the merger, of 500 surgical procedures in Canada and/or the European Union utilizing the PSI for the treatment of primary open angle glaucoma or ocular hypertension; and
(3) the concurrent second tranche investment by CIBA of $1,250,000.

The Company had expected that it would meet the conditions precedent to the second tranche funding within a time frame that would allow the Company to continue to fund its operations and FDA clinical trials before funds received from the first tranche were exhausted. However, in June 2003, as a result of the denial of the Company's application by Health Canada for the commercialization of its treatment for primary open angle glaucoma and ocular hypertension (see Note 1), the closing of the second tranche was going to be significantly delayed. Then, under the terms of the Transfer Agreement executed in January 2004, CIBA was relieved of its obligation to make its second tranche investment. Therefore, the investors in the first tranche can no longer be compelled to fund the second tranche and the closing of the second tranche will not occur.

The participants in the first tranche signed lock-up agreements that limited the amount of shares that could be sold each month to 9% of their total holdings beginning on the earlier of the effectiveness of a registration statement covering the shares issued or March 6, 2004. A registration statement covering these shares was filed but was not declared effective prior to March 6, 2004. Some of the first tranche participants had their lock-up agreements waived through their participation in a December 2003 private placement discussed below. Of the shares originally subject to lock-up agreements, 1,806,250 shares are still subject to the monthly 9% limitation.

In April 2003, the Company engaged an agent to conduct a post-closing private placement that was contemplated as part of the financing at the Merger Closing Date. The post-closing private placement expired September 6, 2003 without being funded. The Company wrote off $192,123 of deferred offering expenses in connection with the offering, including the value of the warrant discussed below. These expenses are included in "Selling, general and administrative" expenses for the year ended December 31, 2003. In the event that at least $1,000,000 was not raised in the post-closing private placement within six months of the Merger Closing Date, another party had subscribed to purchase that number of units at $2.00 per unit in order to satisfy the deficiency between the amount of additional capital successfully raised and $1,000,000. Each unit would have consisted of a share of Refocus common stock and a detachable warrant to purchase one-half share of Refocus common stock at an exercise price of $2.50 per share. The Company has renegotiated the terms of this obligation deferring the due date to June 30, 2004. However, the Company may still not receive any funds from this party. See Note 14 – Verus Agreement.

In May 2003, a warrant to purchase 200,000 shares of common stock at an exercise price of $2.50 per share, that expires March 6, 2006, was issued to the agent involved in the post-closing private placement. The warrant was valued at $130,000 using the Black-Scholes option-pricing model with an expected life of approximately 1.8 years, an expected volatility rate of 60%, a 1.31% risk-free interest rate and that no dividends would be paid.

In addition to fees and warrants received by advisors involved in the private placement in March 2003, the Company signed one-year consulting agreements with two of the advisors to provide certain consulting services related to long-range financial planning and investor relations. Each of the firms was to be paid $180,000 plus expenses over a period of twelve months for their services. One of the advisors forgave all fees due after August 2003 as part of the renegotiation of their $1,000,000 commitment discussed above. These contracts were not renewed.

The Company conducted another private placement that closed December 23, 2003. The Company sold 4,425,000 units at $.50 per unit. Each unit consisted of a share of common stock and a warrant to purchase one-half share of common stock at an exercise price of $2.00 per share. The warrants issued to these investors will expire three years from the date of the closing. The agent who conducted the private placement received a warrant to purchase 170,000 shares of common stock with the same terms as the investors in the private placement. The agent also had been previously issued a warrant to purchase 200,000 shares of common stock at an exercise price of $2.50 per share that was to expire March 6, 2006. This warrant was cancelled and a new warrant for the same number of

shares and at the same exercise price was issued but with an expiration date of December 23, 2006. In addition, those investors who participated in the March 2003 private placement, and who invested a dollar amount at least equal to their second tranche commitment, had their lock-up agreements on their first tranche shares waived. A total of 1,068,750 shares of the 2,875,000 shares issued in the first tranche had their lock-up agreements waived.

The warrants issued in connection with this private placement were valued using the Black-Scholes option-pricing model. The Company assumed an expected volatility rate of 111.3%, an expected life of 3 years, a 2.40% risk-free interest rate and that no dividends would be paid. Based on these factors, the Company determined the value of the $2.00 warrants to be $.18, and the value of the $2.50 warrant to be $.16, for each share of common stock that could be acquired, for a total value of $460,850. The warrant that had been previously issued to the agent in the March 2003 private placement that was cancelled had a value of $104,000.

