BIOLASE TECHNOLOGY INC
Form 10-K
March 16, 2009

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UNITED STATES SECURITIES AND EXCHANGE COMMISSION
Washington, D.C. 20549

Form 10-K

(Mark One)

þ **ANNUAL REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934**
For the fiscal year ended December 31, 2008

OR

o **TRANSITION REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934**
For the transition period from to

Commission file number 000-19627

BIOLASE TECHNOLOGY, INC.
(Exact Name of Registrant as Specified in Its Charter)

Delaware	**87-0442441**
(State or Other Jurisdiction of Incorporation or Organization)	*(I.R.S. Employer Identification No.)*

4 Cromwell
Irvine, California 92618
(Address of Principal Executive Offices, including zip code)

(949) 361-1200

(Registrant s telephone number, including area code)

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

(Title of Each Class)	**(Name of Each Exchange on Which Registered)**
Common Stock, par value $0.001 per share	**The NASDAQ Stock Market LLC (NASDAQ Global Market)**

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

Indicate by check mark if the registrant is a well-known seasoned issuer, as defined in Rule 405 of the Securities Act. Yes o No þ

Indicate by check mark if the registrant is not required to file reports pursuant to Section 13 or Section 15(d) of the Act. Yes o No þ

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 þ No o

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 the definitive proxy or information statements incorporated by reference in Part III of this Form 10-K or any amendment to this Form 10-K. o

Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, a non-accelerated filer, or a smaller reporting company. See the definitions of large accelerated filer, accelerated filer and smaller reporting company in Rule 12b-2 of the Exchange Act. (Check one):

Large accelerated filer o Accelerated filer þ Non-accelerated filer o Smaller reporting company o
(Do not check if a smaller reporting company)

Indicate by check mark whether the registrant is a shell company (as defined in Rule 12b-2 of the Act). Yes o No þ

The aggregate market value of the voting and non-voting common equity held by non-affiliates was $79,302,879 on June 30, 2008, based on the closing price per share of $3.42 for the registrant s common stock as reported on the NASDAQ Stock Market LLC on such date.

As of March 12, 2009, there were 24,244,201 shares of the Registrant s common stock, par value $0.001 per share, outstanding.

DOCUMENTS INCORPORATED BY REFERENCE

Part III of this report incorporates information from the registrant s definitive proxy statement for its annual meeting of stockholders, which proxy statement is due to be filed with the Securities and Exchange Commission no later than 120 days after December 31, 2008.

BIOLASE TECHNOLOGY, INC.

ANNUAL REPORT ON FORM 10-K
FOR THE FISCAL YEAR ENDED DECEMBER 31, 2008

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CAUTIONARY STATEMENT REGARDING FORWARD LOOKING STATEMENTS

This Annual Report on Form 10-K, particularly in Item 1. Business, and Item 7. Management s Discussion and Analysis of Financial Condition and Results of Operations, and the documents incorporated by reference, include forward-looking statements within the meaning of Section 27A of the Securities Act of 1933 and Section 21E of the Securities Exchange Act of 1934, as amended. All statements, other than statements of historical fact, are statements that could be deemed forward-looking statements, and include, but are not limited to, statements and predictions regarding our operating expenses, sales and operations, anticipated cash needs, capital requirements and capital expenditures, needs for additional financing, use of working capital, plans for future products and services and for enhancements of existing products and services, anticipated growth strategies, ability to attract customers, sources of net revenue, anticipated trends and challenges in our business and the markets in which we operate, the adequacy of our facilities, the impact of economic and industry conditions on our customers and our business, customer demand, our competitive position, the outcome of any litigation against us, the perceived benefits of any technology acquisitions, critical accounting policies and the impact of recent accounting pronouncements. Additional forward-looking statements include, but are not limited to, statements pertaining to other financial items, plans, strategies or objectives of management for future operations, our financial condition or prospects, and any other statement that is not historical fact, including any statement using terminology such as may, might, will, intend, should, could, can, would, expect, believe, estimate, predict, potential, plan, or the negativities of comparable terminology. For all of the foregoing forward-looking statements, we claim the protection of the Private Securities Litigation Reform Act of 1995. These statements are only predictions and actual events or results may differ materially and adversely from our expectations. Important factors that could cause actual results to differ materially from those stated or implied by our forward-looking statements include, but are not limited to, the impact of changes in demand for our products, our effectiveness in managing manufacturing costs and expansion of our operations, the impact of competition and of technological advances, and the risks set forth under Risk Factors in Item 1A. These forward-looking statements represent our judgment as of the date hereof. We undertake no obligation to revise or update publicly any forward-looking statements for any reason.

The information contained in this Annual Report on Form 10-K is not a complete description of our business or the risks associated with an investment in our common stock. We urge you to carefully review and consider the various disclosures made by us in this Annual Report and in our other reports filed with the Securities and Exchange Commission (the SEC).

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PART I

Item 1. *Business*

Overview

We are a medical technology company that develops, manufactures and markets lasers, related products and services focused on technologies for improved applications and procedures in dentistry and medicine. In particular, our Waterlase Dentistry solution is a comprehensive group of products including dental laser systems that allow general dentists, periodontists, endodontists, oral surgeons and other specialists to perform a broad range of dental procedures, including cosmetic and complex surgical applications. Our systems are designed to provide clinically superior performance for many types of dental procedures, with less pain and faster recovery times than are generally achieved with drills, scalpels and other traditional dental instruments. The Waterlase Dentistry solution offers two categories of laser system products: our Waterlase family of products and our Diode family of products which includes our *ezlase* system, as well as related consumables, training and services.

Waterlase systems. Our Waterlase systems use a patented combination of water and laser to perform most dental procedures currently performed using dental drills, scalpels and other traditional dental instruments for cutting soft and hard tissue plus bone. We refer to our patented interaction of water and laser as YSGG Laser HydroPhotonics. In October 2004, we launched our newest generation Waterlase system, the Waterlase MD. The Waterlase MD has a broad range of clinical capabilities both in dentistry and other medical disciplines. We designed the Waterlase MD to provide the clinical benefits dentists desire, while also providing the comfort sought by patients. Advanced capabilities and new features coupled with innovative, ergonomic styling and design are part of our proprietary MD technology platform. In July 2008, our Waterlase C100 All-Tissue Dental Laser System was introduced into the market. In February 2009, we introduced the Waterlase MD Turbo All-Tissue Dental Laser System, an upgrade to the original Waterlase MD with cutting speeds approaching that of a high speed drill.

Diode systems. We also offer a line of Diode laser systems which use a semiconductor diode laser to perform soft tissue and cosmetic procedures, including teeth whitening. Our Diode systems serve the growing markets of cosmetic and hygiene procedures. In early 2007, we received FDA 510(k) clearance for and launched the new *ezlase* diode laser system. The *ezlase* system s approved indications include incision, excision, vaporization, ablation and coagulation of oral soft tissues as well as laser periodontal procedures, including laser soft tissue curettage and laser removal of diseased, infected, inflamed and necrosed soft tissue within the periodontal pocket, and sulcular debridement. In December 2008, we received an additional 510(k) clearance for tooth whitening using the *ezlase*.

We have clearance from the U.S. Food and Drug Administration, or FDA, to market our laser systems in the United States and also have the necessary approvals to sell our laser systems in Canada, the European Union and certain other international markets. We are currently pursuing regulatory approval to market and sell our Waterlase systems in Japan. Since 1998, we have sold approximately 7,200 Waterlase systems, including over 3,300 Waterlase MD systems, and over 12,000 laser systems in total in over 50 countries.

We believe there is a large market for our products in the United States and internationally. According to the American Dental Association, or ADA, there are over 160,000 practicing dentists in the United States. According to the World Federation of Dentistry, an international dental organization, there are at least 700,000 dentists worldwide, and we believe that a substantial percentage of them practice in major international markets outside the United States. The use of lasers in dentistry is growing. However, we believe only a small percentage of dentists currently use laser systems, and that there is a significant opportunity to increase sales of our products worldwide.

Our goal is to establish our laser systems as essential tools in dentistry and to continue to build a leading position in the dental laser market. Our sales and marketing efforts focus on educating dental professionals and patients on the benefits of our Waterlase Dentistry solution. In 2002, we founded the World Clinical Laser Institute, an association that includes prominent researchers, educators and practicing dentists, to formalize our

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efforts to educate and train dentists and specialists in laser dentistry. We participate in numerous other symposia and dental industry events to educate and stimulate demand for our products. We have also developed numerous relationships with dental schools, research facilities and dental institutes, in the United States and internationally, which use our products for education and training. We believe this will expand awareness of our products among new generations of dental professionals.

We were originally formed as Societe Endo Technic, SA, or SET, in 1984 in Marseilles, France, to develop and market various endodontic and laser products. In 1987, SET was moved to the United States and was merged with a public holding company, Pamplona Capital Corp. In 1994, we changed our name to BIOLASE Technology, Inc. Since 1998, our objective has been to become the leading designer, manufacturer and marketer of laser systems for the dental industry.

Industry Background

General

We estimate that more than 200 million hard tissue procedures are performed annually in the United States. Hard tissue procedures include cavity preparation, root canals and other procedures involving bone or teeth. The survey also indicated that more than 1.2 million soft tissue procedures are performed annually in the United States. Soft tissue procedures include gum line alteration and other procedures involving soft dental tissue. According to statistics compiled by the ADA, over 90% of hard tissue procedures and 60% of soft tissue procedures in the United States are performed by general dentists, and the rest are performed by oral surgeons, endodontists, periodontists and other specialists.

The ADA estimates that the demand for dental services in the United States will continue to grow due to population growth and the increased awareness of the benefits associated with preventive dentistry in reducing the incidence of oral and systemic disease. According to the ADA, annual dental spending in the United States in 2008 was $99.9 billion and is expected to increase by approximately two percent to six percent per year through 2015.

We believe there is a growing awareness among consumers of the value and importance of a healthy smile and its connections to overall systemic health. As such, the dental industry has entered an era of growth and consideration of advanced technologies that allow dentists to perform simple or complex cosmetic dental procedures with minimal trauma, improved patient acceptance and clinically superior results. We believe our product offering corresponds with this trend, and we expect incremental growth from these pressures in the marketplace.

Traditional Dental Instruments

Dental procedures are performed on hard tissue, such as bone and teeth, and soft tissue, such as gum and other oral tissue. Dentists and other specialists choose from a variety of instruments depending on the tissue involved and the type of procedure. Most procedures require the use of multiple instruments to achieve the desired result.

High Speed Drills. Most dentists use high speed drills for hard tissue procedures, such as preparing cavities for filling and gaining access for performing root canals or shaving and contouring oral bone tissue. Potentially adverse effects associated with drills include thermal heat transfer, vibration, pressure and noise. The cutting and grinding action of high speed drills can cause damage to the patient s dental structure and the trauma caused to the surrounding tissues can lead to increased recovery times. Additionally, this grinding action of high speed drills may weaken the tooth s underlying structure, leading to fractures and broken cusps. Crowns and root canals may become necessary as a result of damage caused during previous dental procedures. Anesthesia is generally required for all procedures that involve the use of high speed drills. As a result, dentists often limit procedures to one or two quadrants of the mouth because

of concerns relating to the use of anesthesia in several regions. This can force patients to return several times to complete their treatment plan.

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Cutting Instruments. Soft tissue procedures, such as reshaping gum lines and grafting on new gum tissue, are typically performed by oral surgeons or periodontists using scalpels, scissors and other cutting tools. Due to the pain and discomfort associated with procedures performed with these instruments, most soft tissue procedures require the use of local anesthetic which results in numbness and discomfort, and often require stitches. Use of scalpels, scissors and other cutting tools typically cause bleeding, post-operative swelling and discomfort. Bleeding can impair the practitioner s visibility during the procedure, thereby reducing efficiency. Bleeding is a particular problem for patients with immune deficiencies or blood disorders, and patients taking blood-thinning medications.

Alternative Dental Instruments

Alternative technologies have been developed over the years to address the problems associated with traditional methods used in dentistry. Most alternatives have addressed either hard or soft tissue applications. The predominant alternative technologies are discussed below.

Electrosurge Systems. Electrosurge systems use an electrical current to heat a shaped tip that simultaneously cuts and cauterizes soft tissue, resulting in less bleeding than occurs with scalpels. However, electrosurge can deeply penetrate the soft tissue, which can result in unwanted damage to surrounding tissue, and is generally less precise than lasers. Electrosurge is also not suitable for hard tissue procedures and, due to the depth of penetration, generally requires use of anesthesia and involves a lengthy healing process. Use of electrosurge is generally restricted from the areas near metal fillings and dental implants. Finally, electrosurge generally cannot be used with patients with implanted pacemakers and defibrillators.

Traditional Laser Systems. More recently, lasers have gained acceptance for use in general and cosmetic dentistry. Most lasers used in dentistry have been adapted from other medical applications, such as dermatology, and are not designed to perform a wide range of common dental procedures. Most dental lasers use thermal energy to cut tissue and are used primarily for soft tissue procedures.

Due to the limitations associated with traditional and alternative dental instruments, we believe there is a large market opportunity for all-tissue dental laser systems that provide superior clinical results and help reduce the trauma, pain and discomfort associated with dental procedures.

Our Solution

We believe the potential for increased patient satisfaction, improved outcomes and enhanced practice profitability that can be achieved through use of our products will position our laser systems as the instruments of choice among practitioners and patients. We have developed our laser systems and related products specifically for the dental market to more effectively perform a broad range of dental procedures. We believe the skill level and dexterity necessary to operate our laser systems are similar to those necessary to operate conventional drills and other dental equipment. Our laser systems also have the advantage of being minimally invasive and able to perform procedures in narrow spaces where access by conventional instruments often is limited. Our systems are intended to complement traditional tools, such as dental drills, which perform functions that our systems do not address, such as cutting metal fillings and certain polishing and grinding functions.

Our Waterlase systems precisely cut hard tissue, such as bone and teeth, and soft tissue, such as gums, with minimal or no damage to surrounding tissue and dental structure. Our Diode systems are designed to complement the Waterlase systems, and are used in soft tissue procedures, hygiene and cosmetic applications. The Diode systems, together with our Waterlase systems, offer practitioners a broad product line with a range of features and price points.

A small percentage of dental professionals worldwide currently use lasers. Moreover, our laser systems are more expensive than traditional dental tools. However, we believe that the significant clinical advantages of our systems, patient benefits, the potential return on investment that our systems offer practitioners and the options available to finance the purchase of our systems will enable us to continue to penetrate the dental

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market segment. Laser technologies with similar patient benefits have become standard of care in ophthalmology, dermatology and other medical specialties.

We believe the demand for our systems will continue to expand as we increase awareness of the benefits to patients and dental professionals.

Benefits to Dental Professionals

Expanded range of procedures and revenue opportunities. Our laser systems often allow general dentists to perform surgical and cosmetic procedures that they are unable or unwilling to perform with conventional methods, and which would typically be referred to a specialist. These procedures include crown lengthening, frenectomy and biopsy. Our systems allow dentists to perform these procedures easily and efficiently, increasing their range of skills and professional satisfaction.

Additional procedures through increased efficiency. Our systems can shorten and reduce the number of patient visits, providing dental professionals with the ability to service more patients. For hard tissue procedures, our Waterlase systems can reduce the need for anesthesia, which enables the dental practitioner to perform multiple procedures in one visit. One advantage of this benefit is that it can be used to perform cavity preparations in multiple quadrants. In contrast, many dentists using high speed drills normally cannot perform cavity preparations in more than one quadrant per visit because of concerns relating to use of anesthesia in multiple regions. For soft tissue procedures, the Waterlase and Diode systems allow tissue to be cut more precisely and with minimal bleeding when compared to traditional tools such as scalpels and electrosurge systems. Additionally, the *ezlase* system can be used to quickly perform tooth whitening with our proprietary whitening gel.

Increased loyalty and expanded patient base. We believe the improved patient comfort and convenience offered by our laser systems will help improve patient retention, attract new patients, increase revenue per patient, increase demand for elective procedures, increase acceptance of treatment plans and increase word-of-mouth referrals.

Fewer post-operative complications. Our laser systems can reduce trauma, swelling and general discomfort, resulting in fewer post-operative complications that require follow up treatment. Practitioners can devote time to new cases, rather than treating complications from prior procedures.

Benefits to Patients

Comfort. The Waterlase system is able to perform various types of dental procedures without causing the heat, vibration or pressure associated with traditional dental methods. As a result, patients can experience dramatically improved comfort during and after most procedures. In many cases, procedures can be performed without local anesthesia, which eliminates the pain associated with injections and the feeling of numbness following the procedure.

Convenience. Our Waterlase system does not require anesthesia in many cases, which allows dental practitioners to perform procedures in multiple quadrants of the mouth during a single office visit. This can reduce the number of visits necessary to complete the patient s treatment plan. Similarly, the ability to treat a wider range of procedures in the office reduces referrals with many procedures able to be treated in the same appointment as diagnosed.

Reduced trauma. The Waterlase system avoids the thermal heat transfer, vibration and grinding action associated with the high speed dental drill. For soft tissue applications, our laser systems cut with more precision and less bleeding than typically achieved with conventional instruments. As a result, our systems can result in less trauma, swelling and general discomfort to the patient.

Broader range of available procedures. Due to the improved comfort and convenience of our Waterlase system, we believe patients are more likely to consider cosmetic and other elective procedures that would generally be time consuming and uncomfortable, including osseous crown lengthening, periodontal surgeries and numerous other procedures.

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Business Strategy

Our objectives are to increase our leadership position in the dental laser market and to establish our laser systems as essential tools in dentistry. Our business strategy consists of the following key elements:

Increase awareness of our laser systems among dental practitioners and patients. We intend to further penetrate the dental market by educating dental practitioners and patients about the clinical benefits of Waterlase Dentistry. We plan to increase adoption of our laser systems by dental practitioners through our continued participation in key industry trade shows, the World Clinical Laser Institute, dental schools and other educational forums. We also intend to market our systems to dental practitioners through our laser specialists and advertising. We continue to explore marketing efforts aimed directly at patients.

Expand sales and distribution capabilities. In the United States and Canada, we distributed our products directly to dental practitioners utilizing our direct sales force through August 31, 2006. Effective September 1, 2006, we began distributing our products through a leading U.S. dental products and equipment distributor, Henry Schein, Inc., or HSIC. Over time, we expect HSIC s large direct sales force in the U.S. and Canada to increasingly provide high quality sales leads, while our laser specialists continue to perform technical selling and deal closing. Internationally, we intend to use established dental and medical device distributors and to use a direct sales force in select countries. We are developing an infrastructure to support growth in sales and marketing. This infrastructure includes product management, information technology systems and personnel to manage our sales force, compile sales and marketing data and better serve our customers and distributors.

Additionally, on February 27, 2009, we entered into an agreement with HSIC in which HSIC will become our distributor in certain international countries including Germany, Spain, Australia and New Zealand and will be permitted to distribute our products in those additional markets where we do not have current distribution agreements in place.

Expand product platform and applications. We plan to expand our product line and product applications by developing product enhancements and new laser technologies. We also have an objective to increase our sales of disposable products that are used by dental practitioners when performing procedures using our dental laser systems. Additionally, we may strategically acquire complementary products and technologies.

