BIOLASE, INC
Form 10-K
March 17, 2014

UNITED STATES

SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

FORM 10-K

(Mark One)

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

For the fiscal year ended December 31, 2013

OR

¨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, INC.

(Exact Name of Registrant as Specified in Its Charter)

Delaware (State or Other Jurisdiction of Incorporation or Organization)	87-0442441 (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 Capital 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 ¨ No x

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 ¨ No x

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

Indicate by check mark whether the registrant has submitted electronically and posted on its corporate website, if any, every Interactive Data File required to be submitted and posted pursuant to Rule 405 of Regulation S-T (§ 232.405 of this chapter) during the preceding 12 months (or for such shorter period that the registrant was required to submit and post such files). Yes x No ¨

Indicate by check mark if disclosure of delinquent filers pursuant to Item 405 of Regulation S-K is not contained herein, and will not be contained, to the best of registrant's knowledge, in 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. ¨

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 definition of "large accelerated filer," "accelerated filer" and "smaller reporting company" in Rule 12b-2 of the Exchange Act. (Check one):

Large accelerated filer ¨	Accelerated filer x	Non-accelerated filer ¨ (Do not check if a smaller reporting company)	Smaller Reporting Company ¨

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

The aggregate market value of the Registrant's common stock held by non-affiliates was $96,933,145 based on the last sale price of common stock on June 30, 2013.

As of February 28, 2014, there were 37,407,545 shares of the Registrant's common stock, par value $0.001 per share, outstanding.

DOCUMENTS INCORPORATED BY REFERENCE

Portions of the Registrant's definitive proxy statement related to its 2014 Annual Meeting of Stockholders, to be filed with the Securities and Exchange Commission pursuant to Regulation 14A within 120 days after the Registrant's fiscal year ended December 31, 2013, are incorporated by reference into Part III of this Annual Report on Form 10-K.

BIOLASE, INC.

ANNUAL REPORT ON FORM 10-K

FOR THE FISCAL YEAR ENDED DECEMBER 31, 2013

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CAUTIONARY STATEMENT REGARDING FORWARD LOOKING STATEMENTS

This Annual Report on Form 10-K ("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, includes "forward-looking statements" that involve risks and uncertainties, as well as assumptions that, if they prove incorrect or never materialize, could cause our results to differ materially and adversely from those expressed or implied by such forward-looking statements. Examples of forward-looking statements include, but are not limited to any statements, predictions and expectations regarding our earnings, revenue, sales and operations, operating expenses, 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. Forward-looking statements are often identified by the use of words such as "may," "might," "will," "intend," "should," "could," "can," "would," "continue," " "believe," "anticipate," "estimate," "predict," "potential," "plan," "seek" and similar expressions and variations or the negativit these terms or other comparable terminology.

These forward-looking statements are based on the expectations, estimates, projections, beliefs and assumptions of our management based on information currently available to management, all of which is subject to change. Such forward-looking statements are subject to risks, uncertainties and other factors that are difficult to predict and could cause actual results to differ materially from those stated or implied by our forward-looking statements. Factors that could cause or contribute to such differences include, but are not limited to, those identified under "Risk Factors" in Item 1A in this Form 10-K. We undertake no obligation to revise or update publicly any forward-looking statements to reflect events or circumstances after the date of such statements for any reason except as otherwise required by law.

The information contained in this 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").

PART I

Item 1. Business

Overview

We are a biomedical company that develops, manufactures, and markets lasers in dentistry and medicine and also markets and distributes dental imaging equipment, including cone beam digital x-rays and CAD/CAM intra-oral scanners, and in-office, chair-side milling machines and three-dimensional ("3-D") printers; products that are focused on technologies that advance the practice of dentistry and medicine. Our proprietary dental laser systems allow dentists, periodontists, endodontists, oral surgeons, and other specialists to perform a broad range of dental procedures, including cosmetic, restorative, 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 conventional instruments. We have clearance from the U.S. Food and Drug Administration (the "FDA") to sell our laser systems in the United States and also have the necessary registration to sell our laser systems in Canada, the European Union, and various other international markets. Our licensed dental imaging equipment and other related products are designed to improve diagnoses, applications, and procedures in dentistry and medicine.