The Company paid certain agent fees and legal, audit and other private placement costs from the proceeds received from the offering as follows:

Proceeds from the offering: 4,425,000 units at $.50 per unit	$2,212,500
Amount paid to agent	(185,000)
Legal and audit fees incurred	(69,220)
Expenses incurred by agent	(7,213)
Expenses incurred by the Company	(4,915)
Cash received from the offering	$1,946,152

NOTE 4 – GOING CONCERN

The Company had expected to receive the additional gross proceeds of $5,750,000 from the closing of the second tranche prior to using all the proceeds from the first tranche of the March 2003 private placement. However, in June 2003, as a result of the denial of the Company's application by Health Canada for the commercialization of the PSI (see Note 3), the closing of the second tranche was going to be significantly delayed. Therefore, without the expected funding from the second tranche, additional funds would be needed from other sources in order to continue the Company's operations. On December 23, 2003 the Company completed a private placement that raised $1,946,152 (see Note 3).

As discussed in Notes 1 and 5, the Transfer Agreement was executed by the Company and CIBA in January 2004. As a result of the Transfer Agreement, CIBA was relieved from having to fund their portion of the second tranche commitment. Since the funding by CIBA was a condition precedent for others to fund their second tranche commitments, the second tranche will not close. The loss of the potential $5,750,000 of gross proceeds from the closing was a significant loss for the Company. In addition, the Company will have to assume the manufacturing, distribution, marketing, and regulatory functions that CIBA had previously performed under the CIBA Agreement. The assumption of these activities could result in a substantial increase in costs and in funds needed to continue operations. As a result, the Company will need to find additional financing to complete its FDA clinical trials and fund its operations as the Company assumes the functions formerly performed by CIBA.

Management of the Company has taken certain steps to reduce cash expenditures in the near term while pursuing additional financing. Fees to investment advisors have been deferred or eliminated and expenditures for public relations have been substantially reduced. With these and other reductions, the Company believes that existing funds on hand are adequate to continue operations until approximately the first month of the third quarter of 2004, assuming the Company continues its FDA clinical trials as planned. Management of the Company cannot conclude, based on information available to it currently, that there are adequate cash resources and expected funds to be received that will allow the Company to operate for the next twelve months.

The Company is seeking additional debt and/or equity financing. There can be no assurances that additional financing can be obtained on reasonable terms or at all. The Company may seek a merger partner or the sale of assets if additional financing is not available. The Company's inability to obtain additional financing could have a material adverse effect on the Company.

The accompanying financial statements have been prepared on a going concern basis, which contemplates the realization of assets and the satisfaction of liabilities in the normal course of business. These financial statements do not include any adjustments to the recoverability and classification of recorded asset amounts or the amount and classification of liabilities that might be necessary should the Company be unable to continue as a going concern. The Company's continuation as a going concern is dependent upon its ability to obtain additional financing and, ultimately, to attain successful operations.

NOTE 5 – CIBA AGREEMENTS

In the summer of 2001, CIBA began an extensive period of due diligence on the SSP and concluded that the PSI and the related SSP represented significant market potential. Negotiations between CIBA and Ocular concluded with an exclusive license agreement in March 2002, pursuant to which CIBA had the right to obtain an exclusive worldwide license to market, distribute and sell the PSI, the PresVIEW Incision System and related products. The CIBA Agreement was subject to a number of terms and conditions, which included a requirement for CIBA to purchase equity interests in Ocular. The Company's products were to be marketed under the PresVIEW trademark.

Under the CIBA Agreement, the Company was to receive a percentage royalty on CIBA's worldwide sales of the PSI and related products. CIBA had the option to make minimum royalty payments totaling $13,585,000 during years two through six of its agreement with the Company if it wished to maintain its rights to an exclusive license of the PSI, the PresVIEW Incision System and related products. CIBA paid the Company $2,000,000 as an advance royalty that is shown in the consolidated balance sheets as the "CIBA obligation". CIBA also purchased 625,000 shares of Refocus common stock and a warrant to purchase 312,500 shares of Refocus common stock in the first tranche of the March 2003 private placement (see Note 3) for $1,250,000. CIBA had also committed to purchase, subject to the satisfaction of certain conditions precedent, an additional $1,250,000 of Refocus common stock and warrants in the second tranche of the March 2003 private placement. Subject to certain conditions precedent, CIBA would purchase an additional $2,500,000 of Refocus common stock within 60 days following the enrollment of the first patient in the Company's Phase III FDA clinical trial. Further, CIBA had agreed to pay the Company additional amounts totaling $4,000,000 upon the achievement of certain FDA-related milestones. CIBA had also agreed to assume responsibility for the legal defense of the Company's worldwide PresVIEW patent portfolio against patent infringement, subject to mutual agreement between CIBA and the Company. CIBA also assumed full responsibility for the manufacturing, distribution and marketing of the Company's products at their expense.