Continue high quality manufacturing and customer service. Our manufacturing operations are focused on producing high quality dental laser systems. We intend to continually develop and refine our manufacturing processes to increase production efficiencies and product quality. We provide high quality maintenance and support services through our support hotline and dedicated staff of in-house and field service personnel. Additionally, we maintain a network of factory-trained service technicians to provide maintenance and support services to customers in Europe and other markets outside the United States.

Strengthen and defend technology leadership. We believe our proprietary Waterlase system and YSGG Laser HydroPhotonics technology represent significant advancements in dentistry. We will pursue the protection of our intellectual property rights by expanding our existing patent portfolio in the United States and internationally. We intend to strategically enforce our intellectual property rights worldwide.

Products

Within our Waterlase Dentistry offering, we have two principal product lines. Our family of products includes the Waterlase and Diode systems, which we developed through a combination of our own research and development and

intellectual property obtained via various acquisitions.

Waterlase systems. Our Waterlase systems consist of the Waterlase MD and Waterlase C100 All-Tissue Dental Laser systems. Each of these systems is designed around our patented YSGG Laser HydroPhotonics technology. YSGG is a shortened abbreviation referring to the unique crystal (Er, Cr: YSGG) laser used in the

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Waterlase system, which contains the elements erbium, chromium and yttrium, scandium, gallium and garnet. This unique crystal laser produces energy with specific absorption and tissue interaction characteristics optimized for dental applications. HydroPhotonics refers to the interaction of laser with water to produce energy to cut tissue. Through YSGG Laser HydroPhotonics, the Waterlase systems is minimally invasive and can precisely cut hard tissue, such as bone and teeth, and soft tissue, such as gums, without the heat, vibration or pressure associated with traditional dental treatments. By eliminating heat, vibration and pressure, our Waterlase systems reduce and, in some instances, eliminate the need for anesthesia and also result in faster healing times versus traditional modalities of treatment.

Both Waterlase systems incorporate an ergonomic handpiece and an extensive control panel located on the front of the system with precise preset functionality to control the mix of air and water. Each system has also been designed to be easily moved from operatory to operatory within a practice office. The Waterlase MD has expanded capabilities, features and benefits including white LED handpiece illumination, a full color touch screen improving user friendliness (with a built in user Help system), a more refined water spray that improves cutting, more power, a smaller footprint, with an overall 40% reduction in size, and a Windows CE operating system. In 2008, we introduced the new clinical procedure for endodontics root canal disinfection with radial firing tips. The Waterlase MD Turbo All-Tissue Dental Laser System was introduced in the first quarter of 2009 further enhancing cutting speed to comparable levels of the high speed drill.

Diode system. Our Diode laser system consists of the *ezlase,* a semiconductor diode laser to perform soft tissue, hygiene and cosmetic procedures, including teeth whitening. Our ezlase system serves the growing markets of general, cosmetic, orthodontic, and hygiene procedures. The *ezlase* system was introduced in February 2007 with an award winning design, superior ergonomics and performance characteristics over previous generations of diode lasers. It features a new pulse mode, ComfortPulse, which allows the tissue to cool between pulses resulting in improved patient comfort and reduced need for anesthesia for many common procedures. Other features include wireless foot pedal control, disposable single-use tips, color touch screen activation with up to fifteen procedure based pre-sets, whitening hand piece, rechargeable battery pack and wall mount . We received FDA clearance for tooth whitening using the *ezlase* system in 2008.

We currently sell our products in over 50 countries. The FDA has cleared all of our laser systems for the applications listed below, which enables us to market the systems in the United States. Our systems have the CE Mark and may be sold in the European Union. Additionally, we have approval to sell our laser systems in Canada, Australia, New Zealand and most other Pacific Rim countries.

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Product	Selected Applications	Key Features
Waterlase Systems		
Waterlase MD Turbo *Laser Technology* Solid State Crystal, Erbium, Chromium: Yttrium, Scandium, Gallium, Garnet (Er, Cr: YSGG), Laser with Air-Water Spray *Laser Wavelength* 2780 nm *Power* 0.1 8.0 Watts *Repetition Rate* 10 50 Hz	*Hard Tissue:* Cavity preparation, caries removal, roughening or etching, root canal therapy and disinfection as well as other hard tissue surgical applications. *Bone:* Cutting, shaping, contouring, resection, crown lengthening (restorative), apicoectomy or amputation of root end, and other oral osseous or bone procedures. *Soft Tissue:* Incision, excision and biopsy of soft tissue, frenectomy, troughing, fibroma removal, hemostasis, aphthous oral ulcers, operculectomy and other soft tissue surgical applications. *Cosmetic:* Gingivectomy, gingivoplasty and crown lengthening.	Incorporated new white LED technology to Illuminated Handpiece Full color touch screen Laser Control System MD Flow™ laser detector to determine water level Laser Operatory Management System - smaller footprint versus the Waterlase YSGG. 360-degree contra-angle, rotatable handpiece ComfortJet™ air/water delivery system Windows® CE operating system 16 memory pre-sets LaserPal™ help system
Waterlase C100 *Laser Technology* Solid State Crystal, Erbium, Chromium: Yttrium, Scandium, Gallium, Garnet (Er, Cr: YSGG), Laser with Air-Water Spray *Laser Wavelength* 2780 nm *Power* 0.1 6.0 Watts *Repetition Rate* 10 30 Hz	*Hard Tissue:* Cavity preparation, caries removal, roughening or etching, root canal procedures and other hard tissue surgical applications. *Bone:* Cutting, shaping, contouring, resection, crown lengthening (restorative), apicoectomy or amputation of root end, and other oral osseous or bone procedures. *Soft Tissue:* Incision, excision and biopsy of soft tissue, frenectomy, troughing, fibroma removal, hemostasis, aphthous oral ulcers, operculectomy and other soft tissue	Advanced fiber delivery system Ergonomic handpiece Extensive control panel providing precise digital control of the air and water spray for maximum flexibility Ease of maneuverability from operatory to operatory

surgical applications.

Cosmetic: Gingivectomy, gingivoplasty and crown lengthening.

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Product	Selected Applications	Key Features
Diode System		
ezlase System *Laser Technology* Semiconductor Diode Laser *Laser Wavelength* 810 and 940 nm *Power* 4.5 and 7.0 Watts	*Soft Tissue:* Incision, excision and biopsy of soft tissue, frenectomy, troughing, fibroma removal and other soft tissue surgical applications. *Cosmetic:* Gingivectomy, gingivoplasty and tooth whitening. *Hygiene*: Curettage and sulcular debridement	Color touch screen with 15 pre-sets ComfortPulse Wireless foot pedal Totally portable, lightweight

Related Accessories and Disposable Products

We also manufacture and sell disposable products and accessories for our laser systems. Our Waterlase and *ezlase* systems use disposable laser tips of differing sizes and shapes depending on the procedures being performed. We also market flexible fibers and hand pieces that the dental practitioner will replace at some point after initial purchase of the laser system. For our *ezlase* system, we manufacture and sell tooth whitening gel kits.

Warranties

Our Waterlase laser systems are covered by a warranty against defects in material and workmanship for a period of up to one-year while our *ezlase* system warranty is up to two years. Our warranty covers parts and service for sales in our North American and international direct territories and parts only for international distributor sales. We sell service contracts to our end users that cover the period after the expiration of our standard warranty coverage for our laser systems. Extended warranty coverage provided under our service contracts varies by the type of system and the level of service desired by the customer. Product or accessories remanufactured, refurbished or sold by parties not authorized by BIOLASE, voids all warranties in place for such products and exempts us from liability issues relating to the use of such products.

Insurance

We currently maintain product liability insurance on a per occurrence basis with a limit of $11.0 million per occurrence and $12.0 million in the aggregate for all occurrences. The insurance is subject to various standard coverage exclusions, including damage to the product itself, losses from recall of our product and losses covered by other forms of insurance such as workers compensation. We cannot be certain that we will be able to successfully defend any claims against us, nor can we be certain that our insurance will cover all liabilities resulting from such claims. In addition, we cannot assure you that we will be able to obtain such insurance in the future on terms acceptable to us, or at all.

Manufacturing

Our corporate headquarters in Irvine, California is 57,000 square feet, with approximately 20,000 square feet dedicated to manufacturing and warehouse. All of our manufacturing, assembly and testing occurs at this facility. Our

facility is ISO 13485:2003 certified. ISO 13485 certification provides guidelines for quality of company systems associated with the design, manufacturing, installation and servicing of company products. In addition, our U.S. facility is registered with the FDA and is compliant with the FDA s Good Manufacturing Practice guidelines.

We use an integrated approach to manufacturing, including the assembly of tips, MD and diode hand pieces, fiber assemblies, laser heads, electro-mechanical subassembly, final assembly and test. We obtain components and subassemblies for our products from third party suppliers, most of which are located in the

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United States. We generally purchase components and subassemblies from a limited group of suppliers through purchase orders. We generally rely on purchase orders, and do not have written supply contracts with many of our key suppliers. Three key components used in our Waterlase system: handpieces, laser crystals, and fiber components are each supplied by separate single-source suppliers. In recent years, we have not experienced material delays from the suppliers of these three key components. However, in the event that we experience an unexpected interruption from a single source supplier, manufacturing delays, re-engineering, significant costs and sales disruptions could occur, any of which could have a material adverse effect on our operations. We are currently in the process of identifying and qualifying alternate source suppliers for our key components. There can be no assurance, however, that we will successfully identify and qualify an alternate source supplier for any of our key components or that we could enter into an agreement with any such alternate source supplier on terms acceptable to us.

Marketing and Sales

Marketing

We currently market our laser systems in the United States and worldwide. Our marketing efforts are focused on increasing brand and specific product awareness among dental practitioners. We continue to explore methods to increase awareness of the benefits of our products by marketing directly to patients.

Dental Practitioners. We currently market our laser systems to dental practitioners through regional, national and international trade publications, events, meetings and seminars. We also use brochures, direct mailers, press releases, posters and other promotional materials, as well as print and electronic media news coverage. In 2002, we founded the World Clinical Laser Institute to formalize our efforts to educate and train dental practitioners in laser dentistry. The Institute conducts and sponsors educational programs domestically and internationally for dental practitioners, researchers and academicians, including one, two and three-day seminars and training sessions involving in-depth presentations on the use of lasers in dentistry. In addition, we have developed relationships with research institutions, dental schools and laboratories which use our products in training and demonstrations. We believe these relationships will increase awareness of our products.

Patients. We market the benefits of our laser systems directly to patients through marketing and advertising programs, including print and broadcast media, local television news and radio spots, as well as product placements of our laser systems on television programs. We believe that making patients aware of our laser systems and their benefits will increase demand for our products.

Sales

We currently sell our products primarily to dentists in general practice. The majority of the dentists in the United States, and the majority of our customers, are sole practitioners. We expect our laser systems to gain acceptance among periodontists, endodontists, oral surgeons and other dental specialists, as they become better aware of the clinical benefits and new treatment options available through the use of our laser systems.

International revenue accounts for a significant portion of our total revenue. International revenue accounted for approximately 25%, 38% and 37% of our net revenue in 2008, 2007 and 2006, respectively. Net revenue in Canada, Asia, Latin America and Pacific Rim countries accounted for approximately 16%, 29%, and 27% of our net revenue in 2008, 2007 and 2006, respectively. Net revenue in Europe, Middle East and Africa (EMEA) accounted for approximately 8%, 9%, and 10% of net revenue in 2008, 2007 and 2006, respectively.

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Net revenue by geographic location based on the location of customers was as follows (in thousands):

	Years Ended December 31,		
	2008	2007	2006
United States	$ 48,526	$ 41,598	$ 43,674
Europe, Middle East and Africa	5,453	6,139	7,045
Canada, Asia, Latin America and Pacific Rim	10,646	19,152	18,981
	$ 64,625	$ 66,889	$ 69,700

In the United States and Canada, effective September 1, 2006, we commenced selling our products through a leading U.S. dental products and equipment distributor, HSIC. We expect HSIC s large direct sales force in the U.S. and Canada to increasingly provide high quality sales leads, while our laser specialists continue to perform technical selling and deal closing. Our sales support team is comprised of regional managers and laser specialists. Each of our laser specialists receives a base salary and commissions on sales. As a result of this hybrid distribution relationship, we expect to be able to obtain greater leverage, enabling us to limit the number of additional laser specialists we must add in the future. As part of this agreement, HSIC purchases products from us at negotiated distributor pricing, and invoices the customer directly at the customer s purchase order price.

In August 2006, we entered into a distribution agreement, or License and Distribution Agreement, with Henry Schein, Inc., or Henry Schein, a large distributor of healthcare products to office-based practitioners, pursuant to which we granted Henry Schein the exclusive right to distribute our complete line of dental laser systems, accessories and services in the United States and Canada. The agreement had an initial term of three years, following which it would automatically renew for an additional period of three years, provided that Henry Schein achieved its minimum purchase requirements.

On May 9, 2007, we entered into Addendum No. 1 to License and Distribution Agreement with Henry Schein, which addendum was effective as of April 1, 2007 and modified the License and Distribution Agreement entered into with Henry Schein on August 8, 2006, to add the terms and conditions under which Henry Schein has the exclusive right to distribute our new *ezlase* diode dental laser system in the United States and Canada. In the Addendum, separate minimum purchase requirements are established for the *ezlase* system. If Henry Schein has not met the minimum purchase requirement for any 12-month period ending on March 31, we will have the option, upon 30 days written notice, to (i) convert *ezlase* distribution rights to a non-exclusive basis for a minimum period of one year, after which period we would have the option to withdraw *ezlase* distribution rights, and (ii) reduce the distributor discount on *ezlase* products.

On March 3, 2008, we entered into a second addendum to the Henry Schein agreement that modifies certain terms of the initial agreement as amended. Pursuant to amendment 2 to the agreement, Henry Schein is obligated to meet certain minimum purchase requirements and is entitled to receive incentive payments if certain purchase targets are achieved. If Henry Schein has not met the minimum purchase requirements, we will have the option to (i) shorten the remaining term of the Agreement to one year, (ii) grant distribution rights held by Henry Schein to other persons (or distribute products ourselves), (iii) reduce certain discounts on products given to Henry Schein under the Agreement and (iv) cease paying future incentive payments. Additionally, under certain circumstances, if Henry Schein has not met the minimum purchase requirements, we have the right to purchase back the exclusive distributor rights granted to Henry Schein under the agreement. We also agreed to actively promote Henry Schein Financial Services as our exclusive leasing and financing partner.

On December 23, 2008, we entered into a letter agreement with HSIC which extended the initial term of the License and Distribution Agreement to December 31, 2010.

On February 27, 2009, we entered into a letter agreement with HSIC which adjusted the initial term of the License and Distribution Agreement through March 31, 2010.(See Liquidity and Capital Resources) This amendment includes certain minimum purchase requirements through the term of the agreement. HSIC also has the option to extend the term of the Agreement for two additional one-year terms which require certain

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minimum purchase requirements. In addition, HSIC will become our distributor in certain international countries including Germany, Spain, Australia and New Zealand and will be permitted to distribute our products in those additional markets where we do not have current distribution agreements in place.

International Direct Sales. Through 2008, we sold products in Germany, Spain, Australia and New Zealand through direct sales forces from our company sales and service locations in those respective countries. In the first quarter of 2009, we began transitioning sales in these countries from direct sales to distribution through HSIC.

International Distributors. We sell products outside the United States through a network of independent distributors. Our distributors purchase systems and disposables from us at wholesale dealer prices and resell them to dentists in their sales territories. All sales to distributors are final and we can terminate our arrangements with dealers and distributors for cause or non-performance. In some select territories we have granted certain distributors the right to be our exclusive distributor in that territory. These distributors are generally required to satisfy certain minimum purchase requirements to maintain exclusivity.

Customer Service. We provide maintenance and support services through our support hotline, field and factory service technicians and our network of factory-trained third-party service technicians. We currently provide maintenance and support services in the United States and Canada through our employee service technicians. We provide parts to distributors at no additional charge for products covered under warranty. We maintain a network of service technicians trained at our factory locations, who provide maintenance and support services in all other countries where we do business. Our international distributors are responsible for providing maintenance and support services for products sold by them. We are in the process of transitioning service in Germany, Spain, Australia and New Zealand to HSIC. We provide parts to distributors at no additional charge for products covered under warranty.

Financing Options. Many dentists finance their purchases through third-party leasing companies, banks, or lessors. In the United States and Canada, third party customers enter into a lease with a lessor who purchases the product from HSIC. We are not party to the lease. The lessee pays the lessor in installments, we do not bear the credit risk that the dentist might not make payments. The leasing companies and banks do not have recourse to us for a dentist s failure to make payments, nor do we have any obligation to take back the product at the end of the lease.

Engineering and Product Development

Engineering and development activities are essential to maintaining and enhancing our business. We believe our engineering and development team has demonstrated its ability to develop innovative products that meet evolving market needs. Our research and development group consists of approximately 16 individuals with medical device and laser development experience and other relevant backgrounds, the majority of whom have degrees in physics or engineering, including two Ph.Ds. During the years ended December 31, 2008, 2007 and 2006, our engineering and development expenses were approximately $5.6 million, $5.1 million and $4.9 million, respectively. Our current engineering and development activities are focused on improving our existing products and technology and extending our product range in order to provide dental practitioners and patients with less painful and clinically superior laser systems. Examples of improvements being pursued include faster cutting speed, ease of use, less need for anesthesia injections, and an expanded portfolio of consumable products for use with our laser systems. We also devoted resources in 2006 to develop a new, compact, state-of-the-art diode laser system called *ezlase*, for which we received FDA 510(k) clearance in January 2007. We started marketing and selling the *ezlase* system in February 2007. In February 2008, we received FDA 510(k) clearance for root canal disinfections using our Waterlase systems. In February 2009, we announced the release of our Waterlase MD Turbo All-Tissue Dental Laser System.

We also devote engineering and developments resources toward markets outside of dentistry in which we might exploit our technology platform and capabilities. We believe our laser technology and developments capabilities could

be applicable in the pain management, aesthetic/dermatology, veterinary and consumer products markets. For example, in February 2008, we received 510(k) clearance from the FDA to allow us to

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market our Waterlase MD for use in certain specific dermatological applications as well as general and plastic surgery.

In June 2006 we entered into a binding letter of intent with The Procter and Gamble Company, or P&G, and in January 2007 completed a definitive agreement pursuant to which we granted P&G rights to certain of our intellectual property for use in the development of consumer products in a number of different areas. Any consumer products developed and sold by P&G which are based upon the intellectual property we licensed would result in royalty income to us.

Intellectual Property and Proprietary Rights

We rely, in part, on a combination of patents, trademarks, trade secrets, copyrights and other intellectual property rights to protect our technology. We have approximately 134 issued patents and more than 189 pending patent applications. Approximately two-thirds of our patents were granted in the United States, and the rest were granted in Europe and other countries around the world. Our patents cover the use of laser technologies and fluids for dental, medical, cosmetic and industrial applications, as well as laser characteristics, accessories, future technological developments, fluid conditioning and other technologies and methods for dental, medical and aesthetic applications. We have numerous patent applications pending worldwide and plan to apply for other patents in the future as we develop new technologies. While we hold a variety of patents that cover a broad range of technologies and methods, approximately 70% of these patents provide market protection for our core technologies incorporated in our laser systems, including the Waterlase systems, which accounted for approximately 62% of our net revenue in 2008, approximately 68% of our net revenue in 2007 and approximately 79% of our net revenue in 2006. Existing patents related to our core technology, which are at various stages of being incorporated into our products, are scheduled to expire as follows: fifteen in 2009, twelve in 2010, eight in 2011 and ten in 2012 with the majority having expiration dates ranging from 2013 to 2023. With more than 189 patent applications pending, we expect the number of new grants to exceed the number of patents expiring. We do not expect the expiration of the expired or soon-to-expire patents to have a material effect on our business.

