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LASERSIGHT INC /DE
Form 10-K
April 01, 2002

SECURITIES AND EXCHANGE COMMISSION
Washington, D.C. 20549

FORM 10-K

(Mark One)

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

For the fiscal year ended December 31, 2001

OR

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

Commission file number 0-19671

LASERSIGHT INCORPORATED

(Exact name of registrant as specified in its charter)

Delaware

65-0273162

(State of incorporation)

(I.R.S. Employer
Identification No.)

3300 University Blvd, Suite 140, Winter Park, Florida 32792

(Address of principal executive offices) (Zip Code)

Registrant's telephone number, including area code: (407) 678-9900

Securities Registered Pursuant to Section 12(b) of the Act:

Title of Each Class

Name of Each Exchange on Which Registered

None

N/A

Securities Registered Pursuant to Section 12(g) of the Act:

Common Stock, par value \$.001
Preferred Share Purchase Rights

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

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

The aggregate market value of the voting stock held by non-affiliates
of the registrant based on the closing sale price on March 29, 2002 was
approximately \$13,904,258. Shares of common stock held by each officer and

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director and by each person who has voting power of 10% or more of the outstanding common stock have been excluded in that such persons may be deemed to be affiliates. This determination of affiliate status is not necessarily a conclusive determination for other purposes.

Number of shares of common stock outstanding as of March 29, 2002:
26,554,168.

DOCUMENTS INCORPORATED BY REFERENCE

The information required to be included in Part III is incorporated herein by reference to the Company's definitive proxy materials to be filed with the Securities and Exchange Commission on or before April 30, 2002.

LASERSIGHT INCORPORATED

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The information in this Annual Report on Form 10-K contains forward looking-statements, as indicated by words such as "anticipates," "expects," "believes," "estimates," "intends," "projects," and "likely," by statements of the Company's plans, intentions and objectives, or by any statements as to future economic performance. Forward-looking statements involve risks and uncertainties that could cause the Company's actual results to differ materially from those described in such forward-looking statements. See "Risk Factors and Uncertainties-We have experienced significant losses and operating cash flow deficits and we expect that operating cash flow deficits will continue and absent further financing or significant improvement in sales, potentially result in our inability to continue operations." Factors that could cause or contribute to such differences include, but are not limited to, those discussed in Item 7 under the caption "Risk Factors and Uncertainties" as well as those discussed elsewhere in this Report. All references to "LaserSight(R)" "we," "our" and "us" in this Report refer to LaserSight Incorporated and its subsidiaries unless the context otherwise requires.

PART I

ITEM 1. BUSINESS

OVERVIEW

We develop, manufacture and market quality product technologies for laser refractive surgery and other areas of vision correction. Our products include precision microspot scanning excimer laser systems used to perform procedures that correct common refractive vision disorders such as nearsightedness (myopia), farsightedness (hyperopia) and astigmatism, software for custom ablation planning and programming, diagnostic products for precision measurements of the eye, as well as keratome systems, keratome blades, and other products for use in refractive vision correction procedures. We believe that our precision microspot scanning lasers have significant technological advantages and produce smoother and more precise ablation areas than older, broad-beam laser systems and other scanning systems offered by many of our competitors. We also believe that the breadth of our product offering may provide us with a competitive advantage relative to many other excimer laser system manufacturers because it provides us with a platform to become a single-source supplier of refractive vision correction products to refractive surgeons. Moreover, due to the anticipated growth in refractive laser vision correction procedure volume, our broad product offering affords us the opportunity to generate recurring revenues by collecting per procedure fees and by selling our keratome blades.

We have significant liquidity and capital resource issues. See "--LaserSight Recent Developments" for an important discussion of our significant liquidity and capital resource issues relative to the timing of our accounts receivable collection and the completion of new sales compared to our ongoing payment obligations. Management expects LaserSight's cash and cash equivalent balances and funds from operations (which are principally the result of sales and collection of accounts receivable) will be sufficient to meet its anticipated operating cash requirements for only the next two to four weeks in the absence of LaserSight obtaining an additional source of capital or a significant improvement in our cash flows from operations. Our expectations regarding future working capital requirements and our ability to continue operations are based on various factors and assumptions which are subject to substantial uncertainty and risks beyond our control and no assurances can be given that these expectations will prove correct. The occurrence of adverse developments related to these risks and uncertainties or others could result in LaserSight being unable to generate additional sales and collect new and outstanding accounts receivable and the incurrence of unforeseen expenses or LaserSight being unable to control expected expenses and overhead. If we fail to

generate additional sales and collect new and outstanding accounts receivable or incur unforeseen expenses or fail to control our expected expenses and overhead, we will likely be unable to continue operations for the expected two to four week period in the absence of obtaining additional sources of capital. We are actively seeking investors to invest in the range of \$1.5 million to \$3.0 million, as well as distribution agreements for certain products, which would provide temporary relief from our current liquidity pressures. If we are able to enter transactions to meet our liquidity needs, it could be on terms that seriously dilute our present stockholders or significantly restrict the flexibility of our business.

We have over eight years of experience in the manufacture, sale and service of precision microspot scanning laser systems for refractive vision correction procedures. Since 1994, we have sold our scanning laser systems commercially in over 30 countries worldwide. As a result, we believe that our installed base of approximately 400 scanning laser systems, including over 220 of our most advanced laser system, the LaserScan LSX(R), is among the largest installed bases of scanning laser systems in the industry. In November 1999, the Food and Drug Administration (FDA) approved our LaserScan LSX scanning laser system for commercial sale in the U.S. for the treatment of nearsightedness of up to -6.0 diopters. In September 2001, the FDA approved our LaserScan LSX precision microspot scanning system for the laser in-situ keratomileusis (LASIK) treatment of myopia with and without astigmatism up to a manifest refraction spherical equivalent (MRSE) of -6.0 diopters with maximum refractive astigmatism approved for up to 4.5 diopters. Currently, all of our laser systems delivered into the U.S. and international markets operate at a pulse repetition rate of 200 Hz, which we believe is the fastest pulse repetition rate available in our industry. We currently have pending with the FDA Pre-Market Approval (PMA) Supplement applications seeking approval for the use of our laser system for the LASIK treatment of farsightedness, farsightedness with astigmatism and mixed astigmatism. Our AstraScan features incorporate the same precision microspot scanning features along with an advanced eye tracking system, improved lighting and a redesigned "delivery arm" on the laser to make the microscope and joystick more functional and allow for keratome placement. Available now as an upgrade in many international markets, the AstraScan features will need FDA approval before they can be sold in the U.S. In the U.S. market we are currently pursuing FDA approval through a combination of a real time PMA Supplement and other regulatory pathways.

Our family of products for custom refractive treatments (often referred to as custom ablations) includes the AstraMax(TM) diagnostic workstation designed to provide precise diagnostic measurements of the eye for many refractive purposes, including generating data needed to plan custom ablation procedures, and our Corneal Interactive Programmed Topographic Ablation (CIPTA) and AstraPro(TM) custom ablation planning software that utilize advanced levels of diagnostic measurements from our AstraMax diagnostic workstation to complete the planning of custom ablation treatments. The AstraMax integrated diagnostic workstation was first shown in October 2000 at the Annual Meeting of the American Academy of Ophthalmology and is expected to be commercially launched during the second quarter of 2002. LaserSight distributes the CIPTA custom ablation planning and programming software outside the U.S. under a November 2001 distribution agreement with Ligi Technologie Medicali, Taranto, Italy. The CIPTA software was developed to operate specifically with our precision microspot scanning excimer laser system. The CIPTA custom ablation software was introduced in January 1996 and has received CE Mark certification. We are internally developing the AstraPro custom ablation planning software and international clinical testing of the AstraPro software has begun. We plan to begin our U.S. Investigational Device Exemption (IDE) clinical trials for the

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AstraPro software during 2002.

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Our MicroShape(R) family of keratome products includes our UltraShaper(R) durable keratome, a control console used with our durable keratomes, and our UltraEdge(R) keratome blades. Our MicroShape family of keratome products can be used with the LaserScan LSX and other laser systems used to perform LASIK. We began commercial shipment of our UltraShaper durable keratome and control consoles in November 2001. We anticipate that sales of our UltraEdge keratome blades will provide us with the opportunity to participate in the expected growth in refractive laser vision correction procedure volume by generating recurring revenue streams, regardless of which laser system a refractive surgeon uses. We believe the UltraShaper compares favorably to existing keratome products in the marketplace due to its relative ease of assembly and consistency of performance. We have also developed the UniShaper(TM), a single use keratome, however, we believe that to be commercially viable the UniShaper will need to be reengineered, if possible, to include most or all of the design features included in our UltraShaper durable keratome.

OPERATING SEGMENTS. We have operated in the following operating segments: refractive products, patent services and health care services. In late 2001, we decided to discontinue the health care services operations. Our principal wholly-owned subsidiaries during 2001 included: LaserSight Technologies, Inc. (LaserSight Technologies), LaserSight Patents, Inc. (LaserSight Patents), and MRF, Inc. (The Farris Group or TFG).

Our refractive products segment, primarily including our laser vision correction products and services of LaserSight Technologies, develops, manufactures and markets ophthalmic lasers with a galvanometric scanning system for use in performing refractive surgery. We recently introduced an upgrade to our laser system, our AstraScan, that uses a 0.6 millimeter precision microspot scanning laser beam to ablate microscopic layers of corneal tissue to reshape the cornea and to correct the eye's point of focus in persons with myopia (nearsightedness), hyperopia (farsightedness) and astigmatism. Our patent services segment, consisting primarily of patents licensed by us, included a patent related to the use of excimer lasers to ablate biological tissue until the patent was sold in March 2001 and a license to a patent related to the use of scanning lasers. The health care services segment consisted of TFG until we decided in late 2001 to discontinue its operations. TFG's financial results are accounted for as a discontinued operation for the year ended December 31, 2001. TFG provided health care and vision care consulting services to hospitals, managed care companies and physicians. For information regarding our export sales and operating revenues, operating profit (loss) and identifiable assets by industry segment, see Note 14 of the Notes to Consolidated Financial Statements.

ORGANIZATION AND HISTORY. LaserSight was incorporated in Delaware in 1987, but was inactive until 1991. In April 1993, we acquired LaserSight Centers Incorporated in a stock-for-stock exchange with additional shares issued in March 1997 pursuant to an amended purchase agreement. In February 1994, we acquired TFG. In July 1994, LaserSight was reorganized as a holding company. In October 1995, we acquired MEC Health Care, Inc. (MEC). In July 1996, our LSI Acquisition, Inc. (LSIA) subsidiary acquired the assets of the Northern New Jersey Eye Institute, P.A. On December 30, 1997, we sold MEC and LSIA in connection with a transaction that was effective as of December 1, 1997. Late in 2000, we abandoned the LaserSight Centers mobile laser strategy due to industry conditions and our increased focus on development and commercialization of our refractive products. In December 2001, we decided to discontinue the operations of TFG as described in Note 3 of the Notes to Consolidated Financial Statements. Our principal offices and mailing address are 3300 University Boulevard, Suite

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140, Winter Park, Florida 32792, our telephone number is (407) 678-9900 and our address on the World Wide Web is www.lase.com.

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INDUSTRY OVERVIEW

REFRACTIVE VISION CORRECTION

Laser vision correction is a surgical procedure for correcting vision disorders such as nearsightedness, farsightedness and astigmatism using an excimer laser. This procedure uses ultraviolet laser energy to ablate, or remove, tissue from the cornea and sculpt the cornea into a predetermined shape. Because the excimer laser is a cold laser, it is possible to ablate precise amounts of corneal tissue without causing thermal damage to surrounding tissue. The goal of laser vision correction is to achieve patient vision levels that eliminate or significantly reduce a person's reliance on corrective eyewear. The first laser vision correction procedure on a human eye was conducted in 1985 and the first human eye was treated with the excimer laser in the U.S. in 1988.