At the time the CIBA Agreement was executed in March 2002, the Company had invented and produced a prototype of the PresVIEW Incision System. In preparation for future marketing, the Company and CIBA decided to make further enhancements and improvements to the incision device. CIBA invested a significant amount of time and money in the further development of the device. Late in 2003, a CE Mark certification of the components of the PresVIEW Incision System was obtained by the suppliers of those components.

In August 2003, CIBA announced that it was seeking strategic alternatives for its surgical business unit, including the sale of that unit. CIBA's surgical business unit marketed a variety of ophthalmic products and was primarily responsible for performing the CIBA Agreement. On December 29, 2003, CIBA informed management of the Company that it was exiting the surgical business and expected to complete the sale of the surgical business unit's various product lines to a variety of parties by early 2004. In conjunction with that sale, CIBA received an offer from a third-party to purchase CIBA's rights under the CIBA Agreement. Pursuant to the CIBA Agreement, the transfer of the license required the Company's consent. As a condition to the assumption of CIBA's duties associated with that proposed license assignment, the third-party requested the renegotiation of certain key terms of the license agreement. After deliberation, the Company declined to renegotiate the license and did not permit the assignment of the license to the third-party. As a result, the Company began negotiations with CIBA for the transfer of CIBA's rights under the CIBA Agreement back to the Company and the termination of the license.

In January 2004, the Company entered into the Transfer Agreement with CIBA. Pursuant to the Transfer Agreement, the Company reacquired all worldwide license rights to the Company's patents that were granted to CIBA under the CIBA Agreement, and CIBA was released from all future financial commitments, including its obligations associated with manufacturing, marketing, distribution and regulatory matters. Under the Transfer Agreement, CIBA has agreed to provide the Company with certain transition services during 2004, including efforts to

finalize the CE Mark certification of the PSI. As consideration for the acquisition of CIBA's license rights, the forgiveness of the $2,000,000 in prepaid royalties the Company received under the CIBA Agreement and the transition services to be performed by CIBA under the Transfer Agreement, the Company agreed to pay CIBA an aggregate of $3,000,000 in twelve quarterly installments commencing in the first calendar quarter of 2006. The Company, however, is entitled to prepay and extinguish the payment obligations by paying an aggregate amount of $2,000,000 to CIBA prior to January 1, 2006.

Under the Transfer Agreement, CIBA has also agreed to return the warrant to purchase 312,500 shares of Refocus common stock that it acquired in the March 2003 private placement. While it will retain the 625,000 shares of common stock acquired at the same time, these shares will be subject to certain restrictions on their transfer.

CIBA's transition services include the continuation of manufacturing processes to result in the delivery to the Company of all existing PSI inventory. Prior to the CIBA Agreement executed in March 2002, the Company manufactured a significant quantity of the PSI for future use. The Company no longer has those manufacturing arrangements in place because CIBA assumed responsibility for manufacturing under the CIBA Agreement. Due to the sufficient quantity of PSIs on hand, CIBA did not establish an injection molding manufacturing arrangement during the term of the CIBA Agreement. CIBA did, however, inspect and repackage the Company's PSI inventory for expected marketing by CIBA. The Company believes that it will have adequate inventory of the PSI for the Company's expected requirements over the next 12 to 24 months. As a result of the transition of those manufacturing responsibilities to CIBA, the modifications in the packaging of the PSI, and the resultant changes to those processes, the CE Mark certification obtained by the Company on the PSI no longer applies.

CIBA had been seeking CE Mark certification of the PSI for its planned marketing efforts in the European Union in early 2004. The CE Mark certification of the PSI is still pending. The Transfer Agreement requires CIBA to continue its efforts to obtain CE Mark certification of the PSI. If the CE Mark certification for the PSI is obtained, CIBA and the Company will enter into a technical agreement, which will allow the Company to directly sell its products in CIBA packaging during 2004 in the European Union. The Company cannot be assured, however, that all regulatory requirements will be finalized, and that CIBA can finalize the issuance of the CE Mark certification for the Company's current PSI inventory, since the certification process requires extensive documentation of the manufacturing, packaging, and other processes.

The Company expects that the transition under the Transfer Agreement will result in a significant increase in costs related to performing functions that CIBA had assumed under the CIBA Agreement. Conversely, however, the Company will be entitled to all gross proceeds from the sale of its products instead of a royalty based on a percentage of sales as previously specified in the CIBA Agreement. Even assuming that CIBA obtains the CE Mark certification of the PSI, the Company's ability to directly market its products in the European Union is currently limited. The anticipated date of the initial sale of the Company's products in the European Union is likely to be delayed, and the number of PresVIEW Incision System and PSI units sold is likely to be reduced, in the short term and especially in 2004, relative to the number of unit sales that could have been achieved by CIBA. The Company may seek to market the PSI and PresVIEW Incision System in the European Union and elsewhere directly or through other distribution, license or strategic arrangements. Therefore, as a result of the increased expenses and potential for delayed revenues, management of the Company believes that the Transfer Agreement may have a material adverse impact on the Company' financial condition in the short term. The Company believes that the reacquisition of the license will be in the long-term best interest of its stockholders.