In January 2005, we acquired the intellectual property portfolio of Diodem, LLC, or Diodem, consisting of certain U.S. and international patents of which four were asserted against us, and settled the existing litigation between us and Diodem, for consideration of $3.0 million in cash, 361,664 shares of common stock (valued at the common stock fair market value on the closing date of the transaction for a total of approximately $3.5 million) and a five-year warrant exercisable into 81,037 shares of common stock at an exercise price of $11.06 per share. In addition, 45,208 additional shares of common stock were placed in escrow, to be released to Diodem, if certain criteria specified in the purchase agreement were satisfied in or before July 2006. As of March 31, 2006, we determined that it was probable that these shares of common stock would be released from escrow in or before July 2006. Accordingly, we recorded a patent infringement legal settlement charge of approximately $348,000 in 2006. In July 2006, we released these shares from escrow. The common stock issued, the escrow shares of common stock and the warrant shares had certain registration rights, and a Registration Statement on Form S-3 was filed with the Securities and Exchange Commission, or SEC, to register for sale any of these shares which remained unsold. This Registration Statement became effective on April 17, 2007. The total consideration had an estimated value of approximately $7.4 million including the value of the patents acquired in January 2005. As of December 31, 2004, we accrued approximately $6.4 million for the settlement of the existing litigation with $3.0 million included in current liabilities and $3.4 million recorded as a long-term liability. In January 2005, we recorded an intangible asset of $0.5 million representing the estimated fair value of the intellectual property acquired. The estimated fair value of the patents was determined with the assistance of an independent valuation expert using a relief from royalty and a discounted cash flow methodology. As a result of the acquisition, Diodem immediately withdrew its patent infringement claims against us and the case was formally dismissed on May 31, 2005. We did not pay, and have no obligation to pay, any royalties to Diodem on past or future sales of our products, but we agreed to pay additional consideration if any of the acquired patents held by us are licensed to a third party by a certain date. In order to secure performance by us of these financial obligations, the parties entered into an

intellectual property security agreement, pursuant to which, subject to the rights of

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existing creditors and the rights of any future creditors to the extent provided in the agreement, we granted Diodem a security interest in all of their rights, title and interest in the royalty patents. In September 2007, Diodem filed a motion with the U.S.District Court in the Central District of California requesting that the original case be reopened for limited discovery concerning Diodem s claims that we breached various of our obligations and representations in the settlement agreement and seeking damages in the range of $3.85 million to $5.2 million plus costs and attorneys fees incurred in recovering said alleged damages. The District Court denied Diodem s motion finding, in part, that if Diodem wishes to pursue claims for breach of the settlement agreement, it must file a new lawsuit for breach of contract. On February 20, 2008, Diodem filed a lawsuit for breach of the settlement agreement in Los Angeles Superior Court, naming us and a wholly-owned subsidiary, BL Acquisition II, Inc. as defendants. The complaint asserts two claims, both alleging breaches of the Agreement. Diodem seeks damages of not less than $4.0 million. On April 28, 2008, together with BL Acquisition II, Inc., we filed demurrers and a motion to strike that, in essence, requests the court to dismiss Diodem s complaint. On June 20, 2008 the Court denied the demurrers and the motion and on July 21, 2008 we filed an answer to the complaint denying the allegations. On October 15, 2008 the lawsuit was dismissed with prejudice by Diodem pursuant to a settlement agreement among the parties which resolves all claims in the litigation and provides that we will make four payments to Diodem totaling approximately $950,000 through 2010, of which $85,000 will be paid by our liability insurance carriers. In the settlement agreement, we denied any wrongdoing. The settlement agreement contains confidentiality provisions that limit disclosure of the terms of the settlement except as required by SEC rule or regulation, under GAAP or pursuant to court order or law. Related to this matter, we incurred approximately $1.2 million in charges for the settlement and associated legal fees in the third quarter ended September 30, 2008, which reflected all the settlement payments to be made over the next two years.

In March 2005, we acquired a fully-paid license related to patents owned or licensed by SurgiLight, Inc. As a result of the acquisition, we received fully-paid license rights in the U.S. and international markets to patents in the fields of presbyopia and ophthalmology.

We require our employees, consultants and advisors to execute confidentiality agreements in connection with their employment, consulting or advisory relationships with us. We also require our employees, consultants and advisors who we expect to work on our products to agree to disclose and assign to us all inventions conceived during their term of employment or contract, using our property, or which relate to our business. Despite measures taken to protect our intellectual property, unauthorized parties may attempt to copy aspects of our products or to obtain and use information that we regard as proprietary, or our competitors may independently develop similar technologies.

The medical device industry is characterized by the existence of a large number of patents and frequent litigation based on allegations of patent infringement. Patent litigation can involve complex factual and legal questions and its outcome is uncertain. Our success will depend in part on our not infringing patents issued to others including our competitors and potential competitors. As the number of entrants into our market increases, the risk of an infringement claim against us grows. While we attempt to ensure that our products and methods do not infringe other parties patents and proprietary rights, our competitors may assert that our products, and the methods we employ, are covered by U.S. or international patents held by them. In addition, our competitors may assert that future products and methods we may market infringe their patents.

BIOLASE®, ZipTip®, ezlase®, eztips®, MD Flow® and Waterlase® are registered trademarks of Biolase Technology, Inc., and Diolase™, Comfort Jet™, HydroPhotonics™, LaserPal™, Comfortpulse™, MD Gold™, WCLI™, World Clinical Laser Institute™, Waterlase MD™, HydroBeam™, SensaTouch™, Occulase™ and C100™ are trademarks of BIOLASE Technology, Inc.

Competition

We compete with a number of companies that market traditional dental products, such as dental drills, as well as other companies that market laser technologies in dental and other medical markets. In the domestic hard tissue dental market, we believe our Waterlase systems primarily compete with laser systems manufactured by Hoya ConBio, a subsidiary of Hoya Photonics, a large Japanese manufacturer primarily of optics and

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crystals, Lares, the U.S. distributor of Fotona, a European company and Syneron. In the international market, our Waterlase systems compete primarily with products manufactured by several additional companies, including Fotona, KaVo and Deka Dental Corporation.

Our Waterlase systems also compete with non-laser based systems, including traditional high and low-speed dental drills and air abrasion systems that are used for dental procedures. Our Diode systems, including *ezlase*, compete with other semiconductor diode lasers, as well as with scalpels, scissors and a variety of other cutting tools that have been traditionally used to perform soft tissue procedures. In the market for teeth whitening, our *ezlase* system competes with other products and instruments used by dentists, as well as teeth whitening strips and other over-the-counter products.

Traditional and commonly used cutting tools are less expensive for performing dental procedures. For example, a high speed drill or an electrosurge device can be purchased for less than $1,000 each. In addition, our systems are not designed to perform certain functions that high speed drills can perform, such as cutting metal fillings and certain polishing and grinding functions. High speed drills will still be needed for these functions, and our systems are not intended to replace all applications of the high speed drill.

In general, our ability to compete in the market depends in large part on our:

- acceptance by leading dental practitioners;
- product performance;
- product pricing;
- intellectual property protections;
- customer support;
- timing of new product research; and
- development of successful national and international distribution channels.

Some of the manufacturers that develop competing laser systems have significantly greater financial, marketing and technical resources than we do. In addition, some competitors have developed, and others may attempt to develop, products with applications similar to those performed by our laser systems.

Because of the large size of the potential market for our products, we anticipate that new or existing competitors may develop competing products, procedures or clinical solutions. These products, procedures or solutions could prove to be more effective, safer or less costly than procedures using our laser systems. The introduction of new products, procedures or clinical solutions by competitors may result in price reductions, reduced margins or loss of market share and may render our products obsolete.

Government Regulation

Our products are medical devices. Accordingly, our product development, testing, labeling, manufacturing processes and promotional activities are regulated extensively by government agencies in the United States and other countries in which we market and sell our products. We have clearance from the FDA to market our laser systems for specific clinical indications in the United States. We have the clearances necessary to sell our products in Canada. We also

have the necessary CE Marks or clearances to sell our laser systems in the European Union and other international markets.

United States

In the United States, the FDA regulates the design, manufacture, distribution, quality standards and marketing of medical devices. We have clearance from the FDA to market our Waterlase and Diode systems in the United States for dental procedures on both adult and pediatric patients. In 1998, we received FDA clearance to market the Millennium®, the earlier generation of our current Waterlase system, for certain dental hard tissue applications. This clearance allowed us to commence domestic sales and marketing of our technology for hard and soft tissue applications. During 1999 and 2000, to meet the demand for soft-tissue and

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cosmetic dentistry applications, we designed a semiconductor diode laser system, which is now marketed as our LaserSmile system. We received FDA clearance to market the system for a variety of soft tissue medical applications in September 1999. In 2001, we received FDA clearance to market the LaserSmile system for cosmetic teeth whitening. In October 2003, the LaserSmile received clearance for periodontal procedures for both early and advanced stages of periodontal disease.

In 2002, 2003, 2004, 2008 and 2009, our Waterlase system became the first laser system to receive FDA clearance for several new types of dental procedures. We also received clearance in 2002 to market this system for cutting, shaving, contouring and resection of oral osseous tissues, or bone. In January 2003, we received FDA clearance to market the Waterlase system for use in apicoectomy surgery, a procedure for root canal infections and complications that includes cutting gum, bone (to access the infected area) and the apex of the tooth to access the infected area. The clearance also encompasses flap surgical procedures. Flaps are frequently created in conjunction with many procedures, including periodontal, implant placement and recovery, extraction of wisdom teeth, and exposure of impacted teeth. In January 2004, our Waterlase system received FDA clearance for several new bone, periodontal and soft tissue procedures, including removal of bone to correct defects and create physiologic contours of bone, resection of bone to restore architecture, resection of bone for grafting, preparing full, partial and split thickness flaps for periodontal surgery and removal of granulation tissue from bony defects. In February 2008, we received 510(k) clearance from the FDA for root canal disinfection using our Waterlase MD. In June 2008, our Waterlase C100 All-Tissue Dental Laser System received FDA 510(k) clearance. In February 2009, we received FDA 510(k) clearance for our Waterlase MD Turbo All-Tissue Dental Laser System.

In addition, in July 2006, we received 510(k) clearance from the FDA for our Oculase MD laser for general ophthalmic soft tissue surgical indications such as incision, excision, vaporization and coagulation of ocular tissue and tissue surrounding the eye and orbit. In January 2008, we received 510(k) clearance from the FDA to allow us to market our Waterlase MD for use in dermatological applications as well as general and plastic surgery.

In January 2007, we received 510(k) clearance from the FDA to market *ezlase*, our new soft tissue diode laser system. In November 2008, we received FDA 510(k) clearance to market a 10W version of our ezlase. In December 2008, we received FDA 510(k) clearance for tooth whitening using our *ezlase* system.

As we develop new products and applications or make any significant modifications to our existing products or labeling, we will need to obtain the regulatory clearances or approvals necessary to market such products for dental, cosmetic and other medical procedures in our target markets.

There are two principal methods by which FDA regulated devices may be marketed in the United States: 510(k) clearance and pre-market approval, or PMA. To obtain 510(k) clearance, we must demonstrate that our device is substantially equivalent to a previously cleared 510(k) device or a device that was in commercial distribution before May 28, 1976 for which the FDA has not yet called for the submission of PMA applications. By statute and regulation, the FDA is required to clear, deny or request additional information on a 510(k) request within 90 days of submission of the application. As a practical matter, 510(k) clearance often takes significantly longer. Domestic marketing of the product must be deferred until clearance is received from the FDA. In some instances, an Investigational Device Exemption, or an IDE, is required for clinical trials for a 510(k) clearance. If a request for 510(k) clearance is turned down by the FDA, then a PMA application may be required. We intend to utilize the 510(k) notification procedure whenever possible. To date, all of our regulated products have qualified for 510(k) clearance.

After a device receives 510(k) clearance, any modification that could significantly affect its safety or effectiveness, or that would constitute a major change in its intended use, will require a new 510(k) clearance, or could require a PMA application. The FDA requires each manufacturer to make this determination initially, but the FDA can review any such decision and can disagree with a manufacturer s determination. If the FDA disagrees with a manufacturer s

determination that a new clearance or approval is not required for a particular modification, the FDA can require the manufacturer to cease marketing and/or recall the modified device until 510(k) clearance or PMA is obtained. We have made and plan to continue to make additional product

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enhancements to our laser systems that we believe do not require new 510(k) clearances. We cannot assure you that the FDA will agree with our determinations in these instances.

A PMA application is required for a device that does not qualify for clearance under 510(k) provisions. The FDA is required by law to review a PMA application within 180 days. As part of the approval of a PMA application, the FDA typically requires human clinical testing to determine safety and efficacy of the device. To conduct human clinical testing, typically the FDA must approve an IDE. To date, none of our products have required a PMA to support marketing approval.

After a device is placed on the market, numerous regulatory requirements apply. These include:

quality system regulations, or QSRs, which require manufacturers, including third-party manufacturers, to follow stringent design, testing, control, documentation and other quality assurance procedures during all aspects of the manufacturing process;

labeling regulations, which prohibit the promotion of products for uncleared, unapproved or off label uses;

medical device reporting regulations, which require that manufacturers report to the FDA if their device may have caused or contributed to a death or serious injury or malfunctioned in a way that would likely cause or contribute to a death or serious injury if it were to recur;

correction and removal regulations, which require that manufacturers report to the FDA any corrections to or removals of distributed devices that are made to reduce a risk to health; and

post-market surveillance regulations, which apply when necessary to protect the public health or to provide additional safety and effectiveness data for the device.

We will need to invest significant time and other resources to ensure ongoing compliance with FDA quality system regulations and other post market regulatory requirements.

We have registered with the FDA as a medical device manufacturer and we have obtained a manufacturing license from the California Department of Health Services. Compliance with regulatory requirements is assured through periodic, unannounced facility inspections by the FDA and the Food and Drug Branch of the California Department of Health Services, and these inspections may include the manufacturing facilities of our subcontractors.

Failure to comply with applicable regulatory requirements can result in an enforcement action by the FDA, which may include any of the following sanctions:

fines, injunctions and civil penalties;

recall or seizure of our products;

operating restrictions, partial suspension or total shutdown of production;

refusing our request for 510(k) clearance of or PMA application for new products;

withdrawing 510(k) clearance or PMA applications that are already granted; and

criminal prosecution.

We are also subject to regulation under the Radiation Control for Safety and Health Act of 1968, or the Safety Act, administered by the FDA. The Safety Act regulates the energy emissions of light and sound and electronic waves from electronic products. Regulations implementing the Safety Act require a laser manufacturer to file new product and annual reports, to maintain quality control, product testing and sales records, to distribute product operation manuals, to incorporate certain design and operating features in lasers sold to end users and to certify and label each laser sold to end users as one of four classes of lasers based on the level of radiation emitted from the laser. In addition, various warning labels must be affixed to the product and certain protective features must be installed, depending upon the class of product.

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Various state dental boards allow dental hygienists to use lasers to perform certain dental procedures. In addition, dental boards in a number of states are considering educational requirements regarding the use of dental lasers. The scope of these restrictions and educational requirements is not now known, and they could have an adverse effect on sales of our laser-based products.

International

Foreign sales of our laser system products are subject to the regulatory requirements of the foreign country or, if applicable, the harmonized standards of the European Union. These regulatory requirements vary widely among countries and may include technical approvals, such as electrical safety, as well as demonstration of clinical efficacy. We have a CE Mark for our Waterlase and Diode systems, which permits us to commercially distribute these systems throughout the European Union. We rely on export certifications from the FDA to comply with certain regulatory requirements in several foreign jurisdictions. We are currently working to meet certain foreign country regulatory requirements for certain of our products, including those in Japan. There can be no assurance that additional approvals in Japan or elsewhere will be obtained.

Other Regulatory Requirements

In addition to the regulatory framework for product clearances and approvals, we are subject to extensive and frequently changing regulations under many other laws administered by U.S. and foreign governmental agencies on the national, state and local levels, including requirements regarding occupational health and safety and the use, handling and disposing of toxic or hazardous substances.

Third Party Reimbursement

Our products are generally purchased by dental or medical professionals who have various billing practices and patient mixes. Such practices range from primarily private pay to those who rely heavily on third party payors, such as private insurance or government programs. In the United States, third party payors review and frequently challenge the prices charged for medical services. In many foreign countries, the prices for dental services are predetermined through government regulation. Payors may deny coverage and reimbursement if they determine that the procedure was not medically necessary, such as a cosmetic procedure, or that the device used in the procedure was investigational. We believe that most of the procedures being performed with our current products generally are reimbursable, with the exception of cosmetic applications, such as tooth whitening. For the portion of dentists who rely heavily on third party reimbursement, the inability to obtain reimbursement for services using our products could deter them from purchasing or using our products. We cannot predict the effect of future healthcare reforms or changes in financing for health and dental plans. Any such changes could have an adverse effect on the ability of a dental or medical professional to generate a return on investment using our current or future products. Such changes could act as disincentives for capital investments by dental and medical professionals and could have a negative impact on our business and results of operations.

Employees

At December 31, 2008, we employed approximately 180 people, of which there were 61 in manufacturing and quality and control, 16 in research and development, 50 in sales and sales support, 28 in customer technical support and 25 in administration. Subsequent to December 31, 2008, we continued the implementation of our cost reduction measures including beginning the wind down of our foreign direct operations. As of February 28, 2009 we employed approximately 146 people. Our employees are not represented by any collective bargaining agreement and we believe our employee relations are good.

Financial Information

The additional financial information required to be included in this Item 1 is incorporated herein by reference to Part IV, Item 15 of this report.

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Available Information

Copies of our Annual Report on Form 10-K, Quarterly Reports on Form 10-Q, Current Reports on Form 8-K and amendments to those reports filed or furnished pursuant to Section 13(a) or 15(d) of the Securities Exchange Act of 1934 (the Exchange Act) are available free of charge through our Web site (www.biolase.com) as soon as reasonably practicable after we electronically file the material with, or furnish it to, the SEC. You may read and copy any document we file with the SEC at the SEC s Public Reference Room at 100 F Street N.E., Washington, D.C. 20549. Please call the SEC at 1-800-SEC-0330 for further information on the Public Reference Room. Our SEC filings are also available to the public at the SEC s web site at *http://www.sec.gov*.

PART I

Item 1A. ***Risk Factors***

Risk factors which could cause actual results to differ from our expectations and which could negatively impact our financial condition and results of operations are discussed below and elsewhere in this report. If any of the following risks actually occurs, our business, financial condition, results of operations and our future growth prospects could be materially and adversely affected. Under these circumstances, the trading price of our common stock could decline, and you may lose all or part of your investment. Further, additional risk not currently known to us or that we currently believe are immaterial also may impair our business, operations, liquidity and stock price materially and adversely.