There are currently two principal methods for performing laser vision correction with excimer laser systems: photorefractive keratectomy, or PRK, and LASIK. According to Market Scope, approximately 92% of the refractive vision correction procedures performed in the U.S. in 2000 were LASIK procedures. The Company believes that this trend has continued through 2001. In both PRK and LASIK procedures, a refractive surgeon determines the exact refractive correction required to be made to the cornea, typically using the same examination used to prescribe eyeglasses and contact lenses. Required corrections are then programmed into the excimer laser system's computer. During the procedure, the excimer laser system emits laser pulses, each of which lasts several billionths of a second, to remove submicron layers of corneal tissue. While the length of laser treatments range from 15 to 60 seconds, cumulative exposure to the laser light during each procedure is less than one second. The entire procedure, including patient preparation and post-operative dressing, generally lasts no longer than thirty minutes.

PHOTOREFRACTIVE KERATECTOMY (PRK)

In PRK, the refractive surgeon prepares the eye by gently removing the surface layer of the cornea called the epithelium. The surgeon then applies the excimer laser beam, reshaping the curvature of the cornea. Following PRK, a patient typically experiences blurred vision and discomfort until the epithelium heals. It generally takes one month, but may take up to six months, for the full benefit of PRK to be realized. PRK has been used commercially since 1988.

LASER IN-SITU KERATOMILEUSIS (LASIK)

LASIK was commercially adopted internationally in 1994 and in the U.S. in 1996. Immediately prior to a LASIK procedure, the refractive surgeon uses a surgical instrument called a keratome to create a thin, hinged flap of corneal tissue. Patients do not feel or see the cutting of the corneal flap, which takes only a few seconds. The flap is flipped back, the laser beam is directed to the exposed corneal surface, the flap is placed back and the flap and interface are rinsed with buffered saline solution. Once the procedure is completed, surgeons generally wait two to three minutes to ensure the corneal flap has fully re-adhered. At this point, patients can blink normally and the corneal flap remains secured in position by the natural suction within the cornea. Since the surface layer of the cornea remains intact during LASIK, the patient experiences virtually no discomfort. The LASIK procedure often results in a higher degree of patient satisfaction due to an immediate improvement in visual acuity and generally involves less post-operative discomfort than PRK.

LASER EPITHELIAL KERATOMILEUSIS (LASEK)

Laser refractive surgical procedures have undergone a transition from PRK to the LASIK procedure that has become the procedure of choice for most patients and surgeons. With the anticipated transition to custom ablations, refractive surgeons have expressed concern over the possibility of induced refractive error related to the LASIK flap. A newly developed technique, LASEK is now being considered as an alternative to LASIK when performing custom ablations. During the LASEK procedure a thin epithelial flap is formed using alcohol, the flap is lifted up and repositioned after photorefractive ablation. The LASEK procedure is said to result in less pain and discomfort than the PRK procedure. Healing and recovery of vision is slower than LASIK, but not as long as PRK.

CUSTOM ABLATION

Most laser system manufacturers are attempting to offer a custom ablation solution. Custom ablation is believed to offer higher quality clinical outcomes for patients due to the fact that a specific ablation profile is planned for each eye. Higher quality outcomes are expected to be a significant selling point with surgeons. Custom procedures typically involve gathering diagnostic data from the surfaces of the eye, converting the data into an individualized laser ablation plan based on the specific diagnostic data of each eye, and performing the refractive surgery based on the ablation plan. We believe small spot, high repetition rate scanning lasers are the best suited to perform custom ablation procedures. Custom ablation procedures are not yet commercially available in the U.S., though some manufacturers have commenced clinical trials in anticipation of seeking FDA approval.

REFRACTIVE VISION CORRECTION MARKET

The worldwide market for products and services to correct common refractive vision disorders such as nearsightedness, farsightedness and astigmatism is large and growing. Industry sources estimate that 50% of the U.S. population, or approximately 140 million people, presently wear eyeglasses or contact lenses. There are approximately 14,000 practicing ophthalmologists in the U.S., of whom approximately 4,000 reportedly perform refractive laser vision correction procedures on a regular basis.

Laser vision correction was a fast growing segment of the vision correction market through 2000. According to Market Scope, total laser refractive procedure volume in the U.S. has increased rapidly each year since 1996 to an estimated 1,400,000 procedures in 2000. During 2001 refractive procedures in the U.S. declined 7% to 1,300,000 due to the combined effects of an economic recession and the terrorist attacks of September 2001. An estimated 267,000 procedures were performed in the U.S. during the fourth quarter 2001, compared to 279,000 procedures during the third quarter 2001 and 363,000 procedures during the fourth quarter 2000. Similarly, laser systems sold in the U.S. were reported to have dropped from 490 in 2000 to 261 in 2001. According to Banc of America Securities, the number of U.S. procedures for 2002 are projected to grow 15% to 1,500,000 with a 15% increase to 1,725,000 procedures projected for 2003. A procedure refers to laser treatment on a single eye, and most patients have procedures performed on both eyes during a single visit to a refractive surgeon. Laser vision correction's growth in the U.S. is also reflected in the expansion of excimer laser installations and in the rise in average annual procedure volume per laser.

Many, but not all, manufacturers of excimer laser systems seek to share

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in the anticipated growth in procedure volume by receiving a fee for each

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procedure performed by a refractive surgeon using laser systems manufactured by them. The per procedure fees charged by these manufacturers vary and were significantly reduced during 2000 due to competitive pressures and changing market conditions. See "Business-Competition."

DEVELOPMENT OF EXCIMER LASER SYSTEM, DIAGNOSTIC AND KERATOME TECHNOLOGY

EXCIMER LASER SYSTEMS

The excimer laser systems utilized for laser vision correction have evolved over time with improvements in laser and beam delivery technology. Until recently, broad beam laser systems, that were initially developed during the late 1980's, were the only systems approved by the FDA for commercial use in the U.S. As a result, broad beam laser systems are reported to currently represent about 65% of the installed laser systems in the U.S., down from over 90% at the end of 1999. This downward trend appears to be continuing as the newer scanning laser systems obtain the broader range of treatment approvals originally held by the older broad beam systems. Certain broad beam laser systems have undergone technical changes designed to modify their beam delivery to achieve pseudo-scanning on the cornea. These changes have been accomplished through the use of various optical elements with the effect of reducing beam size and simulating a scanning pattern. These modified broad beam laser systems are still characterized by their use of relatively large laser beams of six to eight millimeters in diameter that deliver relatively high amounts of laser energy (100 - 200 mj) at low laser pulse repetition rates (generally 10 Hz) to the corneal surface. Because of the relatively large diameter of the fundamental laser beam, these systems still require a number of mechanical elements and optics to condition, size, shape and deliver the beam profiles necessary to produce an ablation. These mechanical and optical means of beam shaping and pseudo-scanning still limit the flexibility of broad beam systems and may require additional hardware modifications in order to adapt to more complex applications such as custom ablation.

Glare and halos when looking at lights or other bright objects and reduction in night vision and contrast sensitivity have also been associated with the use of broad beam systems.

Improvements in excimer laser technology during the early 1990's have made it possible to develop refractive excimer laser systems that have significantly narrower laser beams (less than one millimeter in diameter) that use reduced amounts of laser energy (10 mj) at higher pulse repetition rates (up to 200 Hz) to achieve corneal ablations. LaserSight was the leader in the development of precision microspot scanning technology and the first company to commercialize it. This new generation of narrow beam scanning excimer laser systems incorporated scanning mirrors and computer control to shape the ablation profile, making it unnecessary to utilize mechanical elements to size and shape the laser beam to attain the desired results. Techniques incorporated into scanning laser technology such as purposeful overlapping of laser pulses and random scanning patterns can lead to overall improved clinical results as evidenced by smoother ablations, the elimination of corneal ridges and central islands, and the reduction in the incidence of glare, halos, loss or reduction of night vision and contrast sensitivity. Narrow beam scanning excimer laser systems are currently the most flexible laser vision correction platforms available as they can be adapted to expansions in treatment modalities and the incorporation of new technologies such as higher laser pulse repetition rate, active eye tracking and custom ablation through software and minor hardware upgrades.

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DIAGNOSTIC AND CUSTOM ABLATION PRODUCTS

One of the most important tools ophthalmologists have at their disposal is corneal topography. With a corneal topographer the ophthalmologist can

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literally see the refractive problems that might be present in the cornea. Corneal topography is used not only for screening all patients before refractive surgery like LASIK, but also for fitting contacts, adjusting post surgical corneal transplants, and diagnosing refractive disorders and diseases. Fundamentally, a corneal topographer can be described as a computer linked to a lighted bowl with a pattern of concentric rings inside it. Patients are seated at the bowl with their forehead braced against a bar. A technician has only to line the patient up properly and snap an image. The procedure is painless and very fast. The computer then uses the captured image to produce a printout of the corneal shape and elevation using colors to identify different steepnesses, much like a topographic map of the earth describes changes in the land surface. Elevation topography of the anterior cornea enables clinicians to more accurately visualize the shape of abnormal corneas, which leads to more accurate diagnoses and more consistent surgical results.

Of currently available technology, corneal topography provides the most detailed information about the curvature of the cornea. This information is useful to evaluate and correct astigmatism, monitor corneal disease, and detect irregularities in the corneal shape. This diagnostic procedure is essential for patients being considered for refractive vision correction procedures (such as LASIK) and may even be necessary in the follow-up of some patients who have undergone refractive surgical procedures.

Topography instruments have undergone significant changes in technology and functionality since they were first introduced. The technology has progressed from stationary placido-based topography in early generation topographers to scanning slit technology and now to the stereo-based technology in our AstraMax.

The placido-based method of image analysis involves multiple concentric light rings projected on the cornea. The reflected image is captured by a video camera. Computer software analyzes the data and displays the results in a variety of formats that resemble topographic maps. Elevation is not measured directly by placido-based topographers, but certain assumptions allow the mathematical approximation of the corneal surface and the construction of estimated elevation maps.

The introduction of slit-scan imaging advanced the technology and effectiveness of corneal topography. A corneal topography system manufactured by Bausch & Lomb uses a scanning optical slit design that is fundamentally different from the corneal topographer that analyzes the reflected images from the anterior corneal surface. A high-resolution video camera captures individual light slits projected at a 45(degree) angle through the cornea similar to what's seen during an ophthalmic slit lamp examination. Using a combination of reflective corneal topography and information from the scanning slit, the instrument's software analyzes the data points and calculates the anterior and posterior surfaces of the cornea and the corneal thickness. The data points generate a higher quality elevation map than is possible with the placido-based method.

We believe our AstraMax diagnostic workstation is the next-generation topography instrument. The AstraMax uses a unique, patented three-video camera imaging system and stereo ray tracing to achieve high-precision elevation

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measurements of the cornea. In other words, the multiple cameras generate geometrical calculations based on the known distances and angles of the three cameras. Utilizing a patented checkered polar grid and other proprietary features the AstraMax obtains, in a single examination, a series of critical measurements of the cornea and eye including posterior and anterior corneal topography (elevation), thickness of the cornea (pachymetry) and the diameter of the pupil under conditions of both low lighting (scotopic) and normal lighting (photopic). The precision elevation measurements result in elevation maps of the highest available quality.

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Since CIPTA was introduced into international clinical use, 22 refractive surgery centers performing over 15,000 procedures per year have been licensed to perform custom ablations using the CIPTA software and our excimer laser systems. These CIPTA custom treatments using our excimer laser system demonstrate efficacy, safety, predictability and stability and such results have been published in peer-reviewed journals and presented at major ophthalmology venues throughout the world. With over 220 of our LaserScan LSX excimer laser systems installed worldwide, significant opportunity exists to upgrade those systems to our AstraScan model to perform CustomEyes procedures with the CIPTA custom ablation planning software. Also, our AstraPro software is under development by our software engineers and we plan to begin our U.S. IDE clinical trials during 2002.