NOTE 6 – SEPARATION AND CONSULTING AGREEMENT

On February 25, 2003, Dr. Ronald A. Schachar, the Company's founder and former Chief Scientist, and the Company entered into a Severance, Release and Consulting Agreement (the "Consulting Agreement"). In accordance with the Consulting Agreement, Dr. Schachar resigned as an officer, director and employee of the Company at the Merger Closing Date. The Company agreed to retain Dr. Schachar as a consultant for a period of up to five years, and he agreed not to compete with the Company during that time. Dr. Schachar will assist the Company in conducting research and development on its products for the treatment of ARMD for the initial two years of the Consulting Agreement and will assist in maintenance of its patent portfolio and other matters for the entire term of the Consulting Agreement.

Subject to certain conditions, Dr. Schachar will be paid $1,750,000 over the consulting period, of which $950,000 will be paid in the first two years. The timing of the remaining $800,000 due in years three through five is partially dependent on the Company's profitability in those years; however, Dr. Schachar is guaranteed to receive a minimum of $250,000, but not more than $400,000, for each of the third and fourth years with the remainder, if any, to be paid in the fifth year. In addition, Dr. Schachar is to receive a $500 per month supplemental payment for the first 48 full months of the agreement.

As security for the payment of his consulting fees, the Company granted Dr. Schachar a non-exclusive security interest in its patent rights relating to the ARMD device and the SEVFL. Dr. Schachar also received an assignment of the Company's patents for the ARMD device outside the United States, which is revocable under certain conditions. The capitalized value of these assigned patents was $120,355.

The Company determined that the present value of the future cash payments for the $1,750,000 base payment under the Consulting Agreement plus the $24,000 in supplemental payments under the Consulting Agreement was $1,437,270. The present value calculation assumed a 12% interest rate and payments of $400,000 per year in the third and fourth years so that all payments would have been made at the end of four years.

Therefore, the total cost of the Consulting Agreement to the Company is the present value of future cash payments plus the $120,355 capitalized value of the ARMD patents assigned to Dr. Schachar, or $1,557,625. These payments have been allocated to prepaid consulting payments related to our outstanding patents, to prepaid research and development consulting for the treatment of ARMD, to a non-compete agreement and, finally, to severance costs as follows:

Amount allocated to:	
Non-compete agreement	$ 781,134
Consulting over term of the Consulting Agreement	246,673
Research and development for the treatment of ARMD	57,557
Severance	472,261
Total cost of the Consulting Agreement	$ 1,557,625

The amount allocated to the non-compete agreement and prepaid consulting will be expensed over four years. The amount allocated to research and development will be expensed over two years. Therefore, for the year ended December 31, 2003, there were charges totaling $831,650 in connection with the Consulting Agreement.

NOTE 7 – PREFERRED STOCK, COMMON STOCK AND WARRANTS

Ocular had designated 4,500,000 shares of $.001 par value preferred stock as Series B and 65,000 shares of $.001 par value preferred stock as Series C.

Between April 1998 and April 2000, Ocular had issued 2,443,815 shares of Series B preferred stock. Each share was convertible into 2.52 shares of common stock of Ocular at the option of the holder or automatically based on the closing of a public offering. Each share bore interest at 12%. Dividends were accrued but were deferred until October 31, 2002. In the event of liquidation, the Series B preferred stockholders were entitled to $2.046 per share plus unpaid dividends prior to any distribution to the Series C preferred or common stockholders. The Series B preferred stock was redeemable at the option of the holders after May 1, 2005.

Effective July 15, 2002, Ocular reached an agreement with the Series B preferred stockholders whereby Ocular issued 2,012,344 shares of Series B preferred stock in lieu of accrued dividends and in lieu of any future dividends on the Series B preferred stock. The shares were valued at par value and the value of the shares issued over the amount of dividends accrued of $2,454,867 was accounted for as additional dividends on the Series B preferred stock. No future dividends were accrued after this date. The agreement changed the automatic conversion feature by adding a provision that if Ocular completed a sale of common stock where the aggregate gross proceeds were at least $5,000,000, the Series B stock would automatically be converted. This provision was triggered as of the Merger Closing Date.