We offer two categories of laser system products: WaterLase systems and Diode systems. Our flagship product category, the WaterLase system, uses a patented combination of water and laser energy 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, pain therapy, and cosmetic procedures, including teeth whitening. We currently have approximately 180 issued and 120 pending U.S. and international patents, the majority of which are related to our core WaterLase technology and dental and medical lasers. From 1998 through December 31, 2013, we sold over 10,200 WaterLase systems, including more than 6,200 WaterLase MD® and iPlus® systems, and more than 24,800 laser systems in over 70 countries around the world.

We currently operate in a single reportable business segment. We had net revenues of $56.4 million, $57.4 million, and $48.9 million in 2013, 2012, and 2011, respectively, and we had net losses of $11.5 million, $3.1 million, and $4.5 million for the same periods.

We were originally formed as Societe Endo Technic, SA ("SET") in 1984 in Marseilles, France, to develop and market various endodontic and laser products. In 1987, SET merged into Pamplona Capital Corp., a public holding company incorporated in Delaware. In 1994, we changed our name to BIOLASE Technology, Inc. and to BIOLASE, Inc. ("BIOLASE") in 2012. Since 1998, our primary objective has been to be the leading designer, manufacturer, and marketer of laser systems for the dental industry.

Recent Developments

New Product Offerings

In February 2014, we agreed to distribute Stratasys Ltd.'s ("Stratasys'") Objet30 OrthoDesk and a number of its Design Series 3-D printers. The Objet30 OrthoDesk combines precise 3-D printing technology with a small footprint. It is easy to use, and includes specialized dental printing materials in convenient sealed cartridges. Dentists can fabricate stone models, orthodontic appliances, delivery and positioning trays, models for clear aligners, retainers and surgical guides on their desktop. We believe that 3-D printing will be a major factor for dental restorations in the new digital era of dentistry.

In November 2013, we introduced the Galaxy BioMill™ CAD/CAM system which enables dental practitioners to scan, design, mill, and finish crowns, inlays, onlays, and veneers in the dental office in a single appointment. The Galaxy BioMill was developed and designed by us in conjunction with German-based imes-icore GmbH for their milling technologies and Copenhagen-based 3Shape Corporation (“3Shape”) for their CAD/CAM intra-oral scanning technologies. We expect to begin shipping these systems in the second quarter of 2014. Also termed "chair-side" milling, the Galaxy BioMill System will utilize 3Shape’s fast and highly accurate Trios intra-oral scanner to capture high resolution 3-D digital images of the teeth and crown-preparation site, which are then processed through a CAD/CAM software program to design the dental restoration. The design is then transferred to the Galaxy BioMill to mill the crown.

We believe that the addition of the Galaxy BioMill and Objet30 OrthoDesk and Design Series 3-D printers to our suite of advanced technology solutions differentiates us compared to other fragmented product offerings in the marketplace and are an integral part of our strategy of becoming the premier Total Technology Solution™ provider in dentistry. By combining high-end digital imaging, first in class laser tissue management, intra-oral scanning, CAD/CAM design, chair-side milling, and 3-D printing, dental offices can accurately and rapidly produce a wide range of restorations and appliances.

In November 2013, we began shipping the Epic™ 10S in collaboration with Valam, Inc. ("Valam") to develop, market, and sell office-based laser systems to otolaryngologists (also known as 'Ear, Nose, and Throat" or "ENT" doctors) (the "Valam Agreement"). The Valam Agreement provides us with an exclusive worldwide license to Valam's ENT related patents and related applications which complement our patent portfolio.

In June 2013, we began shipping the Epic V-Series which enables a wide range of veterinary applications, including surgical, dental, and pain therapy procedures. These laser systems are based on the Epic platform that we launched in late 2012, with software and delivery adaptations, and broadens our laser technology reach within the medical field.