KERATOMES

Keratomes used to cut the thin corneal flap during the LASIK procedure are similar in design to those used to perform earlier non-laser surgical refractive techniques such as automated lamellar keratoplasty (ALK). The Automated Corneal Shaper (ACS), developed by Luis A. Ruiz, M.D. and Sergio Lenchig, is an example of an ALK keratome that is utilized extensively in association with LASIK procedures without modification from its original design.

The ACS durable keratome, manufactured and marketed by Bausch & Lomb pursuant to a license agreement, was the leading keratome during the early and mid-1990's at a time when many refractive surgeons learned to perform LASIK. After we licensed the rights to commercially market keratomes based on the same technology in 1997, Bausch & Lomb discontinued the ACS, and has introduced an alternative durable keratome product that requires a modified surgical technique. Over the last few years there have been numerous entrants into the keratome market, including most excimer laser manufacturing companies.

LASERSIGHT RECENT DEVELOPMENTS

LIQUIDITY AND FINANCING ISSUES

We have significant liquidity and capital resource issues relative to the timing of our accounts receivable collection and the successful completion of new sales compared to our ongoing payment obligations. We believe we will need to generate increased revenues, collect them and reduce our expenditures relative to our recent history. While we believe these improved results are possible, we cannot assure you that we will be able to generate increased revenues and collections to offset required cash expenditures.

Our working capital remains positive (approximately \$8.0 million as of the end of March 2002), though the timing of the conversion of our current assets into cash is not totally in our control. For example, we cannot dictate the timing of the collection of our accounts receivable with our customers and converting our inventory is dependent on our ability to generate new sales with our products and collect the sales price in a timely manner.

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Management expects LaserSight's cash and cash equivalent balances and funds from operations (which are principally the result of sales and collection of accounts receivable) will be sufficient to meet its anticipated operating cash requirements for only the next two to four weeks in the absence of LaserSight obtaining an additional source of capital or a significant improvement in our cash flows from operations. Our expectations regarding future working capital requirements and our ability to continue operations are based on various factors and assumptions which are subject to substantial uncertainty and

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risks beyond our control and no assurances can be given that these expectations will prove correct. The occurrence of adverse developments related to these risks and uncertainties or others could result in LaserSight being unable to generate additional sales and collect new and outstanding accounts receivable and the incurrence of unforeseen expenses or LaserSight being unable to control expected expenses and overhead. If we fail to generate additional sales and collect new and outstanding accounts receivable or incur unforeseen expenses or fail to control our expected expenses and overhead, we will likely be unable to continue operations for the expected two to four week period in the absence of obtaining additional sources of capital.

We are actively seeking investors to invest in the range of \$1.5 million to \$3.0 million in equity and/or debt, as well as distribution agreements for certain products, which would provide temporary relief from our current liquidity pressures. However, even if we succeed in completing a financing transaction to address our current liquidity concerns, we cannot assure you that we will be able to generate increased revenues and collections to offset required cash expenditures in a timely manner. Additionally, if we are able to enter into transactions to meet our liquidity needs, it could be on terms that seriously dilute our present stockholders or significantly restrict the flexibility of our business. See "Management's Discussion and Analysis of Financial Condition and Results of Operations--Liquidity and Capital Resources," "Risk Factors and Uncertainties--Industry and Competitive Risks--We cannot assure you that we have the liquidity to survive long enough to achieve market acceptance with our products in the U.S." and "--Financial and Liquidity Risks--We have experienced significant losses and operating cash flow deficits and we expect that operating cash flow deficits will continue and absent further financing or significant improvement in sales, potentially result in our inability to continue operations."

PRODUCT-RELATED DEVELOPMENTS

Our LaserScan LSX and our recently introduced AstraScan excimer laser systems are based on patented precision microspot scanning technology rather than broad beam technology, that until recently was the only commercially available excimer laser vision correction technology in the U.S. Subject to satisfactorily addressing our serious liquidity and financing needs, we believe we are well-positioned to become a significant provider of excimer laser systems, diagnostic products, keratomes and blades and other related products as a result of our technology and the following recent developments:

- o REISSUANCE OF SCANNING PATENT. In January 2002, the U.S. Patent and Trademark Office reissued LaserSight's scanning patent U.S. Patent No. 5,520,679, the ('679 Scanning Patent) as U.S. Patent No. RE 37,504 ('504 Scanning Patent), thereby completing the reissue process. After a more than 3 1/2 year review of the reissue application, including detailed analysis of a number of public protests filed by a third party, the U.S. Patent and Trademark Office has confirmed our broad patent rights to

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precision microspot scanning laser refractive surgery and issued LaserSight 68 additional patent claims. Prior to the reissue, the original `679 Scanning Patent included one independent claim and 23 total claims, whereas the `504 Scanning Patent reissue has added nine new independent claims, and a total of 68 additional claims to better encompass the breadth of technology to which we are entitled. The 23 original claims remain essentially unchanged. The reissue should allow us to protect the uniqueness of our precision microspot scanning technology since the fundamental teachings of the original `679 Scanning Patent encompass a refractive laser system utilizing an excimer laser with a low fluence and high repetition rate that ablates corneal tissue using small pulses delivered to the corneal surface in an overlapping pattern. We believe that many of the other laser manufacturers

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will have to respect the intellectual property rights granted to us through the `504 Scanning Patent reissue.

- o LICENSE OF SCANNING PATENT. In September and December 2001, we received a total of \$5.0 million in cash for a non-exclusive license agreement with Bausch & Lomb for our `679 Scanning Patent. See "Reissuance of Scanning Patent" above.
- o COMMERCIAL LAUNCH OF OUR ULTRASHAPER KERATOME PRODUCT. We commercially launched our UltraShaper durable keratome during the fourth quarter of 2001. We believe that the combination of our UltraShaper durable keratome and our UltraEdge keratome blades, that are intended to be replaced after each procedure when used in durable keratomes, provide us with an attractive opportunity to generate recurring revenues on a per procedure basis.
- o CUSTOM ABLATION. In March 2000, we purchased from Premier Laser Systems, Inc. all intellectual property related to a development project designed to provide front-to-back analysis and total refractive measurement of the eye. The technology we acquired included the acquisition of two U.S. patents, six foreign patents, and a pending patent application along with an exclusive license to nine patents that were intended to be used to complete development of an integrated refractive diagnostic workstation. This technology acquisition led to the development of our AstraMax integrated diagnostic workstation. The AstraMax can be utilized as a stand-alone diagnostic unit or as part of our CustomEyes approach to custom ablation plans. We believe that the AstraMax integrated diagnostic workstation is the first product to integrate precision diagnostic measurements such as anterior and posterior corneal elevation, corneal thickness, anterior chamber depth and measurements of photopic and scotopic pupil size into a single instrument. The underlying technology for the AstraMax is the subject of 14 U.S. patents that have either been issued to us or for which we have a license. We plan to add wavefront analysis to the AstraMax's capabilities at a later time. The precision measurements from the AstraMax integrated workstation will be utilized in our CIPTA and AstraPro software for planning custom ablations. CIPTA is a custom ablation planning software to which LaserSight has had distribution rights on a worldwide basis since November 2001. International clinical testing of our internally developed AstraPro planning software has begun and we plan to begin our U.S. IDE clinical trials during 2002. Any custom ablation software will require clinical trials and FDA approval

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prior to sale in the U.S. We believe our CustomEyes approach to custom ablation represents a new standard of eye care that goes beyond conventional laser vision correction by individualizing the laser treatment utilizing a patient-specific set of diagnostic criteria intended to address and control both refractive error and optical aberration that has either been induced by prior refractive surgery or is naturally occurring.

PRODUCTS

EXCIMER LASERS

LaserSight was the first company to develop an advanced precision microspot scanning excimer laser system. The LaserScan LSX and recently announced AstraScan (for international use) excimer laser systems have evolved from the patented optical scanning system incorporated in the Compak-200 Mini-Excimer laser system, introduced internationally in 1994. Since the

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introduction of the Compak-200 laser system we have offered several generations of our scanning laser, each incorporating enhancements and new features. We have sold our precision microspot scanning excimer laser systems in over 30 countries and believe our installed base of approximately 400 scanning laser systems, including over 220 of our advanced laser system, the LaserScan LSX, is among the largest installed bases of scanning laser systems in the industry. The AstraScan model incorporates the same precision microspot scanning features along with an advanced eye tracking system, improved lighting and a redesigned "delivery arm" on the laser to make the microscope and joystick more functional and allow for keratome placement. The AstraScan features will need FDA approval before they can be sold in the U.S. Throughout the evolution of our precision microspot scanning excimer laser systems, the core concept of utilizing our proprietary precision microspot scanning software to ablate corneal tissue with a low energy, microspot laser beam at a rapid pulse repetition rate has remained the underlying basis for our technology platform.

In November 1999, the LaserScan LSX was approved by the FDA for sale in the U.S., and we began commercial shipments to U.S. customers in March 2000. In September 2001, our PMA Supplement for the LASIK treatment of myopia and myopia with astigmatism was approved by the FDA, thereby increasing the range of indications that can be treated in the U.S. using the LaserScan LSX. We believe that the patented precision microspot scanning technology and other advanced features incorporated into our LaserScan LSX excimer laser system offer refractive surgeons and patients significant advantages over broad beam and other scanning laser systems. We believe that the "SFR" technology incorporated into our LaserScan LSX offers advantages over competitive scanning laser systems. We believe that the incorporation of the smallest spot size (S), the lowest laser fluence (F) and highest repetition rate (R), together with techniques like the patented purposeful overlapping of laser pulses and random scanning patterns used by our patented precision microspot scanning technology, can lead to overall improvements in clinical results with smoother ablations, the elimination of surgical anomalies associated with broad beam laser systems such as rings, ridges and central islands, and reductions in the incidence of glare, halos and loss of night vision. We also believe that our patented SFR technology is capable of providing the highest resolution and accuracy in corneal ablations needed for custom ablation treatments. The key benefits of our laser systems include the following:

- o PRECISION MICROSPOT SCANNING LASER. The LSX and AstraScan use patented precision microspot scanning to deliver a high resolution, 0.6 millimeter low-energy "flying spot," in a

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proprietary, randomized pattern. They are true precision scanning software-controlled lasers that use a pair of galvanometer controlled mirrors to reflect and scan the laser beam directly onto the corneal surface, without the mechanical elements used by broad beam excimer laser systems.

- o LOWER FLUENCE. The accuracy and resolution of ablations produced by a refractive laser system is directly related to its laser fluence. Laser fluence is a measurement of the amount of energy in a laser pulse per unit area of the pulse. Lasers with lower fluence remove less corneal tissue with each laser pulse than lasers with higher fluence. When low laser fluence is delivered in a smaller laser spot, the ability of a laser system to accurately produce a predetermined laser ablation pattern is increased. Our lasers operate with a fluence of 89 mj/cm² and have a beam size of 0.6 to 0.8 mm. Many competitive laser systems operate with fluences up to 200 mj/ cm² and have larger laser spots.
- o HIGHER PULSE REPETITION RATE. Operating at higher pulse repetition rates can result in a number of benefits, including reduced

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average procedure times and elimination or reduction of dehydration problems associated with longer exposure of the corneal tissue to ambient conditions. Our lasers operate at a pulse repetition rate of 200 Hz. Many competitive laser systems currently operate at lower pulse repetitions, often 50 Hz or less.