Ocular had an agreement with an entity, RAS Service LP ("Service LP"), owned by the Series B preferred stockholders and certain then current employees of Ocular. The agreement was cancelled in July 2002, and Ocular issued 25,237 shares of Ocular Series B preferred stock to Service LP in lieu of $112,277 due Service LP under their agreement. The difference in the value of the shares issued and the amount due Service LP of $60,642 was added to paid-in capital. These shares were also automatically converted to Ocular common stock on the Merger Closing Date.

The Series C preferred stock was convertible into 21 shares of Ocular's common stock at any time and would automatically convert upon certain events, one of which was the conversion of a majority of the Series B preferred stock into Ocular common stock. In the event of liquidation, the Series C preferred stock would be entitled to received $100 per share after the distribution to holders of the Series B preferred stock but before common stockholders. In June 2001, holders exercised warrants to purchase 214 shares of Series C preferred stock at $100 per share. During 2002, the remainder of the warrants to purchase Series C preferred stock expired. These shares were automatically converted to Ocular common stock on the Merger Closing Date as a result of the conversion of the Series B preferred stock.

Prior to the merger, Ocular had 30,000,000 shares of $.001 par value common stock authorized. On the Merger Closing Date, there was a 2.14-to-1 reverse split of the Company's common shares prior to the merger. At the Merger Closing Date, there were 4,481,396 shares of Series B preferred stock and 21,614 shares of Series C preferred stock outstanding. The Series B preferred stock was converted into 5,277,164 shares of Ocular common stock (after the 2.14-to-1 reverse split). The Series C preferred stock was converted into 212,102 shares of Ocular common stock (after the 2.14-to-1 reverse split). Therefore, with the 6,450,878 shares of Ocular common stock outstanding prior to the conversion of the preferred stock and after the 2.14-to-1 reverse split, there were a total of 11,940,144 shares of common stock outstanding at the Merger Closing Date (see Note 2). These shares were exchanged by the stockholders of Ocular for shares of Refocus on March 6, 2003 as part of the merger of Ocular into a wholly-owned subsidiary of Refocus.

Currently, the Company has 60,000,000 shares of $.0001 par value common stock and 10,000,000 shares of $.0001 par value preferred stock authorized. There are no shares of preferred stock issued or outstanding. The number of shares of common stock outstanding at December 31, 2003 was 23,368,887.

In May 2003, in connection with a consulting contract with an investment banker, in addition to the monthly retainer, the Company issued to the investment banker a warrant to purchase 200,000 shares of the Company's common stock at an exercise price of $2.50 per share that expires March 6, 2006. The Company estimated the value of this warrant to be $130,000, using the Black-Scholes option-pricing model. The value of the warrant was charged to expense as a consulting fee.

The following table lists the exercise price, expiration date and the number of shares of common stock that could be purchased by the exercise of the Company's outstanding warrants at December 31, 2003:

Exercise Price	Expiration Date	Number of common shares issuable on exercise
$2.00	December 23, 2006	2,382,500
$2.00	March 6, 2008	50,000
$2.50	March 6, 2006	2,887,500
$2.50	December 23, 2006	200,000

Warrants for the purchase of 200,000 shares of common stock with an exercise price of $2.50 per share that expire March 6, 2006 cannot be exercised unless the second tranche of the March 2003 private placement is funded. Since the second tranche will not be funded (see Note 3), these warrants will never be exercised.

The Company has reserved 5,520,000 shares of common stock for issuance upon the exercise of outstanding warrants. The Company has also reserved 4,216,465 shares of common stock for grant or issuance under the Amended and Restated Stock Option Plan discussed below.

NOTE 8 – STOCK OPTIONS

On February 25, 2003, Ocular's Board of Directors adopted the Amended and Restated Presby Corp 1997 Stock Option Plan (the "Plan"). Shareholders of Ocular approved the Plan on March 4, 2003. Refocus assumed this Plan on the Merger Closing Date. The Plan provides for the issuance of incentive stock options and non-qualified stock options to key employees, directors and independent contractors of the Company. The exercise price for each incentive stock option granted under the Plan may not be less than the market value of the common stock on the date of the grant. The exercise price for non-qualified stock options granted under the Plan are set by the Board but are, generally, set at the market value of the common stock at the grant date. Unless otherwise determined by the Board, incentive and non-qualified stock options granted under the Plan have a maximum duration of ten and fifteen years, respectively. The vesting periods for these options vary, but they are generally for periods of three years or less.

The total number of shares of common stock available for new grants under the Plan after March 4, 2003, is 4,100,000 shares. There were options to purchase 161,851 shares of common stock outstanding prior to the amendment and restatement of the Plan. Options to purchase 3,105,414 shares of common stock are still available for grant under the Plan at December 31, 2003.