In June 2013, we also expanded our line of digital imaging equipment with the NewTom Biolase VG3 ("VG3"), a readily upgradeable two-dimensional ("2-D")/3-D hybrid system manufactured by Cefla Dental Group, which we began distributing in the United States. We believe that the digital imaging products included in our suite of technology product offerings are integral for dentists to provide accurate diagnoses to their patients.

Credit Facilities

On May 24, 2012, we entered into two revolving credit facility agreements with Comerica Bank (the "Credit Agreements"), as amended. As of December 31, 2013, the Credit Agreements provided for borrowings against certain domestic accounts receivable and inventory, as set forth in the $4.0 million revolving credit facility agreement (the "Domestic Revolver"), and borrowings against certain export related accounts receivable and inventory, as set forth in the $4.0 million revolving credit facility agreement (the "Ex-Im Revolver"), for a combined aggregate commitment of borrowings up to $8.0 million. The lines of credit mature on May 1, 2014, at which date any remaining borrowings and accrued interest under the lines of credit become due and payable. As of December 31, 2013, we had outstanding borrowings totaling approximately $4.6 million, which included $1.8 million under the Domestic Revolver and $2.8 million under the Ex-Im Revolver.

The Credit Agreements require us to maintain compliance with certain monthly financial and non-financial covenants, as defined therein. Any noncompliance with these covenants may result in default interest rates and penalties, and Comerica Bank could declare the amounts outstanding immediately due and payable. We were either in compliance with these covenants at December 31, 2013, or had received a waiver in the event of non-compliance. On March 4, 2014, we received a waiver for noncompliance with certain financial and nonfinancial covenants as of January 31, 2014 and December 31, 2013, which reduced the aggregate borrowing limits on the Credit Agreements to $5.0 million.

January 2014 Shelf Registration

On January 17, 2014, the Company filed a registration statement to register an indeterminate number of shares of common stock, preferred stock, and warrants with a total offering price not to exceed $12.5 million.

February 2014 Subscription Agreement

On February 10, 2014, the Company entered into a subscription agreement under which the Company offered an aggregate of 1,945,525 unregistered shares of common stock in a private placement at a price of $2.57 per share. Gross proceeds from the sale totaled $5 million, and net proceeds, after offering expenses of approximately $208,000, totaled approximately $4.8 million.

Industry Background

General

Dental procedures, including medical and cosmetic treatment, are performed on hard tissue, such as bone and teeth, and soft tissue, such as gum and other oral tissue.

A 2007 American Dental Association ("ADA") Survey of Dental Services Rendered (the "ADA Study") has estimated 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 ADA study also indicated that more than 1.2 million soft tissue procedures are performed annually in the United States. Soft tissue procedures include operations such as gum line alteration. According to statistics compiled in the ADA's study, 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 estimated 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 2007 Public Opinion Survey: Oral Health of the US Population, 48.7% of adults said they last saw a dentist less than six months ago, while an additional 18.9% saw a dentist between six months ago and a year.

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. There are studies that indicate a possible linkage between periodontitis and several other health conditions such as heart disease, diabetes, or stroke. Oral health care is a priority for many as evidenced by the significant number of dental practitioners both in the U.S. and abroad. According to the 2009 Distribution of Dentists in the U.S. by Region and State, as of 2009, there were 186,084 professionally active dentists, including 170,694 active private practitioners in the U.S. According to the World Health Organization in 2012, as of 2004, there were 1.8 million dentists worldwide, with the most dentists in the U.S., Brazil, and China. As many developing nations continue to experience fiscal growth we believe those nations will also experience higher demand for improved healthcare. Corresponding growth in dental practice competition for patients could create further demand for 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 offerings correspond with this trend, and we expect incremental growth from these pressures in the marketplace.