- o EYE TRACKING. Proper alignment of the refractive correction is important in all laser vision correction procedures, and is essential in order to perform custom ablations. Our advanced adaptive eye tracking system maintains alignment of the refractive correction relative to the visual axis of the eye, and can be turned on or off based on the refractive surgeon's clinical preference. The LaserSight advanced adaptive eye tracker is a high speed, synchronous, "active" system that is capable of following even small, involuntary eye movements. The tracking system eliminates most errors normally introduced by eye movements during untracked laser refractive surgery, and does not require dilation of the pupil or any apparatus to be in contact with the eye. Our advanced adaptive eye tracking system is currently available only on international versions of the AstraScan, and we are currently pursuing a "real time" PMA Supplement that seeks approval for use of this feature in the U.S., which could result in FDA approval in as few as 30 days.
- o SOFTWARE DRIVEN FLEXIBLE PLATFORM. Custom ablations have resulted in increased patient satisfaction in international clinical use and we believe the ability to perform custom ablations will generally result in improved visual quality, more predictable results and less post-operative regression relative to other refractive surgery techniques. We also believe that custom ablation will be the technique most preferred by refractive surgeons for correction of irregular astigmatism, decentered ablations and other surgically induced corneal irregularities. In our scanning laser, ablation profiles and spot location are determined by system software, not mechanical elements. When programmed by custom ablation software tools, our laser is able to perform custom ablations because its software has the ability to move the "flying spot" beam to the precise predetermined areas on

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the cornea requiring treatment. Upon receipt of FDA approvals, software upgrades can be used to readily update U.S. models to include features currently available only on international models, including the ability to treat farsightedness, astigmatism and mixed astigmatism.

- o ADVANCED DESIGN AND ERGONOMICS. Our laser's relatively light weight and compact design allows it to fit into small spaces, and its wheels enable it to be easily moved around in a multi-surgeon practice. This allows for higher utilization of the laser system. The efficient design also enables users to transport the laser to other locations.
- o IMPROVED RELIABILITY AND LOWER MAINTENANCE REQUIREMENTS. Our laser system uses a smaller lower energy laser and fewer optical elements compared to broad beam laser systems and other scanning systems on the U.S. market. This design requires less frequent replacement of expensive optical elements and a lower volume of laser gas. Savings achieved from less frequent replacement of optical elements and reduced laser gas usage translate directly into reduced down time and maintenance costs.
- o ASTRASCAN IMPROVEMENTS AND UPGRADES--CUSTOM ABLATION READY. Our AstraScan model was first introduced in November 2001 and is a custom ablation ready excimer laser system that incorporates performance improvement and features needed to produce the precise custom ablations planned with CIPTA and AstraPro software. The AstraScan incorporates the latest in technology for adaptive

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active eye tracking, improvements to lighting systems for surgeon viewing and eye tracking and increased working distance for the surgeon. The system also has the ability to link directly with CIPTA and AstraPro software. The AstraScan system is currently available in the international market as an upgrade to an existing LaserScan LSX system. In the U.S. market we are currently pursuing FDA approval through a combination of a real time PMA Supplement and other regulatory pathways.

CLINICAL EXPERIENCE AND OUTCOME QUALITY

We believe that there are several measures that should be evaluated with regard to the safety and clinical effectiveness of laser vision correction systems. These measurements include the incidence of adverse effects such as double vision, night driving problems like glare, halos or haze, the post-operative best visual acuity that can be obtained using corrective eyewear such as glasses or contact lenses, BSCVA, and the post-operative uncorrected visual acuity, or UCVA (such as whether the patient is seeing 20/20 or 20/40).

We believe that the degree to which negative, and sometimes permanent, side effects occur as a result of refractive procedures performed using a laser system is a key measure of a laser system's performance. In some cases, the BSCVA deteriorates following a laser vision correction procedure. In addition, the incidence of side effects such as double vision or haze can substantially reduce patient satisfaction, or visual quality, even if a high level of post-operative visual acuity is achieved. The data from FDA clinical trials shows that with respect to symptoms such as corneal haze and night vision problems, the LaserSight LSX compared favorably to the data for the Visx and/or Summit broad beam laser systems. We believe these qualitative improvements are a result of the technological features of the LaserScan LSX, including larger

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treatment zones and a small scanning microspot that provides a smoother corneal ablation.

CLINICAL RESULTS

FDA clinical trials for the treatment of PRK with the LaserScan LSX laser were conducted in the U.S. on patients with nearsightedness with required levels of correction of 6 diopters and less. We believe that the average pre-operative level of required correction is a significant factor that must be taken into account in evaluating the clinical results of an excimer laser system. The average pre-operative level of required correction in our FDA clinical trials was 4.8 diopters. Six months following the procedure, approximately 85% of patients could see 20/40 or better, the refractive condition required to drive in most states without corrective lenses.

In December 2000, we submitted to the FDA a PMA supplement for the treatment of myopia with and without astigmatism using LASIK. The prospective clinical study was performed at 10 U.S. sites by 23 surgeons. The approval received in September 2001 was for the reduction or elimination of myopia ranging from -0.5 to less than -6 diopters manifest spherical refractive error with astigmatism less than or equal to -4.5 diopters. At three months following the surgery, 90% of patients could see 20/40 or better and at six months 93% could see 20/40 or better.

We expect the post-procedure UCVA of patients treated with our LaserScan LSX laser system following FDA approval to exceed the results obtained in our FDA clinical trials as refractive surgeons gain experience using our laser system.

Subject to satisfactorily addressing our serious liquidity and financing needs, we intend to continue to develop and improve our technology and to aggressively continue the process of gaining regulatory approvals for our laser products in order to expand our access to the U.S. market for refractive

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procedures. We currently have a PMA supplement pending with the FDA to expand the use of our laser systems for the LASIK treatment of farsightedness with and without astigmatism and mixed astigmatism.

DIAGNOSTIC AND CUSTOM ABLATION PRODUCTS

Our CustomEyes family of diagnostic instruments and custom ablation planning tools includes the AstraMax integrated diagnostic workstation and CIPTA and AstraPro custom ablation planning software.

ASTRAMAX. The AstraMax is an integrated diagnostic workstation that obtains precision diagnostic measurements such as anterior and posterior corneal elevation, corneal thickness, anterior chamber depth and measurements of photopic and scotopic pupil size. Prior to the AstraMax these measurements would have to be taken utilizing two or more instruments. In addition to its value as a stand-alone system, the precision diagnostic measurements provided by the AstraMax integrated workstation will be utilized in both the CIPTA software and our upcoming AstraPro software for planning custom ablations.

We believe the primary benefits of the AstraMax system include:

- o MULTIPLE CAMERAS - The AstraMax has three stereo cameras allowing for the truest rendering of corneal data to date. Three stereo cameras capture corneal depth with greater precision and accuracy. In laser vision correction, height and depth data are essential to

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perform an accurate laser surgery with reliable accurate results. The Orbscan is a one-camera system.

- o SCOTOPIC AND PHOTOPIC PUPILOMETRY - The AstraMax is the only topographer that offers a full range of measurements including scotopic and photopic pupil size. We believe the quality of the patients vision is partly dependent on the size of the ablation zone equaling or exceeding the size of the scotopic pupil, something no other topographer measures.
- o POLAR GRID - Instead of the conventional concentric rings offered in most topography systems, the AstraMax contains a patented polar grid allowing the surgeon to obtain both radial and tangential information that adds to the accuracy of the data.

The technology incorporated into our AstraMax integrated workstation is covered by a six U.S. patents assigned to LaserSight, licenses to related technologies and a number of patent applications currently undergoing examination in the U.S. and internationally.

CIPTA AND ASTRAPRO. CIPTA was introduced to clinical use during 1996. Since that time 23 refractive surgery centers in Europe have been licensed to perform custom ablations using the CIPTA software. CIPTA is currently available in the international market. We believe our CustomEyes approach to custom ablations will represent a new standard of eye care that goes beyond conventional laser vision correction by individualizing the laser treatment utilizing a patient-specific set of diagnostic criteria intended to correct both refractive error and optical aberrations.

For custom ablation treatments, the diagnostic data from the AstraMax will be exported to our CIPTA or AstraPro custom ablation planning software

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where the data will be used initially to plan custom ablation profiles intended to correct visual anomalies that may have been induced by prior refractive procedures and improve the overall quality of a patient's vision. LaserSight's approach to custom ablation is somewhat different from other competitors in that our focus has been on developing diagnostic and planning tools and techniques that improve the qualitative aspect of visual performance. Because wavefront devices have tended to focus on detecting and correcting for spherical aberrations that may be present in a patient's eye, correction of such visual defects addresses only visual acuity, or the quantitative aspect, of visual performance. Such treatments do not address the qualitative aspect of visual performance, or how well a patient is seeing under a variety of conditions.

Our approach to custom ablation treatment uses precise measurements of corneal elevation, corneal thickness and pupil size to plan a custom ablation intended to improve visual performance by post-operatively retaining the natural prolate shape of the patient's cornea.

KERATOME PRODUCTS

Our MicroShape family of keratome products includes our UltraShaper durable keratome, a control console and our UltraEdge keratome blades. We commercially launched our UltraShaper durable keratome during the fourth quarter of 2001.

The introduction of our MicroShape family of keratome products provides refractive surgeons with the opportunity to not only utilize keratomes based on the original design of the ACS, but to also take advantage of a number of

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significant improvements intended to make the performance of the instruments safer and more consistent. Working with refractive surgeons we were able to develop an advanced design for our UltraShaper durable keratome incorporating advancements that address a number of the issues encountered with current keratome designs. Ease of assembly after cleaning has been improved by utilizing a three-piece construction. Drive gears have been recessed to minimize the possibility of lid or lash entrapment, a constant speed drive motor is utilized and the applanation plate has been integrated into the keratome head. The blade angle is 25 degrees for a more predictable flap thickness and cut. The open design of the keratome head allows the surgeon to observe the creation of the flap. The unique blade handling and insertion system allows the surgeon to inspect the blade and insert it into the keratome head without the blade ever being touched by hands or instruments. This handling system also ensures a more positive blade location and alignment. In addition, the UltraShaper can accommodate a surgeon's preference by creating nasal and temporal flaps.

The MicroShape control console utilized with the UltraShaper incorporates operating and safety features not available with prior generation systems. A high and low suction level have been incorporated into the console, allowing use of a lower suction setting during fixation of the keratome on to the globe of the eye. A "low suction" warning prevents the keratome from advancing when the console detects suction below a preset limit.

We believe that future design activities may bring the performance of the UniShaper single use keratome up to the standards demonstrated by the UltraShaper and could provide the refractive surgeon with a sterilized, fully assembled and tested keratome solution that eliminates the cleaning and maintenance associated with durable keratomes.

We acquired the right to manufacture and sell our keratomes in September 1997 from inventors Ruiz and Lenchig, who had invented the ACS (that had been manufactured and sold by Bausch & Lomb). The UniShaper single-use keratome and the UltraShaper durable keratome each incorporate the market proven

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features found in the ACS with new enhancements and features, including pre-assembly, transparent components for improved visibility while cutting the flap, and a dual drive mechanism with covered gears. We launched our UltraShaper durable keratome during the fourth quarter of 2001 after we completed the quality evaluation phase of our product release requirements. We believe that the UltraShaper has undergone a more rigorous clinical evaluation than any other keratome currently on the market. See "Risk Factors - Company and Business Risks - Required minimum payments under our keratome license agreement may exceed our gross profits from sales of our keratome products."