Risks Relating to Our Business

We may have difficulty achieving profitability and may experience additional losses.

We have an accumulated deficit of $89.7 million at December 31, 2008. We recorded net losses of $9.1 million and $7.3 million for the years ended December 31, 2008 and 2007, respectively. In order to achieve profitability, we must control our costs and increase net revenue through new sales. Failure to increase our net revenue and decrease our costs could cause our stock price to decline.

The general slowdown of the economy and uncertainties in the global financial markets, our reliance on a primary distributor, and our lack of financing may adversely affect our liquidity, operating results, and financial condition.

We are substantially dependent on our major distributor and the continued performance of this distributor to make committed purchases of our products and associated consumables under our distribution agreement, and the receipt of cash in connection with those purchases, is essential to our liquidity. In addition, on February 5, 2009, our loan agreement with our bank was terminated. We presently do not have any debt financing in place with a bank or other financial institution. The absence of such debt financing availability could adversely impact our operations. Our obligations and operating requirements may require us to seek additional funding through public or private equity or debt financing, and we have no commitments for financing of any kind at this time. We may not be able to obtain requisite financing if necessary to fund existing obligations and operating requirements on acceptable terms or at all.

Our business is sensitive to changes in general economic conditions. Financial markets inside the United States and internationally have experienced extreme disruption in recent months, including, among other things, extreme volatility in security prices, severely diminished liquidity and credit availability and declining valuations of investments. These disruptions are likely to have an ongoing adverse effect on the world economy. A continuing economic downturn and financial market disruptions may:

reduce demand for our products and services, increase order cancellations and result in longer sales cycles and slower adoption of new technologies;

increase the difficulty of collecting accounts receivable and the risk of excess and obsolete inventories;

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increase price competition in our served markets;

result in supply interruptions, which could disrupt our ability to produce our products.

Dentists and patients may be slow to adopt laser technologies, which could limit the market acceptance of our products.

Our dental laser systems represent relatively new technologies in the dental market. Currently, only a small percentage of dentists use lasers to perform dental procedures. Our future success will depend on our ability to increase demand for our products by demonstrating the potential performance advantages of our laser systems over traditional methods of treatment and over competitive laser systems to a broad spectrum of dentists and patients. Historically, we have experienced long sales cycles because dentists have been, and may continue to be, slow to adopt new technologies on a widespread basis. As a result, we generally are required to invest a significant amount of time and resources to educate customers about the benefits of our products in comparison to competing products and technologies before completing a sale, if any.

Factors that may inhibit adoption of laser technologies by dentists include cost and concerns about the safety, efficacy and reliability of lasers. The list selling price of our Waterlase MD laser system is in excess of $84,000, which is substantially more than the cost of competing non-laser technologies. In order to invest in a Waterlase MD laser system, a dentist generally would need to invest time to understand the technology, the benefits of such technology with respect to clinical outcomes and patient satisfaction, and the return on investment of the product. Absent an immediate competitive motivation, a dentist may not feel compelled to invest the time required to learn about the potential benefits of using a laser system. We also believe that clinical evidence supporting the safety and efficiency of our products, as well as recommendations and support of our laser systems by influential dental practitioners, are important for market acceptance and adoption. In addition, economic pressure, caused for example by an economic slowdown, changes in healthcare reimbursement or by competitive factors in a specific market, may make dentists reluctant to purchase substantial capital equipment or invest in new technologies. Patient acceptance will depend on the recommendations of dentists and specialists, as well as other factors, including without limitation, the relative effectiveness, safety, reliability and comfort of our systems as compared to other instruments and methods for performing dental procedures. The failure of dental lasers to achieve broad market acceptance would limit sales of our products and have an adverse effect on our business and results of operations.

Fluctuations in our revenue and operating results on a quarterly and annual basis could cause the market price of our common stock to decline.

Our revenue and operating results fluctuate from quarter to quarter due to a number of factors, many of which are beyond our control. Historically, we have experienced fluctuations in revenue from quarter to quarter due to seasonality. Revenue in the first quarter typically is lower than average and revenue in the fourth quarter typically is stronger than average due to the buying patterns of dental professionals. In addition, revenue in the third quarter may be affected by vacation patterns which can cause revenue to be flat or lower than in the second quarter of the year. If our quarterly revenue or operating results fall below the expectations of investors, analysts or our previously stated financial guidance, the price of our common stock could decline substantially. Factors that might cause quarterly fluctuations in our revenue and operating results include, among others, the following:

variation in demand for our products, including seasonality;

our ability to research, develop, market and sell new products and product enhancements in a timely manner;

our ability to control costs;

our ability to control quality issues with our products;

regulatory actions that impact our manufacturing processes;

the size, timing, rescheduling or cancellation of orders from distributors;

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the introduction of new products by competitors;

the length of and fluctuations in sales cycles;

the availability and reliability of components used to manufacture our products;

changes in our pricing policies or those of our suppliers and competitors, as well as increased price competition in general;

general economic conditions including the availability of credit for our existing and potential customer base to finance purchases;

the mix of our domestic and international sales and the risks and uncertainties associated with international business;

costs associated with any future acquisitions of technologies and businesses;

limitations on our ability to use net operating loss carryforwards under the provisions of Internal Revenue Code Section 382 and similar state laws;

developments concerning the protection of our intellectual property rights;

catastrophic events such as hurricanes, floods and earthquakes, which can affect our ability to advertise, sell and distribute our products, including through national conferences held in regions in which these disasters strike; and

global economic, political and social events, including international conflicts and acts of terrorism.

The expenses we incur are based, in large part, on our expectations regarding future net revenue. Since many of our costs are fixed in the short term, we may be unable to reduce expenses quickly enough to avoid losses if we experience a decrease in net revenue. Accordingly, you should not rely on quarter-to-quarter comparisons of our operating results as an indication of our future performance.

Any failure to significantly expand sales of our products will negatively impact our business.

We currently handle a significant portion of the marketing, distribution and sales of our products, augmented by our distribution relationship with Henry Schein, Inc. We face significant challenges and risks in expanding, training, managing and retaining our sales and marketing teams, including managing geographically dispersed operations. In addition, we rely on independent distributors to market and sell our products in a number of countries outside of the United States. These distributors may not commit the necessary resources to effectively market and sell our products, and they may terminate their relationships with us at any time with limited notice. If we are unable to expand our sales and marketing capabilities domestically and internationally, or if the relationship with Henry Schein, Inc. does not produce the expected results, we may not be able to effectively commercialize our products, which could harm our business and cause the price of our common stock to decline.

Our distributors may cancel, reduce or delay orders of our products, any of which could reduce our revenue.

Through 2008, we employed direct sales representatives in certain European countries, Australia and New Zealand. In the first quarter of 2009, we began the process of transitioning our sales organizations in those countries to distributors. We also rely on independent distributors for a substantial portion of our sales in other countries outside of the United States and Canada. For the year ended December 31, 2008, revenue from international distributors accounted for approximately 13% of our total revenue. For the year ended December 31, 2007, revenue from international distributors accounted for approximately 19% of our total sales, and one distributor accounted for more than 10% of our revenue. Our ability to maintain or increase our revenue will depend in large part on our success in developing and maintaining relationships with our distributors and upon the efforts of these third parties. Our distributors have significant discretion in determining the efforts and resources they apply to the sale of our products. Our distributors may not commit

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the necessary resources to market and sell our products to the level of our expectations and, regardless of the resources they commit, they may not be successful. Additionally, most of our distributor agreements can be terminated with limited notice, and we may not be able to replace any terminating distributors in a timely manner or on terms agreeable to us, if at all. If we are unable to maintain our distribution network, if our distribution network is not successful in marketing and selling our products, or if we experience a significant reduction in, cancellation or change in the size and timing of orders from our distributors, our revenues could decline significantly.

In August 2006, and as amended, we entered into a distribution agreement with Henry Schein, Inc., or Henry Schein, a large distributor of healthcare products to office-based practitioners, pursuant to which we granted Henry Schein the exclusive right to distribute our complete line of dental laser systems, accessories and services in the United States and Canada. The agreement had an initial term of three years, following which it would automatically renew for an additional period of three years, provided that Henry Schein achieved its minimum purchase requirements.

We intend to continue to augment the activities of Henry Schein in the United States and Canada with the efforts of our direct sales force; however, our future revenue will be largely dependent upon the efforts and success of Henry Schein in selling our products. We cannot assure you that Henry Schein will devote sufficient resources to selling our products or, even if sufficient resources are directed to our products, that such efforts will be sufficient to increase net revenue.

Additionally, on February 27, 2009, we entered into an agreement with HSIC in which HSIC will become our distributor in certain international countries including Germany, Spain, Australia and New Zealand and will be permitted to distribute our products in those additional markets where we do not have current distribution agreements in place.

Components used in our products are complex in design and any defects may not be discovered prior to shipment to customers, which could result in warranty obligations, reducing our revenue and increasing our cost.

In manufacturing our products, we depend upon third parties for the supply of various components. Many of these components require a significant degree of technical expertise to design and produce. If we fail to adequately design or if our suppliers fail to produce components to specification, or if the suppliers, or we, use defective materials or workmanship in the manufacturing process, the reliability and performance of our products will be compromised. We have experienced such non-compliance with manufacturing specifications in the past and may continue to experience such in the future, which could lead to higher costs of revenue and thus reduced gross margins.

Our products may contain defects that cannot be repaired easily and inexpensively, and we have experienced in the past and may experience in the future some or all of the following:

- loss of customer orders and delay in order fulfillment;
- damage to our brand reputation;
- increased cost of our warranty program due to product repair or replacement;
- inability to attract new customers;
- diversion of resources from our manufacturing and research and development departments into our service department; and
- legal action.

The occurrence of any one or more of the foregoing could materially harm our business.

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We must continue to procure materials and components on commercially reasonable terms and on a timely basis to manufacture our products profitably. We have some single-source suppliers.

We frequently do not use written supply contracts with our key suppliers; instead, we purchase certain materials and components included in our products from a limited group of suppliers using purchase orders. Our business depends in part on our ability to obtain timely deliveries of materials and components in acceptable quality and quantities from our suppliers. Certain components of our products, particularly specialized components used in our lasers, are currently available only from a single source or limited sources. For example, the crystal, fiber and hand pieces used in our Waterlase systems are each supplied by a separate single supplier. Our dependence on single-source suppliers involved several risks, including limited control over pricing, availability, quality and delivery schedules. If any one or more of our single-source suppliers cease to provide us with sufficient quantities of our components in a timely manner or on terms acceptable to us, or cease to manufacture components of acceptable quality, we would have to seek alternative sources of manufacturing. We could incur delays while we locate and engage alternative qualified suppliers and we might be unable to engage alternative suppliers on favorable terms. Any such disruption or increased expenses could harm our business efforts and adversely affect our ability to generate sales. Our reliance on these outside manufacturers and suppliers also subjects us to other risks that could harm our business, including:

- we may not be able to obtain adequate supply in a timely manner or on commercially reasonable terms;
- we may have difficulty locating and qualifying alternative suppliers for the various components in our laser systems;
- switching components may require product redesign and submission to the FDA of a 510(k) application, which could significantly delay production;
- our suppliers manufacture products for a range of customers, and fluctuations in demand for the products those suppliers manufacture for others may affect their ability to deliver components for us in a timely manner; and
- our suppliers may encounter financial hardships, be acquired, or experience other business events unrelated to our demand for components, which could inhibit or prevent their ability to fulfill our orders and meet our requirements.

Any interruption or delay in the supply of components or materials, or our inability to obtain components or materials from alternate sources at acceptable prices in a timely manner, could impair our ability to meet the demand of our customers and cause them to cancel orders or switch to competitive procedures. We are currently in the process of identifying and qualifying alternate source suppliers for our key components. There can be no assurance, however, that we will successfully identify and qualify an alternate source supplier for any of our key components or that we could enter into an agreement with any such alternate source supplier on terms acceptable to us.

We may not be able to compete successfully, which will cause our revenue and market share to decline.

We compete with a number of domestic and foreign companies that market traditional dental products, such as dental drills, as well as companies that market laser technologies in the dental and medical markets, including Hoya ConBio, a subsidiary of Hoya Photonics, OpusDent Ltd., a subsidiary of Lumenis, KaVo, Deka Dental Corporation, Ivoclar Vivadent AG, and Fotona d.d. If we do not compete successfully, our revenue and market share may decline. Some of our competitors have greater financial, technical, marketing or other resources than we have, which may allow them to respond more quickly to new or emerging technologies and to devote greater resources to the acquisition or development and introduction of enhanced products than we can. The ability of our competitors to devote greater financial resources to product development requires us to work harder to distinguish our products through improving

our product performance and pricing, protecting our intellectual property, continuously improving our customer support, accurately timing the introduction of new products and developing sustainable distribution channels worldwide. In addition, we expect the rapid technological changes occurring in the healthcare industry to lead to the entry of new competitors, particularly if dental and medical lasers gain increasing market acceptance. We must be able to anticipate technological

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changes and introduce enhanced products on a timely basis in order to grow and remain competitive. Many of these new competitors would be practitioners focusing on a specific product or market segment, making it more difficult for us to expand our overall market position. If these companies become successful, we expect that competition will become even more intense, leading to greater pricing pressure and making it more difficult for us to expand our sales. New competitors or technological changes in laser products and methods could cause commoditization of our products, require price discounting or otherwise adversely affect our gross margins and our financial condition.

Rapidly changing standards and competing technologies could harm demand for our products or result in significant additional costs.

The markets in which our products compete are subject to rapid technological change, evolving industry standards, changes in the regulatory environment, and frequent introductions of new devices and evolving dental and surgical techniques. Competing products may emerge which could render our products uncompetitive or obsolete. The process of developing new medical devices is inherently complex and requires regulatory approvals or clearances that can be expensive, time consuming and uncertain. We cannot guarantee that we will successfully identify new product opportunities, identify new and innovative applications of our technology, or be financially or otherwise capable of completing the research and development required to bring new products to market in a timely manner. An inability to expand our product offerings or the application of our technology could limit our growth. In addition, we may incur higher manufacturing costs if manufacturing processes or standards change, and we may need to replace, modify, design or build and install equipment, all of which would require additional capital expenditures.

Any problems that we experience with our manufacturing operations may harm our business.

In order to grow our business, we must expand our manufacturing capabilities to produce the systems and accessories necessary to meet any demand we may experience. We may encounter difficulties in increasing production of our products, including problems involving production capacity and yields, quality control and assurance, component supply and shortages of qualified personnel. In addition, before we can begin commercial manufacture of our products, we must obtain regulatory approval of our manufacturing facilities, processes and quality systems, and the manufacture of our laser systems must comply with cGMP regulations. The cGMP regulations govern facility compliance, quality control and documentation policies and procedures. In addition, our manufacturing facilities are continuously subject to periodic inspections by the FDA, as well as various state agencies and foreign regulatory agencies. From time to time, we may expend significant resources in obtaining, maintaining and remedying our compliance with these requirements. Our success will depend in part upon our ability to manufacture our products in compliance with the FDA s Quality System regulations and other regulatory requirements. We have experienced quality issues with components of our products supplied by third parties. If we do not succeed in manufacturing our products on a timely basis and with acceptable manufacturing costs while at the same time maintaining good quality control and complying with applicable regulatory requirements, our business could be harmed.

Changes in government regulation or the inability to obtain or maintain necessary government approvals could harm our business.

Our products are subject to extensive government regulation, both in the United States and in other countries. To clinically test, manufacture and market products for human use, we must comply with regulations and safety standards set by the FDA and comparable state and foreign agencies. Regulations adopted by the FDA are wide ranging and govern, among other things, product design, development, manufacture and testing, labeling, storage, advertising and sales. Generally, products must meet regulatory standards as safe and effective for their intended use before being marketed for human applications. The clearance process is expensive, time-consuming and uncertain. Failure to comply with applicable regulatory requirements of the FDA can result in an enforcement action which may include a variety of sanctions, including fines, injunctions, civil penalties, recall or seizure of our products, operating

restrictions, partial suspension or total shutdown of production and criminal prosecution. The failure to receive or maintain requisite approvals for the use of our

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products or processes, or significant delays in obtaining such approvals, could prevent us from developing, manufacturing and marketing products and services necessary for us to remain competitive.

To date, we have been successful in obtaining 510(k) clearances from the FDA to market products. However, should we develop new products and applications or make any significant modifications to our existing products or labeling, we will need to obtain additional regulatory clearances or approvals to market such products. Any modification that could significantly affect a product s safety or effectiveness, or that would constitute a change in its intended use, will require a new 510(k) clearance, or could require a PMA application. The FDA requires each manufacturer to make this determination initially, but the FDA can review any such decision and can disagree with a manufacturer s determination. If the FDA disagrees with a manufacturer s determination, the FDA can require the manufacturer to cease marketing and/or recall the modified device until 510(k) clearance or PMA is obtained. If 510(k) clearance is denied and a pre-market approval application is required, we could be required to submit substantially more data, may be required to conduct human clinical testing and would very likely be subject to a significantly longer review period.

Products sold in international markets are also subject to the regulatory requirements of each respective country. The regulations of the European Union require that a device have a CE Mark, indicating conformance with European Union laws and regulations before it can be sold in that market. The regulatory international review process varies from country to country. We rely on our distributors and sales representatives in the foreign countries in which we market our products to comply with the regulatory laws of such countries. Failure to comply with the laws of such countries could have a material adverse effect on our operations and, at the very least, could prevent us from continuing to sell products in such countries. In addition, unanticipated changes in existing regulatory requirements or the adoption of new requirements could impose significant costs and burdens on us, which could increase our operating expenses and harm our financial condition.

We may have difficulty managing any growth that we might experience.

If we experience growth in our operations, our operational and financial systems, procedures and controls may need to be expanded, which will place significant demands on our management, distract management from our business plan and increase expenses. Our success will depend substantially on the ability of our management team to manage any growth effectively. These challenges may include, among others:

maintaining our cost structure at an appropriate level based on the revenue we generate;

managing manufacturing expansion projects;

implementing and improving our operational and financial systems, procedures and controls; and

managing operations and international distributors in multiple locations and multiple time zones.

In addition, we incur significant legal, accounting, insurance and other expenses as a result of being a public company. The Sarbanes-Oxley Act of 2002, as well as rules subsequently implemented by the SEC and NASDAQ, has required changes in corporate governance practices of public companies. We expect these rules and regulations will continue to result in substantial legal and financial compliance costs and some activities will continue to be more time-consuming and costly. We also expect these rules and regulations may make it more difficult and more expensive for us to maintain director and officer insurance and, from time to time, we may be required to accept reduced policy limits and coverage or incur significantly higher costs to maintain the same or similar coverage. As a result, it may be more difficult for us to attract and retain qualified persons to serve on our Board of Directors or as executive officers. We continue to evaluate and monitor developments with respect to these rules, and we cannot predict or estimate the amount of additional costs we may incur or the timing of such costs.

If we fail to secure or protect our intellectual property rights, competitors may be able to use our technologies, which could weaken our competitive position, reduce our revenue or increase our costs.