Traditional Dental Instruments

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. The trauma caused to the surrounding tissues can lead to increased recovery times and the need for future crowns and root canals. Additionally, this grinding action of high speed drills may weaken the tooth's underlying structure, leading to fractures and broken cusps. Procedures involving high-speed drills typically require anesthesia. Because many dentists do not recommend anesthetizing more than one or two quadrants of the mouth in a single session, patients may need to return several times to complete their treatment plan. Further, based on the results of several recent studies, autoclaving fails to completely decontaminate dental burs and approximately 15% of these "sterilized burs" carry pathogenic micro-organisms, which may be transferred from patient to patient.

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. The 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 and is a particular problem for patients with immune deficiencies or blood disorders, and patients taking blood-thinning medications.

Film Radiography Equipment. Since the early twentieth century, dentists have relied on radiographic images produced by exposing photographic film to X-ray radiation as part of the examination and diagnosis of patients. These X-ray images can help reveal tooth decay, periodontal disease, bone loss, infections, hidden dental structures, abscesses or cysts, developmental abnormalities, some types of tumors, and other issues that might not be detected during a visual examination or upon probing with a handheld instrument. Due to the chemical development process required for film, however, this process is time-consuming, inefficient, and costly for dental offices, and not environmentally friendly. Mistakes in the development process can require retakes which expose patients to additional

radiation. Film X-rays also restrict the abilities of doctors to enhance or further manipulate images for easier and more accurate analysis and treatment planning. Furthermore, one of the most critical limitations of film is that it is restricted to two-dimensional images, which can potentially lead to misdiagnosis.

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 but not both. 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 is generally less precise than lasers and can damage surrounding tissue. Electrosurge is also not suitable for hard tissue procedures and, due to the depth of penetration, generally requires anesthesia and a lengthy healing process. Electrosurge generally cannot be used in areas near metal fillings and dental implants. Finally, electrosurge generally cannot treat 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.

Our Solution

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, help reduce the trauma, pain, and discomfort associated with dental procedures, and increase patient acceptance for treatment protocols. We also believe there is a large market opportunity for digital radiography systems that improve practice efficiency and accuracy of diagnosis, leading to superior treatment planning, increased practice revenue, and healthier outcomes for patients.

Our WaterLase systems precisely cut hard tissue and soft tissue 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, pain therapy, hygiene, and cosmetic applications, including teeth whitening. The Diode systems, together with our WaterLase systems, offer practitioners a broad product line with a range of features and price points.

The Biolase DaVinci Imaging and Cefla NewTom products are state-of-the-art digital radiography systems that provide both two- and three-dimensional X-ray images that allow doctors to visualize and manipulate significantly more information than previously available with film, without the time delay of film development or cost associated with chemicals and the film itself. These imaging systems have been designed to produce the highest quality images while exposing patients to the least amount of radiation necessary. The Trios intra-oral CAD/CAM scanning product offers diversity in our imaging product line with spray-free, high-speed, 3-D color impression capture as well as touch screen and online lab communication capabilities.

The Galaxy BioMill System is an open-architecture CAD/CAM system for scanning, designing, milling and finishing crowns, inlays, and veneers in the dental office in a single appointment. Also termed "chair-side" milling, the Galaxy BioMill System will utilize 3Shape’s fast and highly accurate Trios intra-oral scanner to capture color high resolution 3-D digital images of the teeth and crown-preparation site, which are then processed through a CAD/CAM software program to design the dental restoration. The design is then transferred to the Galaxy BioMill to mill the crown using the latest in aesthetically pleasing, biological compatible, and long-lasting tooth colored materials.

The Stratasys Objet30 OrthoDesk and Design Series 3-D printers combine accurate and precise 3-D printing technology with a small footprint. They are easy to use, and include specialized dental printing materials in convenient sealed cartridges. Dentists can fabricate stone models, orthodontic appliances, delivery and positioning trays, models for clear aligners, retainers and surgical guides on their desktop.