PRODUCT UPGRADES AND OTHER PRODUCTS

As a convenience to our customers, we also offer a number of ancillary products that either complement our core laser system, diagnostic products and keratome product portfolio or leverage our laser technology. We offer various upgrades and modules to purchasers of prior models of our excimer laser systems, including the AstraScan upgrade to international customers for existing LaserScan LSX systems, AccuTrack eye tracking system for international customers, a video display system for observation or recording of refractive procedures, and the latest version of our proprietary software, version 9.0, that provides international users with features including expanded treatment options and patient databases. In addition, we offer certain scientific lasers and related equipment for medical research and scientific research applications. Our revenue from sales of our ancillary and other products generally is included in refractive product net revenue and represents, in the

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aggregate, less than 5% of our total refractive product net revenue.

GROWTH STRATEGY

Our goal, subject to our ability to obtain adequate financing, is to become a significant worldwide provider of excimer laser systems, diagnostic and custom ablation products, single-use and durable keratomes and other products for the refractive vision correction industry. We believe that our more than eight years of experience in the manufacture, sales and service of excimer laser systems, our significant penetration of international markets and the advanced technology of our laser systems diagnostic instruments, ablation planning software and keratome products provide us with a strong platform for future growth as we continue to penetrate the U.S. and international markets for refractive surgical lasers and instruments.

The following are the key elements of our growth strategy:

- o EXPAND MARKET SHARE IN U.S. EXCIMER LASER MARKET. We believe that our LaserScan LSX and AstraScan precision microspot scanning excimer laser systems represent a significant technological advancement over the broad beam and other scanning laser systems currently being marketed in the U.S., as our precision microspot scanning lasers can provide more precise corneal ablations, reduced visual side effects, enhanced visual acuity and shorter procedure times. We also believe that our precision microspot scanning technology can provide the precision and accuracy needed for custom ablations when custom treatments are approved in the U.S. market.
- o EXPAND MARKET SHARE IN INTERNATIONAL EXCIMER LASER MARKET. We believe that our LaserScan LSX and AstraScan precision microspot scanning excimer laser systems represent a significant technological advancement over the other scanning laser systems currently being marketed internationally, as our precision microspot scanning lasers can provide more precise corneal ablations, reduced visual side effects, enhanced visual acuity and shorter procedure times. We also believe that the availability of

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CIPTA and our AstraMax during 2002 will provide a custom ablation solution internationally that will improve our sales opportunities.

- o PENETRATE WORLDWIDE DIAGNOSTIC INSTRUMENT MARKET. We believe that our AstraMax integrated diagnostic workstation also represents a significant technological advancement over existing corneal topographers since it is a single instrument that more precisely obtains a wide variety of diagnostic information not provided by current topographers. In addition, the AstraMax's precise measurements are over the total area of the cornea thus providing the necessary information for planning custom ablations.
- o ESTABLISH STRONG POSITION IN CUSTOM ABLATION MARKET. By combining the capabilities of our laser system with the AstraMax and CIPTA, we believe we will be in a position to benefit from a viable custom ablation package in the international market during 2002. We believe that success in the international market will translate into customer awareness in the U.S. market, improving our custom ablation opportunities domestically in the future.

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- o PENETRATE WORLDWIDE KERATOME AND KERATOME BLADE MARKETS. We believe that a key competitive strength of our MicroShape family of keratome products is the relative simplicity and ease of use of our UltraShaper durable keratome and fact that the flexibility of the keratome control console offers refractive surgeons the option to utilize either a single-use or durable keratome based on their clinical preference. Commercial shipments of our UltraShaper durable keratome began in the fourth quarter of 2001.
- o GENERATE RECURRING REVENUE STREAMS. We have positioned our business to benefit from the anticipated future growth in refractive vision correction procedure volume. In addition to receiving the purchase price for each laser system sold in the U.S., we believe we will generate recurring revenue streams by participating in per procedure fees resulting from the use of our laser systems. We also believe that the license fees related to use of our CIPTA and AstraPro ablation planning software and our UltraEdge keratome blades, that are intended to be replaced after each procedure when used in durable keratomes, all provide potential additional sources of recurring revenue for us. We are also pursuing service contracts for customers with lasers no longer under warranty.
- o PROPRIETARY TECHNOLOGY LEADERSHIP. We believe that technological advances in the refractive vision correction market will continue to evolve through the advancement of existing technologies and the introduction of new treatment modalities. Accordingly, we believe we have developed a strong intellectual property portfolio. For example, in March 2000, we acquired the intellectual property that we have developed into our AstraMax integrated diagnostic workstation. In January 2002, we received notice of allowance of the reissuance of our scanning patent, now known as the `504 Scanning Patent, covering methods for performing ophthalmic surgery using a scanning laser with 68 additional claims.

SALES AND MARKETING

We sell our excimer laser systems, diagnostic products, keratomes and related products through a direct sales force, independent sales representatives and distributors. Since 1994, we have marketed our laser systems commercially in over 30 countries worldwide and currently have an installed base of approximately 400 scanning lasers, including over 220 of our LaserScan LSX laser systems.

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EXCIMER LASER SYSTEMS

Following receipt of FDA approval of the LaserScan LSX in November 1999, we began to commercially market our excimer laser systems in the U.S. We employ four sales professionals targeting key refractive markets within the U.S. These territorial managers are responsible for sales within their respective territories. We are currently considering the use of one or more distributors to expand our market capabilities in the U.S.

Laser system sales in international markets are generally to hospitals, corporate centers or established and licensed ophthalmologists. Internationally we market our excimer laser systems in Canada, Europe, Asia, South and Central America, and the Middle East. We currently employ four territorial managers who are responsible for sales in international markets, both directly and through our approximately 35 independent distributors and representatives within their

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respective territories.

All of our distributors and representatives have been selected based on their experience and knowledge of their respective ophthalmic equipment market. In addition, the selection of international distributors and representatives is also based on their ability to offer technical support. Distributor and representative agreements provide for either exclusive territories, with continuing exclusivity dependent upon achievement of mutually-agreed levels of annual sales, or non-exclusive agreements without sales minimums. Currently, separate distributor and representative agreements are in place for all major market areas. During 2001, approximately 67% of our product sales resulted from distributors and representatives with the balance from sales made by employees of LaserSight. Our distributors in Mexico and China were each responsible for generating sales of 11% of our consolidated revenues in 2001. No single distributor was responsible for generating sales in excess of 10% of our consolidated revenues in 2000.

In conjunction with our sales activities, we participate in a number of foreign and domestic ophthalmology meetings, exhibits and seminars. Historically, two large U.S. meetings, the American Academy of Ophthalmology and the American Society of Cataract and Refractive Surgery, have yielded substantial interest in our products.

We believe that educating our customers and informing them about system developments is an important way to ensure customer satisfaction and desirable clinical results. Our clinical specialists are available to travel to a customer site to train the refractive surgeon on how to safely operate our excimer laser system and keratome products and achieve optimum clinical results. We have also developed an extensive set of written materials to inform refractive surgeons about how our laser system and keratomes work and a series of marketing related materials to assist the surgeon in marketing his refractive practice to his patient base.

DIAGNOSTIC AND CUSTOM ABLATION PRODUCTS

We currently employ two people responsible for the sales of our AstraMax products, in addition to our laser system sales force and distributors, who will offer bundled packages including, for example, a laser system with an AstraMax. In addition, we are in discussions with third parties to distribute our AstraMax product. It is not clear whether we will be able to formalize an AstraMax distribution agreement on terms acceptable to us.

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CIPTA is primarily sold by the same employees or distributors who are responsible for the sales of laser systems. Any custom ablation software will require clinical trials and FDA approval prior to sale in the U.S.

KERATOME PRODUCTS

In 2001, all marketing and manufacturing arrangements with Becton Dickinson were ended. See "Risk Factors and Uncertainties--Industry and Competitive Risks--We cannot assure you that our keratome products will achieve market acceptance." We have an employee responsible for marketing and distributing our keratome products in the U.S. in addition to our laser system sales force and distributors internationally, who will offer bundled packages including, for example, a laser system with an UltraShaper. We are currently in discussions with a managed network of independent sales representatives to distribute our keratome related products. It is not clear whether we will be able to formalize a distribution agreement on terms acceptable to us.

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MANUFACTURING

EXCIMER LASER SYSTEMS

MANUFACTURING FACILITIES. Our manufacturing operations primarily consist of assembly, inspection and testing of parts and system components to assure performance and quality. We acquire components of our laser system and assemble them into a complete unit from components that include both "off-the-shelf" materials and assemblies and key components that are produced by others to our design and specifications. We conduct a series of final system integration and acceptance tests prior to shipping a completed system. The proprietary computer software that operates the scanning system in our laser systems was developed and is maintained internally.

We have excimer laser system manufacturing operations in Winter Park, Florida and San Jose, Costa Rica. LaserScan LSX excimer laser systems assembled in our Florida facility are shipped to U.S. customers and systems assembled in our Costa Rica facility are shipped to our international customers. In October 1996, we received certification under ISO 9002, an international system of quality assurance, for our manufacturing and quality assurance activities in our Florida and Costa Rica facilities. Since that time we have maintained our ISO 9002 certification through a series of periodic surveillance audits and have also been certified at our Winter Park facility to ISO 9001 quality system standards.

AVAILABILITY OF COMPONENTS. We purchase the vast majority of components for our laser systems from commercial suppliers. These include both standard, "off-the-shelf" items, as well as components produced to our designs and specifications. While most components are acquired from single sources, we believe that in many cases there are multiple sources available to us in the event a supplier is unable or unwilling to perform. Since we need an uninterrupted supply of components to produce our laser systems, we are dependent upon these suppliers to provide us with a continuous supply of integral components and sub-assemblies.

We contracted with TUI Lasertechnik und Laserintegration GmbH, Munich, Germany, in 1996 to develop an improved performance laser head based on their innovative technology and our performance specification and laser lifetime requirements. We began to incorporate this new laser head into our products, notably the LaserScan LSX, in the fourth quarter of 1997. Currently, TUI is a single source for the laser heads used in the LaserScan LSX. Currently, SensoMotoric Instruments GmbH, Teltow, Germany, is a single source for the eye

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tracker boards used in the both the LaserScan LSX and the AstraScan. We continue to evaluate joint ventures with critical suppliers as well as other potential supplier relationships.

DIAGNOSTIC AND CUSTOM ABLATION PRODUCTS

Our AstraMax integrated diagnostic workstation is being manufactured in our Winter Park manufacturing facility. These manufacturing operations also primarily consist of assembly, inspection and testing of parts and system components to assure performance and quality. We acquire components of the AstraMax and assemble them into a complete unit from components that include both "off-the-shelf" materials and assemblies and components that are produced by others to our design and specifications. We conduct a series of final system integration and acceptance tests prior to shipping a completed system. The proprietary computer software that operates the diagnostic workstation was developed and is maintained internally.

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The AstraPro software is under development by LaserSight's software engineers and will be distributed from Winter Park when it has been released for commercial shipment. The CIPTA software that is being distributed under an agreement with Ligi Technologie Medicali, Taranto, Italy, was developed by that company. Any custom ablation software will require clinical trials and FDA approval prior to sale in the U.S.

KERATOME PRODUCTS

The components of the UltraShaper durable keratome are being manufactured exclusively for us by Owens Industries, Inc. Owens is experienced in the machining and assembly of precision instruments. The components are then assembled and tested in our Winter Park manufacturing facility. The control console for our keratomes is manufactured for us by Humphrey Instruments, a division of Carl Zeiss, Inc., located in San Leandro, California.

The UniShaper single-use keratome has been manufactured for us under an exclusive agreement with Frantz Medical Development Ltd., an ISO 9001 certified company experienced in the manufacture of disposable medical devices from engineering-grade polymer. This agreement had a 30-month term, expiring in May 2002, that obligated us to purchase 50,000 units during each year of the contract following receipt of final product approval. This agreement has been suspended indefinitely until it is determined that design changes can be incorporated into the UniShaper to make it clinically viable.