Our future success will depend, in part, on our ability to obtain and maintain patent protection for our products and technology, to preserve our trade secrets and to operate without infringing the intellectual

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property of others. We rely on patents to establish and maintain proprietary rights in our technology and products. We currently possess a number of issued patents and patent applications with respect to our products and technology; however, we cannot assure that any additional patents will be issued, that the scope of any patent protection will be effective in helping us address our competition or that any of our patents will be held valid if subsequently challenged. It is also possible that our competitors may independently develop similar products, duplicate our products or design products that circumvent our patents. Additionally, the laws of foreign countries may not protect our products or intellectual property rights to the same extent as the laws of the United States. In addition, there are numerous proposed changes to the patent laws and rules of the U.S. Patent and Trademark Office which, if enacted, may have a significant impact on our ability to protect our technology and enforce our intellectual property rights. For example, Congress is considering several significant changes to the U.S. patent laws, including (among other things) changing from a first to invent to a first inventory to file system, limiting the time for which a patentee may file a patent suit, requiring the apportionment of patent damages, and creating a post-grant opposition process to challenge patents after they have issued. If we fail to protect our intellectual property rights adequately, our competitive position and financial condition may be harmed.

We may be sued by third parties for alleged infringement of their proprietary rights.

We face substantial uncertainty regarding the impact that other parties intellectual property positions will have on the markets for dental and other medical lasers. The medical technology industry has in the past been characterized by a substantial amount of litigation and related administrative proceedings regarding patents and intellectual property rights. From time to time, we have received, and expect to continue to receive, notices of claims of infringement, misappropriation or misuse of other parties proprietary rights. Some of these claims may lead to litigation. We may not prevail in any future intellectual property infringement litigation given the complex technical issues and inherent uncertainties in litigation. Any claims, with or without merit, may be time-consuming and distracting to management, result in costly litigation or cause product shipment delays. Adverse determinations in litigation could subject us to significant liability and could result in the loss of proprietary rights. A successful lawsuit against us could also force us to cease selling or redesign products that incorporate the infringed intellectual property. Additionally, we could be required to seek a license from the holder of the intellectual property to use the infringed technology, and it is possible that we may not be able to obtain a license on acceptable terms, or at all. Any of the foregoing adverse events could seriously harm our business.

We are subject to a variety of litigation in the course of our business that could adversely affect our results of operations and financial condition.

We are subject to a variety of litigation incidental to our business, including claims for damages arising out of the use of our products or services and claims relating to intellectual property matters, employment matters, commercial disputes, competition and sales and trading practices, environmental matters, personal injury and insurance coverage. Some of these lawsuits include claims for punitive as well a compensatory damages. The defense of these lawsuits may divert our management s attention, we may incur significant expenses in defending these lawsuits, and we may be required to pay damage awards or settlement or become subject to equitable remedies that could adversely affect our financial condition, operations and results of operations. Moreover, any insurance or indemnification rights that we may have may be insufficient or unavailable to protect us against potential loss exposures. In addition, developments in legal proceedings in any given period may require us to record loss contingency estimates in our financial statements, which could adversely affect our results of operations in any period.

We have significant international sales and are subject to risks associated with operating in international markets.

International sales comprise a significant portion of our net revenue and we intend to continue to pursue and expand our international business activities. For the fiscal year 2008, international sales accounted for approximately 25% of

our net revenue, as compared to approximately 38% of our net revenue in fiscal year

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2007 and approximately 37% of our net revenue in fiscal 2006. Political and economic conditions outside the United States could make it difficult for us to increase our international revenue or to operate abroad. International operations, including our operations in Germany, Spain, Australia and New Zealand, are subject to many inherent risks, including among others:

- adverse changes in tariffs and trade restrictions;
- political, social and economic instability and increased security concerns;
- fluctuations in foreign currency exchange rates;
- longer collection periods and difficulties in collecting receivables from foreign entities;
- exposure to different legal standards;
- transportation delays and difficulties of managing international distribution channels;
- reduced protection for our intellectual property in some countries;
- difficulties in obtaining domestic and foreign export, import and other governmental approvals, permits and licenses and compliance with foreign laws;
- the imposition of governmental controls;
- unexpected changes in regulatory or certification requirements;
- difficulties in staffing and managing foreign operations; and
- potentially adverse tax consequences and the complexities of foreign value-added tax systems.

We believe that international sales will continue to represent a significant portion of our net revenue, and we intend to expand our international operations further. Our direct net revenue in Australia, Germany, New Zealand and Spain is denominated principally in local currency, while our net revenue in other international markets is primarily in U.S. dollars. As a result, an increase in the relative value of the dollar against these currencies would lead to less income from those sales, unless we increase prices, which may not be possible due to competitive conditions. We could experience losses from foreign transactions if the relative value of the dollar were to increase in the future. Additionally, in international markets where our sales are denominated in U.S. dollars, an increase in the relative value of the dollar against the currency in such markets could indirectly increase the price of our products in those markets and result in a decrease in sales. Furthermore, increases or decreases in the U.S. dollar or foreign currencies could result in significant period to period fluctuations of our operating results. For example, in 2007, we recognized a gain of $1.4 million on foreign currency transactions due to fluctuations in currency rates. In mid-October 2008, we significantly reduced the inter-company payable due from the foreign subsidiaries to us by making an approximately equal capital contribution which did not result in a significant change in global cash positions. However, subsequent to the contribution date, foreign currency transactions gains and losses recorded on the remaining inter-company balances are expected to be significantly reduced. Additionally, we are in the process of transitioning from direct sales through our foreign subsidiaries to sales through distributors. Therefore, the amount of inter-company transactions and related balances will likely be reduced. We do not currently engage in any transactions as a hedge against risks of loss due to foreign currency fluctuations, although we may consider doing so in the future.

Expenses relating to our foreign operations are paid in local currencies, therefore, an increase in the value of the local currencies relative to the dollar would increase the expenses associated with those operations and reduce our earnings. In addition, we may experience difficulties associated with managing our operations remotely and complying with local regulatory and legal requirements for maintaining our operations in that country. Any of these factors may adversely affect our future international revenue and, consequently, negatively impact our business and operating results.

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Our products are subject to recall even after receiving FDA clearance or approval, which would harm our reputation, business and financial results.

The FDA and similar governmental bodies in other countries have the authority to require the recall of our products in the event of material deficiencies or defects in design or manufacture. A government mandated or voluntary recall by us could occur as a result of component failures, manufacturing errors or design defects, including defects in labeling. Any recall would divert management s attention and financial resources and harm our reputation with customers. Any recall involving our laser systems could harm the reputation of the product and our company and would be particularly harmful to our business and financial results, in part because the laser systems compose such an important part of our portfolio of products.

We may not successfully address problems encountered in connection with any future acquisition.

We expect to continue to consider opportunities to acquire or make investments in other technologies, products and businesses that could enhance our capabilities, complement our current products or expand the breadth of our markets or customer base. We have limited experience in acquiring other businesses and technologies. Potential and completed acquisitions and strategic investments involve numerous risks, including, among others:

- problems assimilating the purchased technologies, products or business operations;
- problems maintaining uniform standards, procedures, controls and policies;
- unanticipated costs associated with the acquisition;
- diversion of management s attention from our core business;
- adverse effects on existing business relationships with suppliers and customers;
- risks associated with entering new markets in which we have no or limited prior experience;
- potential loss of key employees of acquired businesses; and
- increased legal and accounting costs as a result of the rules and regulations related to the Sarbanes-Oxley Act of 2002.

If we fail to properly evaluate and execute acquisitions and strategic investments, our management team may be distracted from our day-to-day operations, our business may be disrupted and our operating results may suffer. In addition, if we finance acquisitions by issuing equity or convertible debt securities, our stockholders would be diluted.

If our customers cannot obtain third party reimbursement for their use of our products, they may be less inclined to purchase our products.

Our products are generally purchased by dental or medical professionals who have various billing practices and patient mixes. Such practices range from primarily private pay to those who rely heavily on third party payors, such as private insurance or government programs. In the United States, third party payors review and frequently challenge the prices charged for medical services. In many foreign countries, the prices for dental services are predetermined through government regulation. Payors may deny coverage and reimbursement if they determine that the procedure was not medically necessary, such as a cosmetic procedure, or that the device used in the procedure was investigational. We believe that most of the procedures being performed with our current products generally are

reimbursable, with the exception of cosmetic applications, such as tooth whitening. For the portion of dentists who rely heavily on third party reimbursement, the inability to obtain reimbursement for services using our products could deter them from purchasing or using our products. We cannot predict the effect of future healthcare reforms or changes in financing for health and dental plans. Any such changes could have an adverse effect on the ability of a dental or medical professional to generate a return on investment using our current or future products. Such changes could act as disincentives for capital investments by dental and medical professionals and could have a negative impact on our business and results of operations.

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The recent financial crisis and general slowdown of the economy may adversely affect the credit availability and liquidity of our dental customers and suppliers.

The credit availability and liquidity of our customers and suppliers may be materially affected by the current financial crisis. If our suppliers experience credit or liquidity problems, important sources of raw materials or manufactured goods may be affected. We currently sell our products primarily to dentists in general practice. These dentists often purchase our products with funds they secure through various financing arrangements with third party financial institutions, including credit facilities and short-term loans. If interest rates increase or the availability of credit is otherwise negatively impacted by market conditions, these financing arrangements will be more expensive to our dental customers, which would effectively increase the overall cost of owning our products for our customers and, thereby, may decrease demand for our products. Any reduction in the sales of our products would cause our business to suffer.

Product liability claims against us could be costly and could harm our reputation.

The sale of dental and medical devices involves the inherent risk of product liability claims against us. We currently maintain product liability insurance on a per occurrence basis with a limit of $11.0 million per occurrence and $12.0 million in the aggregate for all occurrences. The insurance is subject to various standard coverage exclusions, including damage to the product itself, losses from recall of our product and losses covered by other forms of insurance such as workers compensation. We cannot be certain that we will be able to successfully defend any claims against us, nor can we be certain that our insurance will cover all liabilities resulting from such claims. In addition, there is no assurance that we will be able to obtain such insurance in the future on terms acceptable to us, or at all. Regardless of merit or eventual outcome, any product liability claim brought against us could result in harm to our reputation, decreased demand for our products, costs related to litigation, product recalls, loss of revenue, an increase in our product liability insurance rates or the inability to secure coverage in the future, and may cause our business to suffer.

Our operations are consolidated primarily in one facility. A disaster at this facility is possible and could result in a prolonged interruption of our business.

Substantially all of our administrative operations and our manufacturing operations are located at our facility in Irvine, California, which is near known earthquake fault zones. We have taken precautions to safeguard our facilities including disaster recovery planning and off-site backup of computer data; however, a natural disaster such as an earthquake, fire or flood, could seriously harm our business, adversely affect our operations and damage our reputation with customers. We maintain commercial insurance that includes business interruption coverage; however it may not be adequate to cover our losses and may provide only limited coverage for a natural disaster.

Our ability to use net operating loss carryforwards may be limited.

Section 382 of the Internal Revenue Code of 1986 generally imposes an annual limitation on the amount of net operating loss carryforwards that may be used to offset taxable income when a corporation has undergone significant changes in its stock ownership. In 2006, we completed an analysis to determine the applicability of the annual limitations imposed by Section 382 caused by previous changes in our stock ownership and determined that such limitations should not be significant. Based on our analysis, we believe that, as of December 31, 2008, approximately $59.5 million of net operating loss carryforwards were available to us for federal income tax purposes. A detailed analysis will be required at the time we begin utilization of any net operating losses to determine if there is a Section 382 limitation. In addition, any ownership changes qualifying under Section 382 including changes resulting from or affected by our public offering or our stock repurchase plan may adversely affect our ability to use our remaining net operating loss carryforwards. If we lose our ability to use net operating loss carryforwards, any income

we generate will be subject to tax earlier than it would be if we were able to use net operating loss carryforwards, resulting in lower profits.

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Our business is capital intensive and the failure to obtain capital could require that we curtail capital expenditures.

To remain competitive, we must continue to make significant investments in the development of our products, the expansion of our sales and marketing activities and the expansion of our operating and management infrastructure as we increase sales domestically and internationally. We expect that substantial capital will be required to expand our operations and fund working capital for anticipated growth. We may need to raise additional funds through further debt or equity financings, which may affect the percentage ownership of existing holders of common stock and which may have rights, preferences or privileges senior to those of the holders of our common stock or may be issued at a discount to the market price of our common stock thereby resulting in dilution to our existing stockholders. If we raise additional funds by raising debt, we may be subject to debt covenants which could place limitations on our operations. We may not be able to raise additional capital on reasonable terms, or at all, or we may use capital more rapidly than anticipated. If we cannot raise the required capital when needed, we may not be able to satisfy the demands of existing and prospective customers and may lose revenue and market share.

The following factors among others could affect our ability to obtain additional financing on favorable terms, or at all:

- our results of operations;
- general economic conditions and conditions in the electronics industry;
- the perception of our business in the capital markets;
- our ratio of debt to equity;
- our financial condition;
- our business prospects; and
- interest rates.

If we are unable to obtain sufficient capital in the future, we may have to curtail our capital expenditures. Any curtailment of our capital expenditures could result in a reduction in net revenue, reduced quality of our products, increased manufacturing costs for our products, harm to our reputation, reduced manufacturing efficiencies or other harm to our business.

Our charter documents and Delaware law may inhibit a takeover that our stockholders consider favorable and could also limit the price of our stock.

We have adopted anti-takeover defenses that could delay or prevent an acquisition of our company and may affect the price of our common stock. Certain provisions of our certificate of incorporation, and the existence of our stockholder rights plan, could make it difficult for any party to acquire us, even though an acquisition might be beneficial to our stockholders, and could limit the price that investors might be willing to pay in the future for shares of our common stock.

In December 1998, we adopted a stockholder rights plan, which was extended in December 2008, pursuant to which one preferred stock purchase right was distributed to our stockholders for each share of our common stock held. In connection with the stockholder rights plan, the Board of Directors has designated 500,000 shares of Series B Junior Participating Cumulative Preferred Stock. If any party acquires 15% or more of our outstanding common stock while the stockholder rights plan remains in place (i.e., if such party does not negotiate with the Board of Directors, which

has the power to redeem the rights and terminate the plan), the holders of these rights (other than the party acquiring the 15% position) will be able to purchase shares of our common stock (or other securities or assets) at a discounted price, causing substantial dilution to the party acquiring the 15% position. Following the acquisition of 15% or more of our stock by any person (without a redemption of the rights or a termination of the stockholder rights plan by the Board of Directors), if we are acquired by or merged with any other entity, holders of these rights (other than the party acquiring the 15%

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position) will also be able to purchase shares of common stock of the acquiring or surviving entity if the stockholder rights plan continues to remain in place.

In addition, under our certificate of incorporation, the Board of Directors has the power to authorize the issuance of up to 500,000 shares of preferred stock that is currently undesignated, and to designate the price, rights, preferences, privileges and restrictions, including voting rights, of those shares without further vote or action by the stockholders. Accordingly, our Board of Directors may issue preferred stock with terms that could have preference over and adversely affect the rights of holders of our common stock. The issuance of any such preferred stock may:

delay, defer or prevent a change in control of our company;

adversely affect the voting and other rights of the holders of our common stock; or

discourage acquisition proposals or tender offers for our shares without the advance approval of the Board of Directors, including bids at a premium over the market price for our common stock

We are also subject to the provisions of Section 203 of the Delaware General Corporation Law, which may prohibit certain business combinations with stockholders owning 15% or more of our outstanding voting stock or any of our associates or affiliates who at any time in the past three years have owned 15% or more of our outstanding voting stock. These provisions and the others discussed above may have the effect of entrenching our management team and deprive stockholders of the opportunity to sell their shares to potential acquirers at a premium over market prices. The potential inability to obtain a control premium could reduce the price of our common stock.

Our common stock could be diluted by the conversion of outstanding convertible securities.

We have issued and will continue to issue convertible securities in the form of options and warrants as incentive compensation for services performed by our employees, directors, consultants and others. As of December 31, 2008, we had options and warrants to purchase 4,581,000 shares of our common stock outstanding, of which options and warrants to purchase 2,786,000 shares of common stock were exercisable. If these options or warrants were exercised, it would dilute the ownership of our stock and could adversely affect our common stock s market price.

We may not be able to maintain effective internal controls.

Management is responsible for establishing and maintaining adequate internal control over financial reporting. Our internal control over financial reporting is a process designed to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements in accordance with generally accepted accounting principles. In making its assessment of internal control over financial reporting as of December 31, 2008, management used the criteria described in *Internal Control Integrated Framework issued by the Committee of Sponsoring Organizations of the Treadway Commission* (COSO). A material weakness is a control deficiency, or combination of control deficiencies, that results in a more than remote likelihood that a material misstatement of the annual or interim financial statements will not be prevented or detected.

Management determined that no material weaknesses in our internal control over financial reporting existed as of December 31, 2008, and concluded that our internal control over financial reporting was effective as of December 31, 2008 based on the criteria of the *Internal Control Integrated Framework* issued by COSO. Management determined that one material weakness in our internal control over financial reporting existed as of December 31, 2007, and therefore concluded that our internal control over financial reporting was not effective as of December 31, 2007. This material weakness was remediated in the first quarter of 2008.

While management will continue to review the effectiveness of our disclosure controls and procedures and internal control over financial reporting and take appropriate remediation efforts to address any identified control weaknesses or deficiencies, we cannot assure you that our disclosure controls and procedures or

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internal control over financial reporting will be effective in accomplishing all control objectives all of the time. Other deficiencies, particularly a material weakness in internal control over financial reporting which may occur in the future could result in misstatements of our results of operations, restatements of our financial statements, a decline in our stock price, or otherwise materially adversely affect our business, reputation, results of operations, financial condition or liquidity.

If future data proves to be inconsistent with our clinical results, our revenues may decline.

If new studies or comparative studies generate results that are not as favorable as our clinical results, our revenues may decline. Furthermore, physicians may choose not to purchase our laser systems until they receive additional published long-term clinical evidence and recommendations from prominent physicians that indicate our laser systems are effective for dental applications.

If we are unable to attract and retain personnel necessary to operate our business, our ability to develop and market our products successfully could be harmed.

Our success is dependent upon our senior management team, as well as our ability to attract and retain qualified personnel. We can provide no assurance that we will be able to retain our existing senior management team or that we will be able to attract qualified replacement personnel. Changes in our senior management and on the Board may be disruptive to our business, and, during this a transition period, there may be uncertainty among investors, vendors, customers, rating agencies, employees and others concerning our future direction and performance. In the first quarter of 2009, we issued a press release announcing that, effective March 5, 2009; Jake P. St. Philip resigned from his position as Chief Executive Officer, and the Board of Directors appointed our Chief Financial Officer, David M. Mulder, to the position of Chief Executive Officer. If we are unable to effectively manage and maintain our business through this transition in management, including the timely hiring of a new Chief Financial Officer, our results of operations and financial condition may be adversely affected.

Our future success also depends on our ability to attract and retain additional qualified management, engineering, sales and marketing and other highly skilled technical personnel.

Any failure in our efforts to train dental practitioners could reduce the market acceptance of Waterlase Dentistry and reduce our revenues.