In March 2003, after the Plan was amended and restated, the Company granted options to purchase 557,635 shares of common stock pursuant to the employment and option contracts with our Chief Executive Officer. These options were contingent on the closing of the merger. In addition, the Company issued additional options to purchase 510,000 shares of common stock to directors and officers during 2003. See Note 1 for the calculation of the weighted average fair value of options issued for the three years ended December 31, 2003, as well as the weighted average factors used to calculate that value.

The following table summarizes the information with respect to stock options for the years ended December 31, 2003, 2002 and 2001, respectively:

	2003		2002		2001	
	Shares	Weighted Average Exercise Price	Shares	Weighted Average Exercise Price	Shares	Weighted Average Exercise Price
Outstanding, beginning of year	161,851	$0.104	189,922	$0.098	180,693	$0.092
Granted	1,067,635	$1.986	7,010	$0.193	11,682	$0.193
Exercised	(19,136)	$0.092	-	-	-	-
Canceled or expired	(99,299)	$1.509	(35,081)	$0.092	(2,453)	$0.092
Outstanding, end of year	1,111,051	$1.787	161,851	$0.104	189,922	$0.098
Exercisable	323,648		143,159		178,240	

The following table summarizes information for options outstanding and exercisable at December 31, 2003:

	Options Outstanding			Options Exercisable	
Exercise Prices	Shares	Weighted Average Remaining Contractual Life	Weighted Average Exercise Price	Shares	Weighted Average Exercise Price
$ 0.092-$ 0.193	116,465	4.2 years	$0.108	109,455	$0.103
$1.98 - $2.31	994,586	5.6 years	$1.984	214,193	$1.998
	1,111,051	5.5 years	$1.787	323,648	$1.357

NOTE 9 – SUPPLEMENTAL CASH FLOW AND BALANCE SHEET INFORMATION

The following supplemental cash flow information is provided for interest and income taxes paid and for non-cash transactions for the years ended December 31:

	2003	2002	2001
Interest paid	$ 667	$ -	$ -
Income taxes paid	-	-	-
Non-cash transactions:			
Accretion of discount on Series B preferred stock	4,306	23,482	23,501
Accrual of dividends on Series B preferred stock	-	322,195	594,106
Series B preferred stock issued in lieu of dividends	-	2,454,867	-
Series B preferred stock issued to RAS Service LP	-	112,277	-
Value of warrants issued in private placements to agents or advisors	641,600	-	-
Conversion of Series B preferred stock	9,118,450	-	-
Conversion of Series C preferred stock	1,049,104	-	-
Value of separation and non-compete agreement	1,557,625	-	-
Value of warrant issued to investment banker	130,000	-	-
Value of warrant issued to agent in post-closing private placement	130,000	-	-
Value of Refocus common stock issued to advisor	21,750	-	-

The following supplemental balance sheet information is provided for prepaid expenses, other long-term assets and accrued expenses:

	December 31, 2003	December 31, 2002
Prepaid expenses:		
Prepaid insurance	$ 62,826	$ 79,022
Prepaid consulting expenses	61,668	-
Prepaid research and development costs	28,779	-
Prepaid FDA trial costs	75,007	-
Other prepaid expenses	2,184	4,711
Total	$ 230,464	$ 83,733
Other long-term assets:		
Prepaid consulting expenses	$ 133,615	$ -
Prepaid research and development costs	4,797	-
Deferred offering expenses	-	194,447
Total	$ 138,412	$ 194,447
Accrued expenses:		
Accrued salaries, wages and benefits	$ 36,228	$ 46,848
Liability for possible replacement of product already shipped	50,000	50,000
Audit fee accrual	30,000	45,000
Accrual for amount due on former office lease	-	48,000
Director fees	131,500	-
Accrued taxes	9,779	1,135
Other	19,805	-
Total	$ 277,312	$ 190,983

NOTE 10 – COMMITMENTS AND CONTINGENCIES

The Company is involved in various legal proceedings arising in the normal course of business. Management believes the outcome of these matters will not materially affect the financial condition, results of operations or cash flows of the Company.

The Company leases a facility in Dallas, Texas and, until September 2003, a facility in Denison, Texas. Total lease expense for the years ended December 31, 2003, 2002 and 2001 were approximately $48,000, $204,000 and $141,000, respectively. There are no leases with remaining terms of one year or more at December 31, 2003.

Until April 1, 2003, the Company carried product liability insurance coverage with a limit of $10,000,000 in the aggregate and per occurrence. At that time, the policy was changed to a limit of $5,000,000 in the aggregate and $1,000,000 per occurrence. The change was made as a result of the assumption of manufacturing and distribution by CIBA under the CIBA Agreement. As a result of the Transfer Agreement, the Company has again assumed responsibility for the manufacturing and distribution of the PSI and related equipment. Although the Company has reassumed this responsibility, it will likely not increase the amount of product liability coverage until higher volumes of its products are being used.