Our UltraEdge keratome blades have historically been manufactured by Becton Dickinson pursuant to our manufacturing agreement with them. That agreement was terminated during 2001. See "Risk Factors and Uncertainties--Industry and Competitive Risks--We cannot assure you that our keratome products will achieve market acceptance." We are currently in discussions with another company to manufacture our keratome blades. It is not clear whether we will be able to formalize a keratome blade manufacturing agreement on terms acceptable to us. We currently have in inventory enough keratome blades to satisfy anticipated demand through 2002.

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COMPETITION

EXCIMER LASER SYSTEMS

The vision correction industry is subject to intense, increasing competition. We operate in this highly competitive environment that has numerous well-established U.S. and foreign companies with substantial market shares, as well as smaller companies. Many of our competitors are substantially larger, better financed, better known, and have existing products and distribution systems in the U.S. marketplace. FDA approval requirements are a significant barrier to entry into the U.S. market for commercial sales of medical devices. Two of our competitors, Visx and Alcon (Summit), received FDA approval of their broad beam laser systems several years ago, and have manufactured and sold laser systems that currently account for about 60% of the installed excimer laser systems in the U.S.

We believe competition in the excimer laser system market is primarily based on safety and effectiveness, technology, price, regulatory approvals, per procedure fee payments, royalty payments, dependability, warranty coverage and customer service capabilities. We believe that safety and effectiveness, technology, price, dependability, warranty coverage and customer service capabilities are among the most significant competitive factors, and we believe that we compete favorably with respect to these factors.

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Currently, five manufacturers, Visx, Alcon, Nidek, Bausch & Lomb and LaserSight, have excimer laser systems with the required FDA approval to commercially sell the systems in the U.S. Some of the approvals are for broader labeled indications, a key competitive element in the industry. A laser system with broader labeling approvals is attractive because it enlarges the pool of laser vision correction candidates to whom the procedure can be marketed. At present, the laser systems manufactured by our competitors in the U.S. market have FDA approval to perform a wider range of treatments than our laser system, including higher degrees of nearsightedness and in the case of Visx and Alcon, farsightedness. These approvals have given Visx a competitive advantage, with laser systems sold by Visx having performed nearly 60% of the laser vision correction procedures performed in the U.S. in 2001. Our LaserScan LSX excimer laser system is not presently approved to treat farsightedness or more than -6 diopters of nearsightedness in the U.S. with our PRK approval or up to a spherical equivalent of -6 diopters of nearsightedness and astigmatism with our LASIK approval. Our PMA supplements for treatment of farsightedness with astigmatism and mixed astigmatism are presently pending. While regulatory approvals play a significant role with respect to the U.S. market, competition from new entrants may be prevalent in other countries where regulatory barriers are lower.

In February 2000, Visx announced that it was reducing the fee it charges to customers from \$250 to \$100 for each laser vision correction procedure performed on an excimer laser manufactured by Visx. Shortly after this announcement, Alcon announced it would also reduce its licensing fee to \$100, plus an additional \$25 for astigmatism and hyperopia correction and \$150 for its Ladarvision systems. Bausch & Lomb has indicated it will charge a fee of up to \$130 for each laser vision correction procedure performed on an excimer laser manufactured by Bausch & Lomb. We are currently charging a per procedure fee of up to \$130. Nidek has not charged per procedure fees. The per procedure fees received by us as well as our competitors who currently receive such fees are subject to change based on competitive factors and changing market conditions, and there can be no assurance that such fees will not be reduced or eliminated in the future.

In addition to conventional vision correction treatments such as eyeglasses and contact lenses, we also compete against other surgical

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alternatives for correcting refractive vision disorders such as surgically implantable rings that recently received FDA approval, as well as implantable intraocular lenses and a holmium laser system developed for the treatment of farsightedness, that have also been approved by the FDA.

DIAGNOSTIC AND CUSTOM ABLATION PRODUCTS

The topography market is segmented into higher priced (Bausch & Lomb's Orbscan) and lower priced markets (manufactured by Humphrey, Tomey and others). We expect to primarily compete against the Orbscan. Our AstraMax instrument will also be competing against another class of instruments based on wavefront technology for use in planning custom ablation treatments. The target market for higher-priced topographers is refractive surgeons, general ophthalmologists and optometrists. Sales for the AstraMax will initially be targeted mostly to refractive surgeons. The market has shown acceptance of new technology, and is being fueled by the need to obtain more accurate corneal height data in an effort to provide consistent and accurate results in LASIK surgery as well as screen out poor candidates for the procedure.

We believe the Orbscan system has the highest market share of

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topographers in the market today. We believe, subject to satisfactorily addressing our serious liquidity and financing needs, the AstraMax will compete well against the features offered by the Orbscan as well as provide the additional benefits described earlier that should position the AstraMax as the next generation in corneal topography.

KERATOME PRODUCTS

In the market for keratome products, Bausch & Lomb sold a majority of the keratomes and keratome blades used by refractive surgeons in the U.S. in 2000 and 2001. We believe competition in the market for keratome products is primarily on the basis of performance, ease of use, design, automation, price, availability, regulatory approvals, royalty payments, warranty coverage and customer service capabilities. We believe that performance, ease of use, design, automation, and price are among the most significant, and believe that we compete favorably with respect to these factors. In addition to Bausch & Lomb, our principal competitors in the keratome and keratome blade business include Moria and Innovative Optics.

INTELLECTUAL PROPERTY

There are a number of U.S. and foreign patents or patent rights relating to the broad categories of laser devices, use of laser devices in refractive surgical procedures, delivery systems for using laser devices in refractive surgical procedures, keratometers, and keratomes. We maintain a portfolio of what we believe to be strategically important patents, patent applications, and licenses. Our patents, patent applications and licenses generally relate to the following areas of technology: UV and infrared-wavelength laser ablation for refractive surgery, our precision microspot laser scanning system, harmonic conversion techniques for solid state lasers, calibration of refractive lasers, eye tracking, treatment of glaucoma and other retinal abnormalities, keratometer design, enhanced techniques for corneal topography, techniques for treatment of nearsightedness and farsightedness, techniques to optimize clinical outcomes of refractive procedures, and keratome design. We monitor intellectual property rights in our industry on an ongoing basis and take action, as we deem appropriate, including protecting our intellectual property rights and securing additional patent or license rights.

Among the more significant of our intellectual properties are our `504 Scanning Patent, solid-state laser-related, and keratometer patents. In May

1996, we were granted the original '679 Scanning Patent relating to an ophthalmic surgery method utilizing a non-contact scanning laser. In 1998 we petitioned the U.S. Patent and Trademark Office for reissue of this patent, and in January 2002 the U.S. Patent and Trademark Office reissued the `679 Scanning Patent as the `504 Scanning Patent. Prior to reissue, the original '679 Scanning Patent included one independent claim and 23 total claims. The reissue application added nine new independent claims, and a total of 67 additional claims to better encompass the breadth of technology to which we are entitled. The 23 original claims remain essentially unchanged. The fundamental teachings of the original '679 Scanning Patent cover a refractive laser system using an excimer laser with low energy and a high laser pulse repetition rate to ablate corneal tissue with small pulses delivered to the corneal surface in an overlapping pattern. Through the reissue process, we were able to broaden several elements of the `679 Scanning Patent's original claims by removing certain restrictive elements. In September 2001, we received \$3.0 million in cash for a non-exclusive license agreement with Bausch & Lomb for what is now our `504 Scanning Patent. In December 2001, Bausch & Lomb exercised an option to

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license additional intellectual property owned by us for an additional payment of \$2.0 million. Of this total, approximately \$0.8 million was due to TLC Laser Eye Centers Inc. (TLC) under a separate license agreement. See "-Other Intellectual Property."

Our U.S. Patent No. 5,144,630 relates to a solid-state laser operating at multi-wavelengths using harmonic frequency conversion techniques. This is the technology incorporated into our developmental solid-state system that can produce both infrared and ultraviolet wavelengths.

Two of our U.S. patents, Nos. 5,847,804 and No. 5,953,100, cover a multi-camera corneal analysis system that is the underlying technology for our AstraMax diagnostic workstation. This state-of-the-art multi camera (stereo) technology provides the precise corneal height measurements that will be critical for the planning of custom ablation treatments when these treatments are commercially available.

A number of our competitors, including Visx and Alcon, have asserted broad intellectual property rights in technology related to excimer laser systems and related products, and intellectual property lawsuits are sometimes a competitive factor in our industry. We believe that we own or have a license to all intellectual property necessary for commercialization of our products.

PATENT SEGMENT. Prior to 2001, we generated royalty income pursuant to license agreements with respect to certain of our intellectual property rights, primarily the Blum Patent and related license agreements we acquired from International Business Machines Corporation (IBM) in August 1997. These patents (IBM Patents), the Blum Patent and U.S. Patent No. 4,925,523 (Braren Patent) relate to the use of ultraviolet light for the removal of organic tissue and may be used in laser vision correction, as well as for non-ophthalmic applications, and is the fundamental blocking patent that underlies the technology of ultraviolet laser refractive surgery. Under the license agreements with Visx and Alcon we acquired from IBM, Visx and Alcon were each obligated to pay a royalty to us on all excimer laser systems they manufacture, sell or lease in the U.S., excluding those systems manufactured in the U.S. and sold into a country where a foreign counterpart to the IBM Patents exists.

We purchased the Blum and Braren patents from IBM in August 1997 for \$14.9 million. Shortly thereafter, we granted an exclusive paid up license in the cardiovascular field in exchange for a payment of \$4 million. In February 1998, we entered into an agreement with Nidek pursuant to which we retained all of the IBM Patent rights within the U.S. and sold to Nidek, for \$7.5 million, the foreign counterparts to those patents. We also granted Nidek a non-exclusive license to utilize the IBM Patents in the U.S. In addition, Nidek granted us an exclusive license to the foreign counterparts to the IBM Patents in the

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non-ophthalmic, non-vascular and non-cardiovascular fields. Since our 1997 purchase of the IBM Patents we have realized over \$5 million in royalty revenues from licenses to the patent.

In March 2001, we entered into a business arrangement with Alcon regarding the Blum Patent. As part of the arrangement, we sold the Blum Patent to Alcon for \$6.5 million and assigned to Alcon certain licenses to the Blum Patent. We retained a non-exclusive royalty free license under the Blum Patent and at the time retained the license to the Blum Patent that was granted to Visx. LaserSight and Alcon will share in royalties received from any future licenses to the Blum Patent and we will also receive a portion of any recovery from parties found to be infringing the Blum Patent. Including the transaction with Alcon, we will have received a total of approximately \$24 million from the

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Blum Patent and will continue to enjoy a royalty free license in the U.S.

In May 2001 as part of our Settlement and License Agreement with Visx we sold them a fully paid up license to the Blum Patent.

OTHER INTELLECTUAL PROPERTY. We believe that our other intellectual property rights are valuable assets of our business. For example, our U.S. Patent No. 6,213,605 covers the checkered polar grid utilized in our AstraMax diagnostic workstation and our U.S. Patent No. 6,234,631 covers the combination of advanced corneal topography and wavefront aberration measurement into a single instrument and relates to future plans for our AstraMax diagnostic workstation. We entered into an agreement with a subsidiary of TLC in October 1998 that grants us an exclusive license under U.S. Patent No. 5,630,810 (TLC Patent) relating to a treatment method for preventing the formation of central islands during laser surgery. Central islands are a problem generally associated with laser refractive surgery performed with broad beam laser systems used to ablate corneal tissue. We have agreed to pay TLC for the term of the exclusive license 20% of the aggregate net royalties we receive in the future from licensing the TLC patent and other patents currently owned by us. We owe TLC 20% of the net proceeds of this license, or approximately \$0.8 million. Approximately half of this amount will be offset against a laser receivable owed to us by TLC. The TLC Patent is currently in reissue at the U.S. Patent and Trademark Office.