There is a learning process involved for dental practitioners to become proficient in the use of our laser systems. It is critical to the success of our sales efforts to adequately train a sufficient number of dental practitioners and to provide them with adequate instruction in the use of our laser systems. Following completion of training, we rely on the trained dental practitioners to advocate the benefits of our products in the broader marketplace. Convincing dental practitioners to dedicate the time and energy necessary for adequate training is challenging, and we cannot assure you that we will be successful in these efforts. If dental practitioners are not properly trained, they may misuse or ineffectively use our products, or fail to recognize the benefits provided by our laser systems. This may also result in unsatisfactory patient outcomes, patient injury, negative publicity or lawsuits against us, any of which could negatively affect our reputation and sales of our laser systems.

We spend considerable time and money complying with federal, state and foreign regulations and, if we are unable to fully comply with such regulations, we could face substantial penalties.

We are directly or indirectly, through our customers, subject to extensive regulation by both the federal government and the states and foreign countries in which we conduct our business. The laws that directly or indirectly affect our ability to operate our business include, but are not limited to, the following:

The Federal Food, Drug, and Cosmetic Act, which regulates the design, testing, manufacture, labeling, marketing, distribution and sale of prescription drugs and medical devices;

state food and drug laws;

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the federal Anti-Kickback Law, which prohibits persons from knowingly and willfully soliciting, offering, receiving or providing remuneration, directly or indirectly, in cash or in kind, to induce either;

the referral of an individual, or furnishing or arranging for a good or service, for which payment may be made under federal healthcare programs such as the Medicare and Medicaid Programs;

Medicare laws and regulations that prescribe the requirements for coverage and payment, including the amount of such payment, and laws prohibiting false claims for reimbursement under Medicare and Medicaid;

the federal physician self-referral prohibition, commonly known as the Stark Law, which, in the absence of a statutory or regulatory exception, prohibits the referral of Medicare patients by a physician to an entity for the provision of designated healthcare services, if the physician or a member of the physician s immediate family has a direct or indirect financial relationship, including an ownership interest in, or a compensation arrangement with, the entity and also prohibits that entity from submitting a bill to a federal payor for services rendered pursuant to a prohibited referral;

state laws that prohibit the practice of medicine by non-physicians and fee-splitting arrangements between physicians and non-physicians, as well as state law equivalents to the Anti-Kickback Law and the Stark Law, which may not be limited to government reimbursed items; and

the Federal Trade Commission Act and similar laws regulating advertising and consumer protection.

If our past or present operations are found to be in violation of any of the laws described above or the other governmental regulations to which we or our customers are subject, we may be subject to the applicable penalty associated with the violation, including civil and criminal penalties, damages, fines, exclusion from the Medicare and Medicaid programs and the curtailment or restructuring of our operations. If we are required to obtain permits or licensure under these laws that we do not already possess, we may become subject to substantial additional regulation or incur significant expense. Any penalties, damages, fines, curtailment or restructuring of our operations would adversely affect our ability to operate our business and our financial results. The risk of our being found in violation of these laws is increased by the fact that many of them have not been fully interpreted by applicable regulatory authorities or the courts, and their provisions are open to a variety of interpretations and additional legal or regulatory change. Any action against us for violation of these laws, even if we successfully defend against it, could cause us to incur significant legal expenses, divert our management s attention from the operation of our business and damage our reputation.

Product sales or introductions may be delayed or canceled as a result of the FDA regulatory process, which could cause our sales or profitability to decline.

The process of obtaining and maintaining regulatory approvals and clearances to market a medical device from the FDA and similar regulatory authorities abroad can be costly and time consuming, and we cannot assure you that such approvals and clearances will be granted. Pursuant to FDA regulations, unless exempt, the FDA permits commercial distribution of a new medical device only after the device has received 510(k) clearance or is the subject of an approved pre-market approval application. The FDA will clear marketing of a medical device through the 510(k) process if it is demonstrated that the new product is substantially equivalent to other 510(k)-cleared products. The pre-market approval application process is more costly, lengthy and uncertain than the 510(k) process, and must be supported by extensive data, including data from preclinical studies and human clinical trials. Because we cannot assure you that any new products, or any product enhancements, that we develop will be subject to the shorter 510(k) clearance process, significant delays in the introduction of any new products or product enhancement may occur. We

cannot assure you that the FDA will not require a new product or product enhancement to go through the lengthy and expensive pre-market approval application process. Delays in obtaining regulatory clearances and approvals may:

delay or eliminate commercialization of products we develop;

require us to perform costly procedures;

diminish any competitive advantages that we may attain; and

reduce our ability to collect revenues or royalties.

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Although we have obtained 510(k) clearance from the FDA to market our dental laser systems, we cannot assure you that the clearance of these systems will not be withdrawn or that we will not be required to obtain new clearances or approvals for modifications or improvements to our products.

Item 1B. ***Unresolved Staff Comments***

None.

Item 2. ***Properties***

In January 2006, we entered into a five-year lease for our 57,000 square foot corporate headquarters and manufacturing facility located at 4 Cromwell, Irvine, California. We believe that our current facility will be sufficient for our current needs and that suitable additional or substitute space will be available as needed to accommodate foreseeable expansion of our operations.

Our wholly-owned subsidiary, BIOLASE Europe, owns a facility totaling approximately 20,000 square feet of space in Floss, Germany. In addition, we lease facilities in Australia and New Zealand. During the first quarter of 2009, we began the process of transitioning our international direct sales operations to a distributor model. As part of this transition, we expect to sell the Floss land and building and exit the facility leases in Australia and New Zealand. Other than the land and building in Germany, with a recorded net book amount of approximately $679,000, the majority of our long-lived assets are located in the United States.

Item 3. ***Legal Proceedings***

In January 2005, we acquired the intellectual property portfolio of Diodem, LLC, or Diodem, consisting of certain U.S. and international patents of which four were asserted against us, and settled the existing litigation between us and Diodem, for consideration of $3.0 million in cash, 361,664 shares of common stock (valued at the common stock fair market value on the closing date of the transaction for a total of approximately $3.5 million) and a five-year warrant exercisable into 81,037 shares of common stock at an exercise price of $11.06 per share. In addition, 45,208 additional shares of common stock were placed in escrow, to be released to Diodem, if certain criteria specified in the purchase agreement were satisfied in or before July 2006. As of March 31, 2006, we determined that it was probable that these shares of common stock would be released from escrow in or before July 2006. Accordingly, we recorded a patent infringement legal settlement charge of approximately $348,000 in 2006. In July 2006, we released these shares from escrow. The common stock issued, the escrow shares of common stock and the warrant shares had certain registration rights, and a Registration Statement on Form S-3 was filed with the Securities and Exchange Commission, or SEC, to register for sale any of these shares which remained unsold. This Registration Statement became effective on April 17, 2007. The total consideration had an estimated value of approximately $7.4 million including the value of the patents acquired in January 2005. As of December 31, 2004, we accrued approximately $6.4 million for the settlement of the existing litigation with $3.0 million included in current liabilities and $3.4 million recorded as a long-term liability. In January 2005, we recorded an intangible asset of $0.5 million representing the estimated fair value of the intellectual property acquired. The estimated fair value of the patents was determined with the assistance of an independent valuation expert using a relief from royalty and a discounted cash flow methodology. As a result of the acquisition, Diodem immediately withdrew its patent infringement claims against us and the case was formally dismissed on May 31, 2005. We did not pay, and have no obligation to pay, any royalties to Diodem on past or future sales of our products, but we agreed to pay additional consideration if any of the acquired patents held by us are licensed to a third party by a certain date. In order to secure performance by us of these financial obligations, the parties entered into an intellectual property security agreement, pursuant to which, subject to the rights of existing creditors and the rights of any future creditors to the extent provided in the agreement, we granted Diodem a security interest in all of their

rights, title and interest in the royalty patents. In September 2007, Diodem filed a motion with the U.S.District Court in the Central District of California requesting that the original case be reopened for limited discovery concerning Diodem s claims that we breached various of our obligations and representations in the settlement agreement and seeking damages in the range of $3.85 million to $5.2 million plus costs and attorneys fees incurred in recovering said alleged damages. The District Court

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denied Diodem s motion finding, in part, that if Diodem wishes to pursue claims for breach of the settlement agreement, it must file a new lawsuit for breach of contract. On February 20, 2008, Diodem filed a lawsuit for breach of the settlement agreement in Los Angeles Superior Court, naming us and a wholly-owned subsidiary, BL Acquisition II, Inc. as defendants. The complaint asserts two claims, both alleging breaches of the Agreement. Diodem seeks damages of not less than $4.0 million. On April 28, 2008, together with BL Acquisition II, Inc., we filed demurrers and a motion to strike that, in essence, requests the court to dismiss Diodem s complaint. On June 20, 2008 the Court denied the demurrers and the motion and on July 21, 2008 we filed an answer to the complaint denying the allegations. On October 15, 2008 the lawsuit was dismissed with prejudice by Diodem pursuant to a settlement agreement among the parties which resolves all claims in the litigation and provides that we will make four payments to Diodem totaling approximately $950,000 through 2010, of which $85,000 will be paid by our liability insurance carriers. In the settlement agreement, we denied any wrongdoing. The settlement agreement contains confidentiality provisions that limit disclosure of the terms of the settlement except as required by SEC rule or regulation, under GAAP or pursuant to court order or law. Related to this matter, we incurred approximately $1.2 million in charges for the settlement and associated legal fees in the third quarter ended September 30, 2008, which reflects all the settlement payments to be made over the next two years.

National Laser Technology, Inc, or NLT, buys used dental lasers, predominately those originally sold by Biolase, and resells them to other dentists. On August 19, 2008, NLT brought an action against us in federal court in the Southern District of Indiana. NLT alleged that we violated Sections 1 and 2 of the Sherman Act, Section 43(a) of the Lanham Act, Section 17200 et seq. of the California Unfair Competition Act and tortiously interfered with NLT s business relationships and prospective business advantage. NLT seeks a monetary award of three times the unquantified damages that NLT has allegedly sustained because of our alleged Sherman Act violations, unquantified damages for the rest of the claims, punitive damages and preliminary and permanent injunctive relief. On October 6, 2008, we answered the complaint, asserted several affirmative defenses and filed a counterclaim. We alleged that NLT violated Sections 1114 and 1125(a) of the Lanham Act and Section 17200 et seq. of the California Unfair Competition Act. We seek unquantified damages and a permanent injunction. NLT amended its Complaint on December 23, 2008, to add a claim for conspiracy to monopolize in violation of Section 2 of the Sherman Act; we answered the Amended Complaint on January 15, 2009. We amended our counterclaims on February 19, 2009 to add a claim for federal copyright infringement and to seek associated damages. On October 21, 2008, NLT filed a motion for a preliminary injunction seeking to enjoin us from certain actions that NLT alleged violated section 1 and 2 of the Sherman Act. On November 24, 2008, we filed a motion for preliminary injunction seeking to enjoin NLT from selling modified Biolase lasers or using Biolase s trademarks. Both motions are currently pending, and oral argument is scheduled for March 23, 2009. On March 10, 2009, we filed a motion to strike one of NLT s witnesses from testifying at the preliminary injunction hearing or, in the alternative, continuing the hearing. That motion has not been ruled on.

On December 19, 2005, we entered into a Vendor Agreement with National Technology Leasing Corporation, or NTLC, in which NTLC was designated as our Preferred Leasing/Financing Provider. In September 2006, we gave notice to NTLC of the termination of the Vendor Agreement, and subsequently entered into a financing and distribution agreement with Henry Schein, Inc. On August 26, 2008, NTLC filed a lawsuit against us, Henry Schein, Inc. and a former employee of NTLC in California Superior Court in Placer County. NTLC alleges that we breached the Vendor Agreement by failing to provide the required notice of termination and asserts a claim for damages without specifying an amount. On October 10, 2008, we answered the complaint and asserted several affirmative defenses. On March 2, 2009, the lawsuit was dismissed with prejudice by NTLC pursuant to a settlement agreement among the parties which resolves all claims in the litigation and provides that we will make two payments to NTLC totaling approximately $20,000 during the first and second quarters of 2009. In the settlement agreement, we denied any wrongdoing. The settlement agreement contains confidentiality provisions that limit disclosure of the terms of the settlement except as required by SEC rule or regulation, under GAAP or pursuant to court order or law.

From time to time, we are involved in other legal proceedings incidental to our business, but at this time we are not party to any other litigation that management believes is material to our business.

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Item 4. ***Submission of Matters to a Vote of Security Holders***

None.

PART II

Item 5. ***Market for the Registrant s Common Equity, Related Stockholder Matters and Issuer Purchases of Equity Securities***

Market Information

Our common stock is listed on the NASDAQ Stock Market LLC under the symbol BLTI. During the period in 2006 in which we have not been in compliance with NASDAQ rules, our stock has traded under the symbol BLTIE. The following table sets forth, for the periods indicated, the high and low sale prices of our common stock as reported by the NASDAQ Stock Market LLC and the dividends per share paid by us for each quarter of 2008 and 2007:

	High	Low
Fiscal Year Ended December 31, 2008		
First Quarter	$ 4.64	$ 2.22
Second Quarter	4.05	2.38
Third Quarter	3.47	1.69
Fourth Quarter	2.16	0.55
Fiscal Year Ended December 31, 2007		
First Quarter	$ 10.09	$ 7.89
Second Quarter	10.50	5.70
Third Quarter	8.10	5.51
Fourth Quarter	7.00	2.20

No dividends were paid by us during 2008 or 2007.

As of March 11, 2009, the total number of record holders of our common stock was approximately 197. Based on information provided by our transfer agent and registrar, we believe that there are approximately 5,837 beneficial owners of our common stock.

Dividend Policy

In July 2004, the Board of Directors approved a dividend policy to pay a cash dividend of $0.01 per share every other month to the stockholders of record at the time when declared by the Board of Directors. In August 2005, our Board of Directors authorized to discontinue payment of our dividend indefinitely. We anticipate that we will retain any earnings to support our operations and finance any growth and development of our business. Therefore we do not expect to pay cash dividends in the future.

Securities Authorized for Issuance under Equity Compensation Plans

See the information incorporated by reference to Part III, Item 12 of this report for information regarding securities authorized for issuance under our equity compensation plans.

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Stock Performance Graph (1)

The graph below compares the cumulative total stockholder return on $100 invested, assuming the reinvestment of all dividends, on December 31, 2003, the last trading day before our 2004 fiscal year, through the end of fiscal 2008 with the cumulative total return on $100 invested for the same period in the NASDAQ Composite Index and the NASDAQ Medical Equipment Index.

COMPARISON OF 5 YEAR CUMULATIVE TOTAL RETURN*
Among Biolase Technology, Inc., The NASDAQ Composite Index
And The NASDAQ Medical Equipment Index

ASSUMES $100 INVESTED ON DECEMBER 31, 2003
ASSUMES DIVIDENDS REINVESTED
FISCAL YEAR ENDED DECEMBER 31, 2008

	Years Ended December 31,					
	2003	**2004**	**2005**	**2006**	**2007**	**2008**
Biolase Technology, Inc.	$ 100.00	$ 65.72	$ 48.50	$ 53.11	$ 14.32	$ 9.04
NASDAQ Composite Index	100.00	110.06	112.92	126.61	138.33	80.65
NASDAQ Medical Equipment	100.00	117.61	133.99	139.10	177.55	98.76

(1) This section is not soliciting material, is not deemed filed with the Securities and Exchange Commission and is not to be incorporated by reference into any filing of BIOLASE Technology, Inc. under the Securities Act of 1933, as amended, or the Securities Exchange Act of 1934, as amended, whether made before or after the date hereof and irrespective of any general incorporation language in any such filing.

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Item 6. ***Selected Financial Data***

The following selected consolidated financial data should be read in conjunction with our consolidated financial statements and related notes contained elsewhere in this report and in our subsequent reports filed with the SEC, as well as Item 7 titled Management s Discussion and Analysis of Financial Condition and Results of Operations.

	Years Ended December 31,				
	2008	2007	2006	2005	2004
	(In thousands, except per share data)				
Consolidated Statements of Operations Data:					
Net revenue	$ 64,625	$ 66,889	$ 69,700	$ 61,980	$ 60,651
Cost of revenue(1)	31,963	32,364	33,211	31,051	24,642
Gross profit	32,662	34,525	36,489	30,929	36,009
Other income, net			6	80	32
Operating expenses:					
Sales and marketing(1)	22,040	26,648	24,400	24,730	23,126
General and administrative(1)	12,006	10,941	11,709	16,869	11,506
Engineering and development(1)	5,580	5,104	4,876	6,390	3,576
Patent infringement legal settlement(3)	1,232		348		6,446
Impairment of intangible asset(4)	232				747
Impairment of property, plant and equipment(5)	355				
Restructuring charge(2)		802			
Total operating expenses	41,445	43,495	41,333	47,989	45,401
(Loss) income from operations	(8,783)	(8,970)	(4,838)	(16,980)	(9,360)
Non-operating (loss) income	(225)	1,853	311	(261)	559
(Loss) income before income taxes	(9,008)	(7,117)	(4,527)	(17,241)	(8,801)
Income tax provision	121	163	162	269	14,413
Net (loss) income as reported	$ (9,129)	$ (7,280)	$ (4,689)	$ (17,510)	$ (23,214)
Net (loss) income per share:					
Basic	$ (0.38)	$ (0.31)	$ (0.20)	$ (0.76)	$ (1.00)
Diluted	(0.38)	(0.31)	(0.20)	(0.76)	(1.00)
Dividends declared and paid, per share	$ 0.00	$ 0.00	$ 0.00	$ 0.03	$ 0.03
Shares used in computing net (loss) income per share:					
Basic	24,178	23,853	23,472	23,051	23,181
Diluted	24,178	23,853	23,472	23,051	23,181

Consolidated Balance Sheet Data*:					
Working capital	$ 5,023	$ 10,993	$ 17,299	$ 12,822	$ 29,950
Total assets	35,708	44,308	48,578	45,129	58,746
Long-term liabilities	2,547	3,034	4,922	202	3,623
Stockholders equity	9,390	16,491	21,966	21,294	33,978

(1) 2008, 2007 and 2006 includes $1.7 million, $1.3 million and $1.5 million, respectively, in total compensation cost related to stock options classified in cost of revenue, sales and marketing, general and administrative and engineering and development expenses.

(2) Refer to Note 11 in the notes to the Consolidated Financial Statements.

(3) Refer to Note 7 in the notes to the Consolidated Financial Statements.

(4) Refer to Note 4 in the notes to the Consolidated Financial Statements.

(5) Refer to Note 1 in the notes to the Consolidated Financial Statements.

* Certain amounts have been reclassified to conform to current year presentation.

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Item 7. *Management s Discussion and Analysis of Financial Condition and Results of Operations*

The following discussion of our results of operations and financial condition should be read together with the consolidated financial statements and the notes to those statements included elsewhere in this report and other information incorporated by reference in this report, if any. This discussion may contain forward-looking statements that involve risks and uncertainties. Our actual results could differ materially from the results anticipated in any forward-looking statements as a result of a variety of factors, including those discussed in Risk Factors and elsewhere in this report.

Overview

We are a medical technology company that develops, manufactures and markets lasers and related products focused on technologies for improved applications and procedures in dentistry and medicine. In particular, our principal products provide dental laser systems that allow dentists, periodontists, endodontists, oral surgeons and other specialists to perform a broad range of dental procedures, including cosmetic and complex surgical applications. Our systems are designed to provide clinically superior performance for many types of dental procedures, with less pain and faster recovery times than are generally achieved with drills, scalpels and other dental instruments. We have clearance from the U.S. Food and Drug Administration, or FDA, to market our laser systems in the United States and also have the necessary approvals to sell our laser systems in Canada, the European Union and certain other international markets. Since 1998, we have sold approximately 7,200 Waterlase systems including over 3,300 Waterlase MD systems and more than 12,000 laser systems in total in over 50 countries.