As a result of the Company's suspension of sales of the PSI in 2001, while the Company was developing the PresVIEW Incision System, and the continued suspension of sales as a result of the CIBA Agreement, pursuant to which CIBA was supposed to exclusively handle the Company's future sales and marketing, the Company has encouraged customers not to perform the SSP using the PSI until the PresVIEW Incision System was available, and the Company and/or CIBA was ready to begin sales of the PSI again. The packaging of the PSI provided guaranteed sterility only for a limited period of time, and the sterility dating on PSIs still held by the Company's customers has expired. An estimated liability of $50,000 was established for the possible replacement of these PSIs. The liability was based on the Company's estimated manufacturing cost and the total number of PSIs that had been sold less an estimate of the number already used. Rather than replace all the expired inventory, the Company may instead grant special pricing on future purchases to these surgeons. The actual claims by customers may exceed, and/or the cost of replacing the PSIs may be higher than, the Company's estimate and additional charges may have to be taken.

The Company has been informed by two of its former foreign distributors that they are seeking refunds on unsold products remaining in their inventory. The Company did not sell its products with a right of return and does not believe it has any liability to repurchase these products.

Certain physicians may have purchased surgical kits in anticipation of taking part in the FDA clinical trials. Several of these physicians have requested a refund or have informed the Company that if they are not selected to participate in the clinical trials, they will be seeking a refund. These kits were not sold with a right of return. Since the Company did not sell its products with a right of return, the Company does not believe it has any liability to repurchase these products.

As a result of the Transfer Agreement, the Company will be responsible for all future marketing. As part of future marketing programs in the United States or internationally, the Company may determine that it is in its best interest to provide some compensation in the form of product discounts or by other means to the surgeons who bought our kits, and did not get to participate in the FDA trials, or to foreign distributors of our products. At this time, the Company is currently unable to determine the amount of possible compensation, if any, that it may agree to pay in the future.

A supplier had indicated to Ocular that it believed it had a firm order for 150 prototypes of the PresVIEW Incision System, which the Company disputed. The Company settled this claim for $15,000 during the year ended December 31, 2003. The charge for the settlement is included in "Research and development" in the consolidated statement of operations for the year ended December 31, 2003.

In 2001, the Company received $115,094, net of legal fees, related to a legal settlement in defense of one of the Company's patents. Two additional settlements also in the defense of the Company's patents resulted in a net expense when netted against the associated legal expenses in 2001. The net settlements are included in "Other income (expense)" in the consolidated statement of operations for the year ended December 31, 2001.

NOTE 11 – OTHER RELATED PARTY TRANSACTIONS

The Company leased its Denison, Texas facility under a monthly operating lease agreement with Dr. Schachar. The lease was terminated August 31, 2003. Total rent expense for the years ended December 31, 2003, 2002 and 2001 was $32,000, $48,000 and $48,000, respectively.

Ocular leased its former Dallas, Texas facility from a substantial holder of its Series B preferred stock. Due to the downsizing of its staff in conjunction with the business changes contemplated in the CIBA Agreement, Ocular negotiated a settlement with its former lessor to abandon that lease for a smaller facility. Under the contract, lease payments to the lessor of approximately $98,000 for the period from January through December 2003 were still due. Ocular negotiated a reduced lease payment of $48,000 to the lessor. This amount was paid by March 2003.

On February 26, 2003, the Chief Executive Officer, three of the Company's other directors and others loaned the Company $250,000 to provide working capital until the Merger Closing Date. The annual interest rate on the loan was 12%, and the loan was due on the Merger Closing Date. All but $25,000 of the amounts repaid were used to purchase Refocus common stock in the March 2003 private placement. Interest paid on the loans was $667.

NOTE 12 – INCOME TAXES

No provision for income taxes has been recognized for the three years ended December 31, 2003 as the Company incurred net operating losses for income tax purposes. The Company did not record any federal income tax benefit for its losses because of the uncertainty of realizing its deferred tax assets. The Company has adjusted the valuation allowance to maintain a full valuation allowance against the net deferred tax assets.

While the Company had generated substantial tax loss carryforwards in prior years, the ability to use these loss carryforwards has been substantially affected as a result of an ownership change (as defined in the Internal Revenue Code of 1986, as amended) that occurred in connection with the merger of Ocular into a subsidiary of Re-focus. Based on preliminary calculations, the Company believes that the use of our loss carryforwards generated prior to the Merger Closing Date will be limited going forward to approximately $1,286,000 per year. The total loss carryforwards subject to the limitation will expire as follows: from 2009-2012 approximately $681,000 and from 2018-2023 approximately $9,514,000.