The extent of protection that may be afforded to us by our patents, or whether any claim embodied in our patents will be challenged or found to be invalid or unenforceable, cannot be determined at this time. Our patents and other pending applications may not afford a significant advantage or product protection to us.

We maintain an internal program that encourages development of patentable ideas. As of March 29, 2002, we have approximately 30 U.S. patent applications undergoing prosecution at the U.S. Patent and Trademark Office and a number of counterparts to these applications filed internationally. Our patent applications generally relate to the use of laser devices in refractive surgical procedures, delivery systems and other technology related to the use of laser devices in refractive surgical procedures, diagnostic devices for eye measurements, and keratomes.

In the U.S., our trademarks include LaserSight(R), LaserSight Technologies, Inc.(R), LSX(R), LaserScan LSX(R), MicroShape(R), UltraShaper(R), UltraEdge(R), UniShaper(R) and AccuTrack(R). We have also applied for registration of eight additional trademarks.

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REGULATION

MEDICAL DEVICE REGULATION

The FDA regulates the manufacture, use, distribution and production of medical devices in the U.S. Our products are regulated as medical devices by the FDA under the Federal Food, Drug, and Cosmetic Act. In order to sell such medical devices in the U.S., a company must file a 510(k) premarket notice or obtain premarket approval after filing a PMA application. Noncompliance with applicable FDA regulatory requirements can result in one or more of the following:

- o fines;
- o injunctions;
- o civil penalties;

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- o recall or seizure of products;
- o total or partial suspension of production;
- o denial or withdrawal of premarket clearance or approval of devices;
- o exclusion from government contracts; and
- o criminal prosecution.

Medical devices are classified by the FDA as Class I, Class II or Class III based upon the level of risk presented by the device and whether the device is substantially equivalent to an already legally marketed Class I or II device. Class III devices are subject to the most stringent regulatory review and cannot be marketed in the U.S. until the FDA approves a PMA for the device.

CLASS III DEVICES. A PMA application must be filed if a proposed device is not substantially equivalent to a legally marketed Class I or Class II device, or if it is a Class III device for which the FDA requires PMAs. The process of obtaining approval of a PMA application is lengthy, expensive and uncertain. It may require the submission of extensive clinical data and supporting information to the FDA. Human clinical studies may be conducted only under an FDA-approved protocol and must be conducted in accordance with FDA regulations. In addition to the results of clinical trials, the PMA application includes other information relevant to the safety and efficacy of the device, a description of the facilities and controls used in the manufacturing of the device, and proposed labeling. After the FDA accepts a PMA application for filing and reviews the application, a public meeting may be held before an FDA advisory panel comprised of experts in the field.

After the PMA is reviewed and discussed, the panel issues a favorable or unfavorable recommendation to the FDA. Although the FDA is not bound by the panel's recommendations, it historically has given them significant weight. If the FDA's evaluation of the PMA application is favorable, the FDA typically issues an "approvable letter" requiring the applicant's agreement to comply with specific conditions (such as specific labeling language) or to supply specific additional data (such as post-approval patient follow-up data) or other information in order to secure final approval. Once the approvable letter is satisfied, the FDA will issue approval for certain indications that may be more limited than those originally sought by the manufacturer. The PMA approval can include post-approval conditions that the FDA believes necessary to ensure the safety and effectiveness of the device including, among other things, restrictions on labeling, promotion, sale and distribution. Failure to comply with the conditions of approval can result in enforcement action, including withdrawal of the approval. Products manufactured and distributed pursuant to a PMA will be subject to extensive, ongoing regulation by the FDA. The FDA review

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of a PMA application generally takes one to two years from the date such application is accepted for filing but may take significantly longer. The review time is often significantly extended by FDA requests for additional information, including additional clinical trials or clarification of information previously provided.

Modifications to a device subject to a PMA generally require approval by the FDA of PMA supplements or new PMAs. We believe that our excimer laser systems require a PMA or a PMA supplement for each of the surgical procedures that they are intended to perform. The FDA may grant a PMA with respect to a particular procedure only when it is satisfied that the use of the device for that particular procedure is safe and effective. In granting a PMA, the FDA may restrict the types of patients who may be treated and the ranges of treatment.

FDA regulations authorize any interested person to petition for

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administrative review of the FDA's decision to approve a PMA application. Challenges to an FDA approval have been rare. We are not aware that any challenge has been asserted against us and do not believe any PMA application has ever been revoked by the agency based on such a challenge.

The QSR/GMP regulations impose certain procedural and documentation requirements upon us with respect to our manufacturing and quality assurance activities. Our facilities will be subject to ongoing inspections by the FDA, and compliance with QSR/GMP regulations is required for us to continue marketing our laser products in the U.S. In addition, our suppliers of significant components or sub-assemblies must meet quality requirements established and monitored by LaserSight, and some may also be subject to FDA regulation.

During 1994, we began the clinical studies required for approval and commercialization of our laser scanning system in the U.S. In April 1998, we filed a PMA application for PRK treatment of nearsightedness using our scanning laser system. We received notification from the FDA that our laser system had received PMA approval for PRK treatment of low to moderate nearsightedness in November 1999.

We also began a clinical trial of our scanning laser system for LASIK treatment of nearsightedness and nearsightedness astigmatism in Canada in late 1998 and received Device License Approval from Canadian Medical Devices Bureau in mid-1999.

In September 2001, we received notification from the FDA that the PMA approval our laser system was expanded to the LASIK treatment of myopia and myopic astigmatism for correction of manifest spherical refractive error of up to -6 diopters with up to -4.5 diopters of astigmatism. We then received FDA approval to increase our laser pulse rate to 200 Hz.

In November 2001, we submitted a PMA supplement seeking approval for the treatment of farsightedness, with and without astigmatism, and mixed astigmatism utilizing the LASIK procedure. The PMA supplement reflecting this data is currently pending with the FDA.

CLASS I OR II DEVICES. Devices deemed to pose relatively less risk are placed in either Class I or II, which requires the manufacturer to submit a 510(k) premarket notification, unless an exemption applies. The premarket notification must demonstrate that the proposed device is "substantially equivalent" to a "predicate device" that is either in Class I or II, or is a "pre-amendment" Class III device that was in commercial distribution before May 28, 1976, for which the FDA does not require PMA approval. The FDA issued

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determinations of equivalency for our UniShaper single-use keratome in January 1998 and for our UltraShaper durable keratome in January 2000. Our UltraEdge keratome blades received 501(k) clearance in May 2000.

After the FDA has issued a determination of equivalency for a device, any modification that could significantly affect its safety or effectiveness, or that would constitute a major change in its intended use, requires a new 510(k) notice. The FDA requires each manufacturer to make this determination in the first instance, but the FDA can review any such decision. If the FDA disagrees with a manufacturer's decision not to submit a new 510(k), the agency may retroactively require the manufacturer to submit a premarket notification. The FDA also can require the manufacturer to cease marketing and/or recall the modified device until receipt of the necessary 510(k).

In January 2001, we received notification from the FDA that the Company

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may begin commercial distribution of its AstraMax diagnostic workstation.

OTHER REGULATORY REQUIREMENTS. Labeling and promotional activities are subject to scrutiny by the FDA and by the Federal Trade Commission. Current FDA enforcement policy prohibits manufacturers from marketing and advertising their approved medical devices for unapproved or off label uses. The scope of this prohibition has been the subject of recent litigation. The only materials related to unapproved devices that may be disseminated by companies are peer reviewed articles. Our lasers are also subject to the Radiation Control for Health and Safety Act administered by the Center for Devices and Radiological Health of the FDA. The law requires laser manufacturers to file new product and annual reports and to maintain quality control, product testing and sales records. In addition, laser manufacturers must incorporate specified design and operating features in lasers sold to end users and comply with labeling and certification requirements. Various warning labels must be affixed to the laser depending on the class of the product under the performance standard. The manufacture, sale and use of our products is also subject to numerous federal, state and local government laws and regulations relating to such matters as safe working conditions, manufacturing practices, environmental protection, fire hazard control and disposal of hazardous or potentially hazardous substances.

INTERNATIONAL REGULATORY REQUIREMENTS. The manufacture, sale and use of our products is also subject to regulation in countries other than the U.S. During November 1996 we completed all requirements necessary to obtain authority to apply the CE Mark to our LaserScan 2000 System, an earlier generation of excimer laser system we sold in international markets. In September 1998, we received similar certification to apply the CE Mark to our LaserScan LSX excimer laser system. The CE Mark, certifying that the LaserScan Models 2000 and LaserScan LSX meet all requirements of the European Community's medical directives, provides our products with marketing access in all member countries of the EU. All countries in the EU require the CE Mark certification of compliance with the EU Medical Directives as the standard for regulatory approval for sale of excimer laser systems.

The EU Medical Directives include requirements under EU laws regarding the placement of various categories of medical devices on the EU market. This includes a "directive" that an approved "Notified Body" will review technical and medical requirements for a particular device. All clinical testing of medical devices in the EU must be done under the Declaration of Helsinki, which means that companies must have ethics committee approval prior to commencement of testing, must obtain informed consent from each patient tested, and the studies must be monitored and audited. Patient records must be maintained for 15 years. Companies must also comply with the Medical Device Vigilance reporting requirements. In obtaining the CE Mark for our excimer laser system, we demonstrated that we satisfied all engineering and electro-mechanical

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requirements of the EU by having our manufacturing processes and controls evaluated by a Notified Body (Semko) for compliance with EN46001, ISO 9002 and ISO 9001 requirements, and conducted a clinical study in France to confirm the safety and efficacy of the excimer laser system on patients.

RESEARCH AND DEVELOPMENT

We continue to research and develop new laser products, laser systems, product upgrades enhancements, keratome products, including alternate ring size and flap thickness for our UltraShaper durable keratome, and ancillary product lines. In March 2000, we acquired the intellectual property that we have developed into the AstraMax that we expect to be commercialized during the second quarter of 2002. We believe the AstraMax will assist us in developing our

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custom ablation treatment plan capabilities.

Other research and development projects include the development of a solid-state laser and enhancements for our advanced eye-tracking system that is standard on the international model of LaserScan LSX. The solid-state laser is the first true non-gas laser capable of delivering a laser beam in the ultraviolet spectrum (common to all excimer lasers used for refractive surgery). In addition, the solid-state laser could be capable of generating multiple wavelengths, thus permitting its use for other ophthalmic procedures that now require separate lasers.

Our historical solid-state research and development efforts have resulted in the identification of many features that have been subsequently incorporated into our excimer laser system. We intend to continue to direct efforts at an appropriate level towards the development of this system as resources allow. As is the case with many new technology products, the commercialization of the solid-state laser is subject to potential delays.

While the risk of failure of these specific activities may be significant, we believe that if developed, these products could provide us with a leading edge technology that would further differentiate our products from other companies in the industry. There is no assurance that any of these research and development efforts will be successful.

HEALTH CARE CONSULTING SERVICES

Our health care services segment has historically provided health care and vision care consulting services to hospitals, managed care companies and physicians through our TFG subsidiary. The core business of TFG was two-fold: developing and maintaining physician databases for clients' needs and providing customized strategic plans. Services included physician recruitment tools, competitive intelligence, demand studies, community health analyses and distribution channel mapping. TFG clients included multi-hospital health systems, community hospitals, academic medical centers, specialty health care providers and manufacturers and distributors of health care products.

This subsidiary's financial results had been improving. However, due to our increased focus on refractive product development and commercialization, management decided, with board affirmation, to wind down the subsidiary within a reasonably short timeframe. Therefore, since this subsidiary has been accounted for as a separate segment, the remaining goodwill associated with TFG has been expensed in 2001 and its results are accounted for as a discontinued operation as of December 31, 2001.