We offer two categories of laser system products: (i) Waterlase systems and (ii) Diode systems. Our flagship product category, the Waterlase system, uses a patented combination of water and laser to perform most procedures currently performed using dental drills, scalpels and other traditional dental instruments for cutting soft and hard tissue. We also offer our diode laser systems to perform soft tissue and cosmetic procedures, including tooth whitening.

On August 8, 2006, we entered into a License and Distribution Agreement with Henry Schein, Inc., or HSIC, a large distributor of healthcare products to office-based practitioners, pursuant to which we granted HSIC the exclusive right to distribute our complete line of dental laser systems, accessories and services in the United States and Canada. The agreement has an initial term of three years, following which it will automatically renew for an additional period of three years, provided that HSIC has achieved its minimum purchase requirements. Under the agreement, HSIC is obligated to meet certain minimum purchase requirements and is entitled to receive incentive payments if certain purchase targets are achieved. If HSIC has not met the minimum purchase requirements at the midpoint of each of the first two three-year periods, we will have the option, upon repayment of a portion of the license fee, to (i) shorten the remaining term of the agreement to one year, (ii) grant distribution rights held by HSIC to other persons (or distribute products ourselves), (iii) reduce certain discounts on products given to HSIC under the agreement and (iv) cease paying future incentive payments. We maintain the right to grant certain intellectual property rights to third parties, but by doing so may incur the obligation to refund a portion of the upfront license fee to HSIC.

On May 9, 2007, we entered into *Addendum 1 to License and Distribution Agreement* with HSIC, which addendum was effective as of April 1, 2007 and modified the License and Distribution Agreement entered into with HSIC on August 8, 2006, to add the terms and conditions under which HSIC has the exclusive right to distribute our new *ezlase* diode dental laser system in the United States and Canada. In the Addendum, separate minimum purchase requirements are established for the *ezlase* system. If HSIC has not met the minimum purchase requirement for any 12-month period ending on March 31, we will have the option, upon 30 days written notice, to (i) convert *ezlase* distribution rights to a non-exclusive basis for a minimum period of one year, after which period we would have the option to withdraw *ezlase* distribution rights, and (ii) reduce the distributor discount on *ezlase* products.

On March 3, 2008, we entered into a second addendum to the HSIC agreement that modifies certain terms of the initial agreement as amended. Pursuant to amendment 2 to the agreement, HSIC is obligated to meet certain minimum purchase requirements and is entitled to receive incentive payments if certain purchase

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targets are achieved. If HSIC has not met the minimum purchase requirements, we will have the option to (i) shorten the remaining term of the Agreement to one year, (ii) grant distribution rights held by HSIC to other persons (or distribute products ourselves), (iii) reduce certain discounts on products given to HSIC under the Agreement and (iv) cease paying future incentive payments. Additionally, under certain circumstances, if HSIC has not met the minimum purchase requirements, we have the right to purchase back the exclusive distributor rights granted to HSIC under the agreement. We also agreed to actively promote Henry Schein Financial Services as our exclusive leasing and financing partner.

On December 23, 2008, we entered into a letter agreement with HSIC to extend the term of the agreement through December 31, 2010.

On February 27, 2009, we entered into a letter agreement with HSIC amending the term of the License and Distribution Agreement through March 31, 2010.(See Liquidity and Capital Resources) This amendment includes certain minimum purchase requirements through the term of the agreement. HSIC also has the option to extend the term of the Agreement for two additional one-year terms based on certain minimum purchase requirements. In addition, HSIC will become our distributor in certain international countries including Germany, Spain, Australia and New Zealand and will be permitted to distribute our products in those additional markets where we do not have current distribution agreements in place.

We intend to augment the activities of HSIC in the United States and Canada with the efforts of our direct sales force; however, our future revenue will be largely dependent upon the efforts and success of HSIC in selling our products. Since September 1, 2006, nearly all of our domestic sales were made through HSIC and we expect this to continue for the foreseeable future. We cannot assure you that HSIC will devote sufficient resources to selling our products or, even if sufficient resources are directed to our products, that such efforts will be sufficient to increase net revenue.

Critical Accounting Policies

The preparation of consolidated financial statements and related disclosures in conformity with accounting principles generally accepted in the United States requires us to make judgments, assumptions and estimates that affect the amounts reported. The following is a summary of those accounting policies that we believe are necessary to understand and evaluate our reported financial results.

Revenue Recognition. Effective September 1, 2006, nearly all of our domestic sales are to HSIC; prior to this date, we sold our products directly to customers through our direct sales force. Internationally, we sell products through direct sales representatives and through distributors. We recognize revenue in accordance with SEC Staff Accounting Bulletin No. 104, *Revenue Recognition*, which requires that four basic criteria must be met before revenue can be recognized: (i) persuasive evidence of an arrangement exists; (ii) delivery has occurred and title and the risks and rewards of ownership have been transferred to our customer, or services have been rendered; (iii) the price is fixed or determinable; and (iv) collectibility is reasonably assured.

We apply Emerging Issues Task Force (EITF) 00-21, *Accounting for Revenue Arrangements with Multiple Deliverables*, which requires us to evaluate whether the separate deliverables in our arrangements can be unbundled in our revenue recognition. Sales of our Waterlase systems include separate deliverables consisting of the product, disposables used with the Waterlase system, installation and training. For these sales, we apply the residual value method, which requires us to allocate to the delivered elements the total arrangement consideration less the fair value of the undelivered elements. Sales of our Diode systems include separate deliverables consisting of the product, disposables and training. For these sales, we apply the relative fair value method, which requires us to allocate the total arrangement consideration to the relative fair value of each element. Revenue attributable to the undelivered elements, primarily training and installation, are included in deferred revenue when the product is shipped and are

recognized when the related service is performed or upon expiration of time offered under the agreement.

The key judgment related to our revenue recognition relates to the collectibility of payment from the customer. We evaluate the customer s credit worthiness prior to the shipment of the product. Based on our

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assessment of the credit information available to us, we may determine the credit risk is higher than normally acceptable, and we will either decline the purchase or defer the revenue until payment is reasonably assured.

Although all sales are final, we accept returns of products in certain, limited circumstances and record a provision for sales returns based on historical experience concurrent with the recognition of revenue. The sales returns allowance is recorded as a reduction of accounts receivable and revenue.

We recognize revenue for royalties under licensing agreements for our patented technology when the product using our technology is sold. We estimate and recognize the amount earned based on historical performance and current knowledge about the business operations of our licensees. Our estimates have been consistent with amounts historically reported by the licensees.

We may offer sales incentives and promotions on our products. We apply EITF 01-09*, Accounting for Consideration Given by a Vendor to a Customer (Including a Reseller of the Vendor s Products)*, in determining the appropriate treatment of the related costs of these programs.

Accounting for Stock-Based Payments. Effective January 1, 2006, we adopted the provisions of Financial Accounting Standard 123 (revised), *Share-Based Payment*, or FAS 123R, using the modified prospective transition method. Prior to the adoption of FAS 123R, we accounted for share-based payments to employees using the intrinsic value method under Accounting Principles Board Opinion No. 25, or APB 25, *Accounting for Stock Issued to Employees*, and the related interpretations. Under the provisions of APB 25, stock option awards were accounted for using fixed plan accounting whereby we recognized no compensation expense for stock option awards because the exercise price of options granted was equal to the fair value of the common stock at the date of grant. In March 2005, the SEC issued Staff Accounting Bulletin 107, or SAB 107, regarding the SEC Staff s interpretation of FAS 123R, which provides the Staff s views regarding interactions between FAS 123R and certain SEC rules and regulations and provides interpretations of the valuation of share-based payments for public companies. We have incorporated the provisions of SAB 107 in our adoption of FAS 123R.

Under the modified prospective transition method, the provisions of FAS 123R apply to new awards and to awards outstanding on January 1, 2006 and subsequently modified, repurchased or cancelled. Under the modified prospective transition method, compensation expense recognized in 2006 includes compensation costs for all share-based payments granted prior to, but not yet vested as of January 1, 2006, based on the grant-date fair value estimated in accordance with the original provisions of FAS 123, and compensation cost for all share-based payments granted subsequent to January 1, 2006, based on the grant-date fair value estimated in accordance with the provisions of FAS 123R.

Valuation of Accounts Receivable. We maintain an allowance for uncollectible accounts receivable to estimate the risk of extending credit to customers. We evaluate our allowance for doubtful accounts based upon our knowledge of customers and their compliance with credit terms. The evaluation process includes a review of customers accounts on a regular basis which incorporates input from sales, service and finance personnel. The review process evaluates all account balances with amounts outstanding 60 days and other specific amounts for which information obtained indicates that the balance may be uncollectible. The allowance for doubtful accounts is adjusted based on such evaluation, with a corresponding provision included in general and administrative expenses. Account balances are charged off against the allowance when we feel it is probable the receivable will not be recovered. We do not have any off-balance-sheet credit exposure related to our customers.

Valuation of Inventory. Inventory is valued at the lower of cost, determined using the first-in, first-out method, or market. We periodically evaluate the carrying value of inventory and maintain an allowance for excess and obsolete inventory to adjust the carrying value as necessary to the lower of cost or market. We evaluate quantities on hand,

physical condition and technical functionality, as these characteristics may be impacted by anticipated customer demand for current products and new product introductions. Unfavorable changes in estimates of excess and obsolete inventory would result in an increase in cost of revenue and a decrease in gross profit.

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Valuation of Long-Lived Assets. Property, plant and equipment, and certain intangibles with finite lives are amortized over their useful lives. Useful lives are based on our estimate of the period that the assets will generate revenue or otherwise productively support our business goals. We monitor events and changes in circumstances which could indicate that the carrying balances of long-lived assets may exceed the undiscounted expected future cash flows from those assets. If such a condition were to exist, we would recognize an impairment loss based on the excess of the carrying amount over the fair value of the assets.

Valuation of Goodwill and Other Intangible Assets. Goodwill and other intangible assets with indefinite lives are not amortized but are tested for impairment annually or whenever events or changes in circumstances indicate that the asset might be impaired. We conducted our annual impairment analysis of our goodwill and trade names as of June 30, 2008, 2007 and 2006, and concluded there had been no impairment in trade names and no impairment in goodwill. Due to the decline in our stock price and market capitalization during the fourth quarter of 2008 caused by adverse equity market conditions and the general economic environment, we updated our impairment analysis. We concluded that there had not been any impairment. However, we will closely monitor our stock price and market capitalization and will perform such analysis on a quarterly basis, if needed. If our stock price and market capitalization continue to decline, we may need to impair our goodwill and other intangible assets. At December 31, 2008, as a result of our new Waterlase Dentistry branding strategy, we recorded an impairment of trade names in the amount of $232,000. During the period June 30, 2008 through December 31, 2008, we reviewed critical indicators and determined that no other triggering events occurred that would have a material effect on the value of the remaining assets.

Warranty Cost. Waterlase systems sold are covered by a warranty against defects in material and workmanship for a period of one year while our *ezlase* system warranty period is up to two years. Estimated warranty expenses are recorded as an accrued liability, with a corresponding provision to cost of revenue. This estimate is recognized concurrent with the recognition of revenue. The accrual is based on our historical experience and our expectation of future conditions. An increase in warranty claims or in the costs associated with servicing those claims would result in an increase in the accrual and a decrease in gross profit.

Litigation and Other Contingencies. We regularly evaluate our exposure to threatened or pending litigation and other business contingencies. Because of the uncertainties related to the amount of loss from litigation and other business contingencies, the recording of losses relating to such exposures requires significant judgment about the potential range of outcomes. As additional information about current or future litigation or other contingencies becomes available, we will assess whether such information warrants the recording of expense relating to contingencies. To be recorded as expense, a loss contingency must be both probable and reasonably estimable. If a loss contingency is material but is not both probable and estimable, we will disclose the matter in the notes to the consolidated financial statements.

Income Taxes. Based upon our operating losses during 2008 and 2007 and the available evidence, management determined that it is more likely than not that the deferred tax assets as of December 31, 2008 will not be realized, excluding a portion of the foreign deferred assets in the amount of $29,000. Consequently, we established a valuation allowance against our net deferred tax asset, excluding the foreign operations, in the amount of $27.4 and $25.8 million as of December 31, 2008 and December 31, 2007, respectively. In this determination, we considered factors such as our earnings history, future projected earnings and tax planning strategies. If sufficient evidence of our ability to generate sufficient future taxable income tax benefits becomes apparent, we may reduce our valuation allowance, resulting in tax benefits in our statement of operations and in additional paid-in-capital. Management evaluates the potential realization of our deferred tax assets and assesses the need for reducing the valuation allowance periodically.

Off-Balance Sheet Arrangements.

We have no off-balance sheet financing or contractual arrangements.

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Results of Operations

The following table sets forth certain data from our consolidated statements of operations for the years ended December 31, 2008, 2007 and 2006, expressed as percentages of revenue:

	Years Ended December 31,		
	2008	2007	2006
Net revenue	100.0%	100.0%	100.0%
Cost of revenue	49.5	48.4	47.6
Gross profit	50.5	51.6	52.4
Operating expenses:			
Sales and marketing	34.1	39.8	35.0
General and administrative	18.5	16.4	16.8
Engineering and development	8.6	7.6	7.0
Patent infringement legal settlement	1.9		0.5
Impairment of intangible asset	0.4		
Impairment of property, plant and equipment	0.6		
Restructuring		1.2	
Total operating expenses	64.1	65.0	59.3
Loss from operations	(13.6)	(13.4)	(6.9)
Non-operating (loss) income, net	(0.3)	2.8	0.4
Loss before income taxes	(13.9)	(10.6)	(6.5)
Income tax provision	0.2	0.3	0.2
Net loss	(14.1)%	(10.9)%	(6.7)%

In the fourth quarter of fiscal 2007, we recorded certain amounts to *gain (loss) on foreign currency transactions* relating to prior 2007 quarters resulting in a reduction of our net loss by $1.0 million (or $0.04 per share) for the quarter and year ended December 31, 2007. The adjustments resulted from the misapplication of Statement of Financial Accounting Standard No. 52, *Foreign Currency Translation*, to certain foreign-currency transactions between BIOLASE Technology, Inc. and certain of our foreign subsidiaries. We concluded that the amounts were not material to previously-reported interim periods.

The following table summarizes our net revenues by category for the years ended December 31, 2008, 2007 and 2006 (dollars in thousands):

	Years Ended December 31,					
	2008		2007		2006	
Waterlase systems	$ 40,328	62%	$ 45,279	68%	$ 55,161	79%

Diode systems	12,040	19%	9,453	14%	3,557	5%
Non-laser systems	8,642	13%	8,353	12%	10,134	15%
Products and services	61,010	94%	63,085	94%	68,852	99%
License fees and royalty	3,615	6%	3,804	6%	848	1%
Net revenue	$ 64,625	100%	$ 66,889	100%	$ 69,700	100%

Year Ended December 31, 2008 Compared With Year Ended December 31, 2007

Net Revenue. Net revenue for the year ended December 31, 2008 was $64.6 million, a decrease of $2.3 million, or 3%, as compared with net revenue of $66.9 million for the year ended December 31, 2007.

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Laser system net revenues decreased by approximately 4% in 2008 compared to 2007. Sales of our Waterlase systems decreased $5.0 million, or 11%, for the year ended December 31, 2008 compared to the prior year. We feel the continued adverse worldwide economic environment has been a significant cause for the decreased sales as dentists may be delaying their decision to purchase higher priced capital equipment. Sales of our Diode systems increased $2.6 million, or 27% in 2008 compared to 2007. Our ezlase diode system, which was released in limited quantities in the first quarter of 2007, accounted for the increase.

Non-laser system net revenue, which includes consumable products, advanced training programs and extended service contracts and shipping revenue, increased by approximately 3% for the year ended December 31, 2008 as compared to the same period of 2007. An increase in training and services revenues was partially offset by a decrease in consumable product sales in 2008 compared to 2007.

Domestic revenues were $48.5 million, or 75% of net revenue, for the year ended December 31, 2008 versus $41.6 million, or 62% of net revenue, for the year ended December 31, 2007. International revenues for 2008 were $16.1 million, or 25% of net revenues compared to $25.3 million, or 38% of net revenue for 2007.

License fees and royalty income decreased to $3.6 million for 2008 from $3.8 million for 2006, as a result of lower amortization of license fees in 2008 and lower royalties received from third parties.

Gross Profit. Gross profit for the year ended December 31, 2008 was $32.7 million, or 51% of net revenue, a decrease of $1.9 million, as compared with gross profit of $34.5 million, or 52% of net revenue for the year ended December 31, 2007. Gross profit excluding license fees and royalty revenue was 48% of products and service revenue for 2008 compared to 49% for 2007. The decrease in gross margin was a result of discounts and promotions.

Operating Expenses. Operating expenses for the year ended December 31, 2008 were $41.4 million, or 64% of net revenue, a $2.1 million decrease as compared with $43.5 million, or 65% of net revenue for the year ended December 31, 2007. The decrease was driven mainly by our corrective actions taken in reducing sales and marketing expenses partially offset by increases in legal and legal settlement expenses.

Sales and Marketing Expense. Sales and marketing expenses for the year ended December 31, 2008 decreased by $4.6 million, or approximately 17%, to $22.0 million, or 34% of net revenue, as compared with $26.6 million, or 40% of net revenue, for the year ended December 31, 2007. Convention and seminar expenses decreased by $2.0 million in 2008 compared to 2007. Also decreasing were commission on lower sales and travel and entertainment expenses compared to 2007. While we expect to continue investing in sales and marketing expenses and programs in order to grow our revenues, we believe it is likely that these expenses, excluding commissions, will decrease in 2009 compared to 2008.

General and Administrative Expense. General and administrative expenses for the year ended December 31, 2008 increased by $1.1 million, or 10%, to $12.0 million, or 19% of net revenue, as compared with $10.9 million, or 16% of net revenue, for the year ended December 31, 2007. The increase in general and administrative expenses resulted primarily from a $665,000 increase in legal fees as well as increased payroll related expense partially offset by reduced audit fees. We believe that our general and administrative expenses are likely to decrease in 2009. However, we are currently involved in certain litigation matters that may result in larger than expected fees.

Engineering and Development Expense. Engineering and development expenses for the year ended December 31, 2008 increased by $476,000, or 9%, to $5.6 million, or 9% of net revenue, as compared with $5.1 million, or 8% of net revenue, for the year ended December 31, 2007. The increase was primarily related to an increase in payroll related expenses of $441,000. We expect to continue to invest in development projects and personnel in 2009, however, we expect the overall expense to decrease in 2009.

Patent Infringement Legal Settlement. In October 2008, we reached a settlement agreement with Diodem, LLC and recorded a charge of $1.2 million for the settlement and associated legal fees.

Impairment of Intangible Asset. In connection with our recently established product branding strategy, we have recorded an impairment of $232,000 related to trademarks.