Deferred tax assets consist of the following:

	Year Ended December 31,	
	2003	2002
Deferred tax assets:		
Net operating loss carryforwards	$ 4,943,152	$ 3,375,691
Advance royalty payment	680,000	680,000
Stock option compensation	326,263	57,086
Consulting Agreement	86,990	-
Fixed assets and other items	20,235	20,017
Total deferred tax assets	6,056,640	4,132,794
Valuation allowance	(6,056,640)	(4,132,794)
Recognized deferred tax assets	$ -	$ -

The increase in the deferred tax asset valuation allowance for the year ended December 31, 2003 was $1,923,846.

At December 31, 2003, the Company had net operating loss carryforwards of approximately $4,343,000 for income tax purposes since the Merger Closing Date. These net operating loss carryforwards will expire in 2023.

The difference between the Company's effective tax rate and the federal statutory rate of 34% are as follows:

	Year Ended December 31,		
	2003	2002	2001
Income tax benefit at statutory rate	(34)%	(34)%	(34)%
Valuation allowance	34	34	34
Total income tax expense	0%	0%	0%

NOTE 13. EMPLOYEE BENEFIT PLAN

Presby has a retirement savings plan under Section 401(k) of the Internal Revenue Code covering substantially all employees. The Company's contributions to the plan totaled $0, $14,713 and $2,500 for the years ended December 31, 2003, 2002 and 2001, respectively.

NOTE 14 – VERUS AGREEMENT

In the event that at least $1,000,000 was not raised in a post-closing private placement within six months of March 6, 2003, on terms no less favorable than the private placement consummated in March 2003, another party, Verus Support Services, Inc. ("Verus") subscribed to purchase that number of units at $2.00 per unit in order to satisfy the deficiency between the amount of additional capital successfully raised and $1,000,000 (see Note 3). Since no funds were received from a post-closing private placement, Verus is required to fund the entire $1,000,000. The Company had previously given Verus an 120-day extension to January 6, 2004 to their funding requirement in exchange for their forgiveness of $60,000 in consulting fees due them.

In January 2004, a dispute arose as to the continuing obligation of Verus under this agreement. As a means of deferring and ultimately resolving this dispute, the Company entered into an amendment to its agreement to further extend to June 30, 2004, Verus' obligation to purchase up to $1,000,000 of units and to make certain other amendments. Verus has advised the Company that its ability to provide the original subscription amount at a stock price well above current market is limited, and it indicated that current market conditions should be considered. Therefore, the Company agreed to amend the funding obligation to permit Verus to reduce its funding obligation by:

- the surrender and cancellation of shares of our common stock and warrants to purchase shares of our common that were issued to Verus or its affiliates, assigns or designees, or investors in the March 2003 private placement, based on the current market price of our common stock,
- the waiver of the remaining $20,000 in advisory fees due to it under its existing consulting agreement,
- the waiver of up to $60,000 in advisory fees that might become due to it during the extension period, and
- an amount of $25,000 that was received from an investor in the December 2003 private placement since that investor was introduced to the Company by Verus.

Further, after the credit of these amounts to the funding obligation, Verus has agreed to subscribe for and purchase, or cause to be subscribed for and purchased, an amount of Refocus common stock at prevailing market prices equal to 1.25 times the remaining funding obligation. Management of the Company believes that this agreement is in the Company's best interest and may result in funding during this extension period; however, the Company cannot be assured that Verus will not continue to dispute this obligation.

PRINCIPAL OFFICERS AND DIRECTORS

[redacted]

LEGAL COUNSEL

[redacted]

INDEPENDENT AUDITORS

[redacted]

TRANSFER AGENT AND REGISTRAR

[redacted]

INVESTOR/MEDIA RELATIONS CONTACT

[redacted]

EXHIBITS

A copy of any exhibit filed with the Securities and Exchange Commission as part of the Annual Report on Form 10-KSB for the year ended December 31, 2003, will be furnished for a reasonable fee to any shareholder upon written request to Investor Relations, Refocus Group, Inc., 10300 North Central Expressway, Suite 104, Dallas, Texas 75231. You may also view these exhibits on the Securities and Exchange Commission's Edgar system at www.sec.gov.

CODE OF ETHICS

The Corporation will make available to any person, without cost, a copy of its Code of Conduct and Ethics. Persons wishing to receive the Code should contact us in writing at Investor Relations, Refocus Group, Inc., 10300 North Central Expressway, Suite 104, Dallas, Texas 75231, or by email at info@refocus-group.com.

QUARTERLY REPORTS

The Corporation makes available to its shareholders, without cost, a copy of each quarterly Form 10-QSB. Shareholders wishing to receive the Form 10-QSB should contact Investor Relations or go to www.sec.gov.

ADDITIONAL INFORMATION

If you would like to contact the Company, members of the Board of Directors, or Executive Officers by email, our email address is info@refocus-group.com.

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