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EMPLOYEES

As of December 31, 2001, we had 115 full-time employees and one part-time employee. None of our employees is a member of a labor union or subject to a collective bargaining agreement. LaserSight generally considers its employee relations to be good.

ITEM 2. PROPERTIES

Our principal offices, including executive offices and administrative, marketing and laboratory facilities, are located in approximately 17,100 square feet of space that we have leased in Winter Park, Florida. This lease expires on June 14, 2002, however, we have the option to extend the lease through January 15, 2003. We have leased approximately 15,600 square feet of additional space in Winter Park, Florida for administrative office space and manufacturing. The

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lease of this additional space in Winter Park expires January 31, 2004. We lease approximately 5,000 square feet of office space in St. Louis, Missouri, which lease expires July 31, 2006. We are actively looking to sublease this space. We lease approximately 6,400 square feet of space near San Jose, Costa Rica, that we use as a manufacturing facility. The lease of the San Jose manufacturing facility expires November 30, 2003. In our opinion, the various properties used in our operations are generally in good condition and are adequate for the purposes for which we utilize them.

ITEM 3. LEGAL PROCEEDINGS

JARSTAD. In January 2002, a customer filed a lawsuit in the Superior Court of the State of Washington in and for the County of King. The lawsuit was subsequently remanded to federal court. The lawsuit names LaserSight Technologies and an unaffiliated finance company as defendants. The lawsuit alleges various claims related to LaserSight Technologies' sale of a laser system to the plaintiff including breach of contract, breach of express warranty, breach of implied warranty, fraudulent inducement, negligent misrepresentation, unjust enrichment, violation of the consumer protection act and product liability. Plaintiffs request damages to be determined at trial, reimbursement for leasing fees, prejudgment and postjudgment interest, attorneys' fees and costs and other equitable relief. Management believes that LaserSight Technologies has satisfied its obligations under the sale agreement, and that the allegations against it are without merit and intend to vigorously defend this lawsuit. Management believes that the outcome of this litigation will not have a material adverse impact on LaserSight's business, financial condition or results from operations. However, the outcome of litigation is inherently uncertain, and an unfavorable outcome in this litigation could have a material adverse effect on LaserSight's business, financial condition and results from operations.

DISTRIBUTORS. In October 2001, three entities that previously served as distributors for LaserSight's excimer laser system in the United States, Balance, Inc. d/b/a Bal-Tech Medical, Sun Medical, Inc. and Surgical Lasers, Inc., filed a lawsuit in the Circuit Court of the Ninth Judicial Circuit, Orange County, Florida. The lawsuit names LaserSight Technologies, Mr. Farris and James Spivey, LaserSight Technologies' Vice President of Sales, as defendants. The lawsuit alleges various claims related to LaserSight Technologies' termination of the distribution arrangements with the plaintiffs including breach of contract, breach of the covenant of good faith and fair dealing, tortious interference with business relationships, fraudulent misrepresentation, conversion and unjust enrichment. Plaintiffs request actual damages in excess of \$5,000,000, punitive damages, prejudgment interest, attorneys' fees and costs and other equitable relief. Management believes that LaserSight Technologies has satisfied its obligations under the distribution agreements, and that the allegations against LaserSight Technologies, Mr. Farris and Mr. Spivey are

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without merit and intend to vigorously defend this lawsuit. Management believes that the outcome of this litigation will not have a material adverse impact on LaserSight's business, financial condition or results from operations. However, the outcome of litigation is inherently uncertain, and an unfavorable outcome in this litigation could have a material adverse effect on LaserSight's business, financial condition and results from operations.

VISX, INCORPORATED. On May 25, 2001 LaserSight settled the patent infringement action filed by Visx against LaserSight in November 1999 in the United States District Court for the District of Delaware. In connection with the resolution of this litigation LaserSight and Visx entered into a Settlement and License Agreement pursuant to which LaserSight received a license to patents

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held by Visx that relate to refractive excimer lasers, including United States Patents Nos. 4,718,418 and B1 5,108,388 and has agreed to pay a royalty for each procedure performed in the United States using a LaserSight refractive laser. As part of the agreement, Visx purchased a fully paid up license to U.S. Patent No. 4,784,135 (the Blum Patent). Under the Settlement and License Agreement, all economic terms and conditions are confidential. The parties filed a stipulated order dismissing the patent infringement action on June 1, 2001.

FORMER SHAREHOLDER OF TFG. On May 14, 2001, a motion for summary judgment was granted in favor of Michael R. Farris in connection with a lawsuit that was filed on November 12, 1999 in the U.S. District Court for the Eastern District of Missouri on behalf of a former shareholder of TFG, a wholly-owned subsidiary of LaserSight. The lawsuit names Mr. Farris, LaserSight's chief executive officer, as the sole defendant and alleges fraud and breach of fiduciary duty by Mr. Farris in connection with the redemption by TFG of the former shareholder's capital stock in TFG. At the time of the redemption, which redemption occurred prior to LaserSight's acquisition of TFG, Mr. Farris was the president and chief executive officer of TFG. LaserSight's Board of Directors authorized LaserSight to retain and, to the fullest extent permitted by the Delaware General Corporation Law, pay the fees of counsel to defend Mr. Farris, TFG and LaserSight in the litigation so long as a court has not determined that Mr. Farris failed to act in good faith and in a manner Mr. Farris reasonably believed to be in the best interest of TFG at the time of the redemption. The plaintiff appealed the U.S. District Court's order granting summary judgment in favor of Mr. Farris to the United States Court of Appeals for the 8th Circuit. The appeal was heard in January 2002; on March 13, 2002 the 8th Circuit reversed the District Court related to the starting date of the statute of limitations related to an allegation of fraud committed by a fiduciary. Management believes that the allegations made by the plaintiff are without merit and intends to vigorously defend the action. Management believes that this action will not have a material adverse effect on our financial condition or results from operations.

LAMBDA PHYSIK, INC. On January 20, 2000 a lawsuit was filed in the Circuit Court of Broward County, Florida on behalf of Lambda Physik, Inc. ("Lambda") against LaserSight. The action alleges that we breached an agreement we entered into with Lambda for the purchase of lasers from Lambda. Lambda has requested \$1,852,813 in damages, plus interest, costs and attorney's fees. We believe that the allegations made by the plaintiff are without merit, and we intend to vigorously defend the action. Management believes that we have satisfied our obligations under the agreement and that this action will not have material adverse effect on our financial condition or results from operations.

KREMER. On November 16, 2000 a lawsuit was filed in the United States District Court for the Eastern District of Pennsylvania on behalf of Frederic B. Kremer, M.D. and Eyes of the Future, P.C. The action alleges that LaserSight is in breach of certain terms and conditions of an agreement it entered into with Dr. Kremer relating to LaserSight's purchase of a patent from Dr. Kremer. Dr.

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Kremer has requested equitable relief in the form of a declaratory judgment as well as damages in excess of \$1,600,000, plus interest, costs and attorney's fees. LaserSight believes that the allegations made by the plaintiff are without merit, and intends to vigorously defend the action. Management believes that LaserSight has satisfied its obligations under the agreement and that this action will not have material adverse effect on our financial condition or results from operations.

ROUTINE MATTERS. In addition, we are involved from time to time in routine litigation and other legal proceedings incidental to our business. Although no assurance can be given as to the outcome or expense associated with

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any of these proceedings, we believe that none of such proceedings, either individually or in the aggregate, will have a material adverse effect on the financial condition of LaserSight.

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

None.

PART II

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

Our common stock trades on The Nasdaq Stock Market(R) under the symbol LASE. The following table sets forth, for the fiscal quarters indicated, the high and low sale prices for our common stock on The Nasdaq Stock Market.

1999:	High	Low
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First Quarter	\$5.94	\$3.88
Second Quarter	20.38	5.22
Third Quarter	17.63	12.13
Fourth Quarter	18.31	7.19
2000:		

First Quarter	\$13.00	\$5.50
Second Quarter	6.75	3.25
Third Quarter	5.56	3.09
Fourth Quarter	3.81	0.91
2001:		

First Quarter	\$2.47	\$1.00
Second Quarter	3.00	1.28
Third Quarter	2.33	1.00
Fourth Quarter	1.87	0.47

On March 29, 2002, the closing sale price for our common stock on the Nasdaq National Market was \$0.63 per share. As of March 29, 2002, LaserSight had 26,554,168 shares of common stock outstanding held by approximately 262 stockholders of record and, to our knowledge, approximately 8,426 total stockholders, including stockholders of record and stockholders in "street name."

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We have never declared or paid any cash dividends on our common stock and do not anticipate paying cash dividends on our common stock in the foreseeable future. Our current policy is to retain all available funds and any future earnings to provide funds for the operation and expansion of our business. Any determination in the future to pay dividends will depend upon our financial condition, capital requirements, results of operations and other factors deemed relevant by our board of directors, including any contractual or statutory restrictions on our ability to pay dividends.

POSSIBLE DILUTIVE ISSUANCES OF COMMON STOCK

Each of the following issuances of common stock may depress the market price of the common stock. See "Management's Discussion and Analysis - Risk Factors and Uncertainties - Common Stock Risks--The Significant Number of Shares

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Eligible for Future Sale and Dilutive Stock Issuances may Adversely Affect Our Stock Price."

LASERSIGHT CENTERS AND FLORIDA LASER PARTNERS. Based on previously-reported agreements entered into in 1993 in connection with our acquisition of LaserSight Centers (our development-stage subsidiary) and modified in July 1995 and March 1997, we may be obligated to pay to a partnership whose partners include our Chairman of the Board and certain of our former officers and directors a royalty of up to \$43 (payable in cash or in shares of common stock ("Royalty Shares")), for each eye on which PRK is performed on a fixed or mobile excimer laser system owned or operated by LaserSight Centers or its affiliates.

As of March 29, 2002, we have not accrued any obligation to issue Royalty Shares. We cannot assure you that any issuance of Royalty Shares will be accompanied by an increase in our per share operating results. We are not obligated to pursue strategies that may result in the issuance of Centers Contingent Shares or Royalty Shares and, in fact, late in 2000 we abandoned the LaserSight Centers mobile laser strategy due to industry conditions and our increased focus on development and commercialization of our refractive products. It may be in the interest of our Chairman of the Board for us to pursue business strategies that maximize the issuance of Royalty Shares.

FOOTHILL WARRANT. In April 1997, we issued to Foothill Capital Corporation a warrant to purchase 500,000 shares of common stock (the "Foothill Warrant") at a price of \$6.067 per share. We are required to make anti-dilution adjustments to both the number of warrant shares and the warrant exercise price if we sell common stock or common stock-equivalents (such as convertible securities or warrants) at a price per share that is (or could be) less than the fair market value of the common stock at the time of such sale (a "Below-Market issuance"). To date, such anti-dilution adjustments have resulted in (1) an increase in the number of Foothill Warrant shares to 598,414, and (2) a reduction to the exercise price of the Foothill Warrant shares to \$4.91 per share. Additional anti-dilution adjustments to the Foothill Warrant could also result from any future Below-Market Issuance. The Foothill warrants may be exercised at any time through March 31, 2002. As of March 29, 2002, warrants for 101,414 shares of our common stock remain outstanding.

SERIES B WARRANT. In connection with our issuance of the Series B Preferred Stock in August 1997, we issued to the former holders of the Series B Preferred Stock warrants to purchase 750,000 shares of common stock (the "Series B Warrant") at a price of \$5.91 per share at any time before August 29, 2002. In connection with a March 1998 agreement whereby we obtained the option to repurchase the Series B Preferred Stock and a lock-up on conversions, the exercise price of the Series B Warrant shares was reduced to \$2.753 per sha