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Impairment of Property, Plant and Equipment. In the first quarter of 2009, we made the decision to begin transitioning our sales in Germany from direct through our foreign subsidiary to sales through a distributor. In connection with this transition, we have placed our buildings located in Floss, Germany for sale. Based on current market information and economic climate in Germany, we recorded an impairment of $355,000 on the land and building.

Non-Operating Income (Loss)

Gain (Loss) on Foreign Currency Transactions. We realized a $186,000 loss on foreign currency transactions for the year ended December 31, 2008 due to our treatment of inter-company balances as short-term , compared to a $1.4 million gain on foreign currency transactions for the year ended December 31, 2007. The decrease is primarily due to changes in exchange rates between the U.S. dollar and the Euro and the Australian and New Zealand dollar and an increase in foreign currency denominated transactions and balances in 2008 compared to 2007. In mid-October 2008, we significantly reduced the inter-company payable due from the foreign subsidiaries to us by making an approximately equal capital contribution which did not result in a significant change in global cash positions. However, subsequent to the contribution date, foreign currency transactions gains and losses recorded on the remaining inter-company balances are expected to be significantly reduced. Additionally, as we transition from sales through our foreign subsidiaries to sales through distributors, the amount of inter-company transactions and related balances should be reduced.

Interest Income. Interest income results from interest earned on our cash and investments balances. Interest income for the year ended December 31, 2008 was $118,000 as compared to $580,000 for the year ended December 31, 2007 due to lower interest rates on lower average cash balances.

Interest Expense. Interest expense consists primarily of interest on outstanding balances on our line of credit, standby fees under the line of credit, and the periodic use of the line during the year. Interest expense for the year ended December 31, 2008 was $157,000 as compared to $81,000 for the year ended December 31, 2007, due to increased borrowings in 2008 as compared to 2007.

Income Taxes. An income tax provision of $121,000 was recognized for the year ended December 31, 2008 as compared to $163,000 for the year ended December 31, 2007. As of December 31, 2008, we had net operating loss carryforwards for federal and state purposes of approximately $59.5 million and $27.6 million, respectively, which will begin expiring in 2009. As of December 31, 2008, we had research and development credit carryforwards for federal and state purposes of approximately $835,000 and $440,000, respectively, which will begin expiring in 2011 for federal purposes and will carryforward indefinitely for state purposes. The utilization of net operating loss and credit carryforwards may be limited under the provisions of Internal Revenue Code Section 382 and similar state provisions.

Year Ended December 31, 2007 Compared With Year Ended December 31, 2006

Net Revenue. Net revenue for the year ended December 31, 2007 was $66.9 million, a decrease of $2.8 million, or 4%, as compared with net revenue of $69.7 million for the year ended December 31, 2006. Laser system net revenues decreased by approximately 7% in 2007 compared to 2006.

Non-laser system net revenue, which includes consumable products, advanced training programs and extended service contracts and shipping revenue, decreased by approximately 18% for the year ended December 31, 2007 as compared to the same period of 2006. The decrease in non-laser system net revenue is primarily attributed to the recognition in 2006 of $1.3 million of revenue related to training credits that expired during 2006 compared with $164,000 of similar revenue in 2007. Additionally, consumable product sales decreased approximately 9% in 2007 compared to 2006.

Training and shipping revenue also decreased partially offset by an increase in revenue related to the sale of extended service contracts.

Sales of our Waterlase systems comprised 68% and 79% of our net revenue for the years ended December 31, 2007 and 2006, respectively, while sales of our Diode laser systems comprised 14% and 5% of our revenue for the years ended December 31, 2007 and 2006, respectively. The increase in Diode revenue is mainly attributed to the launch of our *ezlase* soft tissue diode laser system in the first quarter of 2007.

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Domestic revenues were $41.6 million, or 62% of net revenue, for the year ended December 31, 2007 versus $43.7 million, or 63% of net revenue, for the year ended December 31, 2006. International revenues for 2007 were $25.3 million, or 38% of net revenues for 2007 compared to $26.0 million, or 37% of net revenue for 2006.

We believe that there were various factors which, in the aggregate, had a negative effect on laser system sales in 2007 compared to 2006. General economic conditions with respect to credit availability may have caused dentists considering the purchase of a Waterlase MD laser system to postpone their purchase decision. Additionally, we believe that a variety of sales and marketing execution issues, which led to a management change in November 2007, negatively affected our Waterlase MD system sales.

License fees and royalty income increased to $3.8 million for 2007 from $848,000 for 2006, reflecting the amortization of license fees and related payments received from HSIC and P&G.

Gross Profit. Gross profit for the year ended December 31, 2007 was $34.5 million, or 52% of net revenue, a decrease of $2.0 million, as compared with gross profit of $36.5 million, or 52% of net revenue for the year ended December 31, 2006. Gross profit excluding license fees and royalty revenue was 49% of products and service revenue for 2007 compared to 52% for 2006. Fixed expenses included in cost of revenue represented a higher percentage of the comparatively lower revenues year over year, resulting in a lower margin on products and services revenue.

Other Income, Net. Other income consists of gain (loss) on sale of assets. There was no other income, net for the year ended December 31, 2007 compared to $6,000 for the year ended December 31, 2006.

Operating Expenses. Operating expenses for the year ended December 31, 2007 were $43.5 million, or 65% of net revenue, a $2.2 million increase as compared with $41.3 million, or 59% of net revenue for the year ended December 31, 2006. The increase was driven mainly by convention, seminar, and travel and entertainment expenses described below under *Sales and Marketing Expense* and severance-related expenses as described below under *Restructuring Charge.*

Sales and Marketing Expense. Sales and marketing expenses for the year ended December 31, 2007 increased by $2.2 million, or approximately 9%, to $26.6 million, or 40% of net revenue, as compared with $24.4 million, or 35% of net revenue, for the year ended December 31, 2006. Convention and seminar expenses increased by $2.0 million in 2007 compared to 2006, and travel and entertainment expenses increased by $670,000 compared to 2006. These increases were partially offset by a $282,000 decrease in payroll related costs primarily due to lower commission expense on decreased sales.

General and Administrative Expense. General and administrative expenses for the year ended December 31, 2007 decreased by $768,000, or 7%, to $10.9 million, or 16% of net revenue, as compared with $11.7 million, or 17% of net revenue, for the year ended December 31, 2006. The decrease in general and administrative expenses resulted primarily from a $1.2 million decrease in the accounts receivable bad debt expense largely due to improved collections from international customers and a $226,000 decrease in legal, regulatory, and consulting expenses. This decrease was offset partially by an increase in audit fees of $463,000 related to increased 2006 audit fees incurred in 2007 and recruiting fees of approximately $209,000 incurred in connection with our search for a new Chief Executive Officer.

Engineering and Development Expense. Engineering and development expenses for the year ended December 31, 2007 increased by $228,000, or 5%, to $5.1 million, or 8% of net revenue, as compared with $4.9 million, or 7% of net revenue, for the year ended December 31, 2006. The increase was primarily related to an increase in payroll related expenses of $316,000.

Restructuring Charge. Restructuring expense for the year ended December 31, 2007 amounted to $802,000, or 1% of net revenue. We incurred no restructuring expense in 2006. The 2007 expense is primarily due to severance-related costs incurred in the fourth quarter of 2007 in connection with the terminations of our President and Chief Executive Officer and our Executive Vice President, Global Sales and Marketing which were both effective November 5, 2007. In the fourth quarter of 2007, we also terminated eleven other employees, across all functions, in an effort to better rationalize resources and streamline operations.

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Patent Infringement Legal Settlement. In January 2005, we acquired the intellectual property portfolio of Diodem, consisting of certain U.S. and international patents of which four were asserted against us, and settled the existing litigation between us and Diodem, for consideration of $3.0 million in cash, 361,664 shares of our common stock, and a five-year warrant to purchase 81,037 shares of common stock at an exercise price of $11.06 per share. In connection with the Diodem patent litigation settlement, 45,208 shares of our common stock were issued to Diodem and placed in an escrow account. In July 2006, we released these shares from escrow and accordingly, we recorded a $348,000 charge based on the fair market value of our common stock.

Non-Operating Income (Loss)

Gain (Loss) on Foreign Currency Transactions. We realized a $1.4 million gain on foreign currency transactions for the year ended December 31, 2007 due to our treatment of intercompany balances as short-term , compared to a $251,000 gain on foreign currency transactions for the year ended December 31, 2006. The increase is due to changes in exchange rates between the U.S. dollar and the Euro and the Australian and New Zealand dollar and an increase in foreign currency denominated transactions and balances in 2007 compared to 2006.

Interest Income. Interest income results from interest earned on our cash and investments balances. Interest income for the year ended December 31, 2007 was $580,000 as compared to $448,000 for the year ended December 31, 2006.

Interest Expense. Interest expense consists primarily of interest on outstanding balances on our line of credit, standby fees under the line of credit, and the periodic use of the line during the year. Interest expense for the year ended December 31, 2007 was $81,000 as compared to $388,000 for the year ended December 31, 2006, given borrowings were lower in 2007 as compared to 2006.

Income Taxes. An income tax provision of $163,000 was recognized for the year ended December 31, 2007 as compared to $162,000 for the year ended December 31, 2006. As of December 31, 2007, we had net operating loss carryforwards for federal and state purposes of approximately $55.8 million and $23.2 million, respectively, which will begin expiring in 2008. As of December 31, 2007, we had research and development credit carryforwards for federal and state purposes of approximately $804,000 and $447,000, respectively, which will begin expiring in 2011 for federal purposes and will carryforward indefinitely for state purposes. The utilization of net operating loss and credit carryforwards may be limited under the provisions of Internal Revenue Code Section 382 and similar state provisions.

Liquidity and Capital Resources

We believe we currently possess sufficient resources to meet the cash requirements of our operations for at least the next year. Our basis for this is the following.

Beginning in the fourth quarter of 2008, we implemented substantial cost reduction measures including the reduction of employment and expenses throughout all functional areas of our business. We have reduced our headcount from approximately 234 at September 30, 2008 to approximately 146 as of February 28, 2009.

On February 27, 2009, we entered into a letter agreement, or Agreement, with HSIC amending the term of the License and Distribution Agreement through March 31, 2010. Included in this Agreement are minimum purchase requirements of approximately $42.7 million over the initial fourteen-month term starting in February 2009. Additionally, the Agreement contains guaranteed bi-monthly minimum purchases of our lasers and associated equipment. The Agreement can be extended for two additional optional twelve month terms and the agreement which require escalation minimums of between 7.5 percent and 20 percent over actual or minimum sales, whichever is greater.

During the first quarter of 2009, we made the decision to begin the transition of sales in countries served by our foreign subsidiaries located in Germany, Spain, Australia and New Zealand from direct to distributor. As part of the Agreement with HSIC, HSIC will become our distributor in each of these countries as well as in the future in additional foreign countries. As a result of these developments, we

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have begun the process of shutting down the foreign subsidiaries which have been recording significant losses ever since being established to sell direct in those countries in 2006.

We are in the process of reviewing our inventory levels and plan to reduce the levels to more historical year end amounts of approximately $7 million. Our new Agreement with HSIC will allow us to better forecast our inventory needs and not having inventory located at our foreign subsidiaries will help in this objective.

Although we believe that we will have sufficient resources to meet our obligations and sustain our operations during the next twelve months, there can be no assurance that the resources we believe will be available will prove to be available or sufficient, or that additional resources will be available if necessary to fund our operations. We are substantially dependent on our major distributor and the continued performance of this distributor to make committed purchases of our products and associated consumables under our distribution agreement, and the receipt of cash in connection with those purchases, is essential to our liquidity. In addition, we presently do not have any debt financing in place with a bank or other financial institution. The absence of such debt financing availability could adversely impact our operations. Our obligations and operating requirements may require us to seek additional funding through public or private equity or debt financing, and we have no commitments for financing of any kind at this time. There can be no assurance that we will be able to obtain requisite financing if necessary to fund existing obligations and operating requirements on acceptable terms or at all.

At December 31, 2008, we had approximately $5.0 million in net working capital, a decrease of $6.0 million from $11.0 million at December 31, 2007. Our principal sources of liquidity at December 31, 2008 consisted of our cash and cash equivalents balance of $11.2 million and a $10.0 million revolving bank line of credit with Comerica Bank (the Lender) of which $5.4 million was utilized as of December 31, 2008 at an interest rate of 3.5% (based on prime rate plus 0.25% as of that date).

On September 28, 2006, we entered into a Loan and Security Agreement (Loan Agreement) with Comerica Bank (the Lender) which replaced the loan agreement previously held with Bank of the West (BOW). Under the Loan Agreement, the Lender agreed to extend a revolving loan (the Revolving Line) to us in the maximum principal amount of $10.0 million. Advances under the Revolving Line could not exceed the lesser of $10.0 million or the Borrowing Base (80% of eligible accounts receivable and 35% of eligible inventory), less any amounts outstanding under letters of credit or foreign exchange contract reserves. Notwithstanding the foregoing, advances of up to $6.0 million could be made without regard to the Borrowing Base. On October 5, 2007, we entered into an Amendment to the Loan Agreement which extended the agreement for an additional year. The entire unpaid principal amount plus any accrued but unpaid interest and all other amounts due under the Loan Agreement would have been due and payable in full on September 28, 2009 (the Maturity Date), but could have been extended by us for an additional year upon Lender approval. Our obligations under the Loan Agreement beared interest on the outstanding daily balance thereof at one of the following rates, to be selected by us: (i) LIBOR plus 2.50%, or (ii) prime rate, as announced by the Lender, plus 0.25%. As security for the payment and performance of our obligations under the Loan Agreement, we granted the Lender a first priority security interest in existing and later-acquired Collateral (as defined in the Loan Agreement, and which excludes intellectual property). Certain subsidiaries of ours had entered into unconditional guaranties, dated as of September 28, 2006, pursuant to which such subsidiaries had guaranteed the payment and performance of our obligations under the Loan Agreement.

The Loan Agreement required compliance with certain financial covenants, including: (i) minimum effective tangible net worth; (ii) maximum leverage ratio; (iii) minimum cash amount at Lender of $6.0 million; and (iv) minimum liquidity ratio. The Loan Agreement also contained covenants that required Lender s prior written consent for us, among other things, to: (i) transfer any part of its business or property; (ii) make any changes in our location or name, or replace our CEO or CFO; (iii) consummate mergers or acquisitions; (iv) incur liens; or, (v) pay dividends or repurchase stock. The Loan Agreement contained customary events of default, any one of which would result in the

right of the Lender to, among other things, accelerate all obligations under the Loan Agreement, set-off obligations under the Loan Agreement against any balances or deposits of ours held by the bank, or sell the Collateral.

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On January 30, 2009, we delivered a compliance certificate to Comerica which set forth non-compliance with certain covenants under the Loan Agreement as of December 31, 2008. The loan agreement was terminated on February 5, 2009 and all outstanding balances were repaid in full with cash available on hand, and under the terms of the Loan Agreement and related note, we and certain of our subsidiaries satisfied all of our obligations under the Loan Agreement.

We are currently pursuing other credit facilities that do not contain the cash deposit requirements set forth in the Comerica Loan Agreement; however, we cannot guarantee that we will be able to obtain such a line, or otherwise obtain additional financing to support our working capital needs.

For the year ended December 31, 2008, our operating activities used cash of approximately $4.5 million, compared to cash used by operations of $3.3 million for 2007. Cash flows from operating activities in 2007 were negatively impacted by the higher net loss in 2008 compared to 2007 as explained under *Results of Operations* . The most significant change in operating assets and liabilities for the year ended December 31, 2008 as reported in our Consolidated Statements of Cash Flow was a decrease in accounts receivable of $7.5 million (before the change in allowance for doubtful accounts) partially offset by an increase of $4.9 million in inventory. The change in accounts receivable was a result of decreased revenues in the fourth quarter of 2008 compared to the fourth quarter of 2007. Also, we received accelerated payments from HSIC on invoices during the fourth quarter of 2008. The increase in inventory was primarily a result of lower than expected sales during the fourth quarter 2008.

In December 2008, we financed approximately $804,000 of insurance premiums payable in eleven equal monthly installments of approximately $75,000 each, including a finance charge of 5.65%. On January 10, 2006, we entered into a five-year facility lease with initial monthly installments of $39,000 and annual adjustments over the lease term. These amounts are included in the outstanding obligations as of December 31, 2008 listed below.

The following table presents our expected cash requirements for contractual obligations outstanding as of December 31, 2008 for the years ending as indicated below (in thousands):

	Less Than 1 Year	1 to 3 Years	3 to 5 Years	More Than 5 years	Total
Operating leases	$ 519	$ 782	$	$	$ 1,301
SurgiLight agreement	25	25			50
Insurance premium financing	732				732
Total	$ 1,276	$ 807	$	$	$ 2,083

In January 2008, Jake St. Philip was appointed our Chief Executive Officer. On March 5, 2009, Mr. St. Philip resigned as our Chief Executive Officer and as a director of our Board of Directors. On March 10, 2009, we entered into a Separation and General Release Agreement, or Agreement, with Mr. St. Philip. Pursuant to the Agreement, we agreed to pay Mr. St. Philip a severance payment of $350,000 of which half will be paid on May 9, 2009 and half will be paid in twelve consecutive equal monthly installments commencing on June 1, 2009. In addition, we agreed to pay COBRA premiums on his behalf for twelve months. The Agreement superseded the Employment Agreement we had with Mr. St. Philip dated January 2, 2008.

On April 30, 2008, we appointed David M. Mulder as Chief Financial Officer. Mr. Mulder has an employment agreement that obligate us to pay him severance benefits under certain conditions, including termination without cause and resignation with good reason. In the event Mr. Mulder is terminated by us without cause or he resigns with good reason, the total severance benefits payable would be approximately $255,000 based on compensation in effect as of April 30, 2008, the date Mr. Mulder was appointed as our current Chief Financial Officer. On March 5, 2009, Mr. Mulder was appointed Chief Executive Officer and appointed to our Board of Directors.

In addition to Mr. Mulder, certain other members of management are entitled to severance benefits payable upon termination following a change in control, which would approximate $2.6 million. Also, we have agreements with certain employees to pay bonuses based on targeted performance criteria.

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In addition to the amounts shown in the table above, $108,000 of unrecognized tax benefits have been recorded as liabilities in accordance with FASB Interpretation No. 48, *Accounting for Uncertainty in Income Taxes, An Interpretation of FASB Statement No. 109* (FIN 48), and we are uncertain as to if or when such amounts may be settled. Related to these unrecognized tax benefits, we have also recorded a liability for potential penalties and interest of $20,000 and $19,000, respectively, at December 31, 2008.

Our capital requirements will depend on many factors, including, among other things, the effects of any acquisitions we may pursue as well as the rate at which our business grows, with corresponding demands for working capital and manufacturing capacity. We could be required or may elect to seek additional funding through public or private equity or debt financing. However, a credit facility, or additional funds through public or private equity or other debt financing, may not be available on terms acceptable to us or at all.

Selected Quarterly Financial Data

The following table presents our operating results for each quarter in our last two fiscal years. This data has been derived from unaudited financial statements that, in the opinion of our management, include all adjustments, consisting of normal recurring adjustments, necessary for a fair presentation of such information when read in conjunction with our annual audited financial statements and notes thereto. These operating results are not necessarily indicative of results for any future operating period.