We believe that the addition of the Galaxy BioMill and Objet30 OrthoDesk and Design Series 3-D printers to our suite of advanced technology solutions is an integral part of our strategy to be the premier Total Technology Solution provider in dentistry. By combining high-end digital imaging, first in class laser tissue management, intra-oral scanning, CAD/CAM design, chair-side milling, and 3-D printing, dental offices can accurately and rapidly produce a wide range of restorations and appliances.

A small percentage of dental professionals worldwide currently use lasers. 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 global dental market. Laser technologies with similar patient benefits have become standard of care in ophthalmology, dermatology, and other medical specialties. When combined with the improved information provided by digital imaging, dental lasers will give the doctor the best treatment options to perform more procedures in a minimally invasive manner. Further, in-office, chair-side milling and 3-D printing gives the doctor the ability to provide same-day restorations. Our combination of high-end digital imaging systems, laser tissue management, intra-oral scanning, chair-side milling, and 3-D printing makes us the only company to offer high-technology solutions for the diagnosis, treatment and restoration planning, and delivery of treatment, in the most minimally invasive manner possible: the Biolase Total Technology Solution™.

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. Our systems allow dentists to perform these procedures easily and efficiently, increasing their range of skills, professional satisfaction, and revenues.
- Additional procedures through increased information and efficiency. Our digital imaging systems allow dentists to diagnose and discover cases that they might not be able to detect with film images and/or two-dimensional images, thereby giving them the ability to offer more treatment options for patients. Our laser 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. 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. We have FDA clearance for treatment protocols including Deep Pocket Therapy with New Attachment™ and subgingival calculus removal using the WaterLase system and the patented Radial Firing Perio Tip. This is a non-surgical alternative treatment for moderate to advanced gum disease, the leading cause for tooth loss for adults over age 35 and a condition impacting more than half of Americans over age 55. In addition, the Epic system can be used to quickly perform teeth whitening with our proprietary whitening gel and to provide temporary pain relief from minor muscle and joint pain and stiffness, minor arthritis pain or muscle spasm, and minor sprains and strains. The Galaxy BioMill System and Stratasys Objet30 OrthoDesk and Design Series 3-D printers will allow for same-day restorations.
- Increased loyalty and expanded patient base. We believe the improved patient comfort and convenience offered by our laser systems, the reduction in chair time and radiation exposure of our digital imaging systems, and the benefits of in-office, chair-side milling and 3-D printing 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. By providing more complete and accurate information, our digital imaging systems make it possible for the doctor to determine the optimal diagnosis and treatment plan. Our laser systems can then be used to reduce trauma, swelling, and general discomfort of the patient, resulting in fewer post-operative complications that require follow up treatment. In addition, our laser systems effectively reduce the risk of cross-contamination that can occur with traditional dental tools. Our chair-side milling machine and 3-D printers will further expand treatment options available to patients and allow for same-day restorations. These factors make it possible for practitioners to 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, microfractures, trauma, or pressure associated with traditional dental methods, without cross-contamination. Further, in many cases procedures can be performed without the need for local anesthesia.
- 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. Digital images are available almost immediately, so patients will not have to spend extra time in the dental chair waiting for film to be developed, which makes dentists more efficient. Combined with the diode lasers, these systems offer a variety of solutions for patients. Further, chair-side milling and 3-D printing will allow for same-day restorations.
- Reduced trauma. The WaterLase system avoids the thermal heat transfer, vibration, and grinding action associated with high speed dental drills. As a result, our systems can result in less trauma, swelling, bleeding, 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. Since digital images are displayed on computer monitors, doctors can make treatment planning a more personal experience with patients. Further, chair-side milling and 3-D printing will offer patients the benefits of same

day restorations. We believe that these factors will lead to greater patient case acceptance.

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Business Strategy

Our objectives are to increase our leadership position in the dental laser market, to establish our laser systems as essential tools in dentistry, and to leverage our existing technology platform into other medical markets where it can provide significant improvements over existing standards of care. Our business strategy includes the following key elements:

- Increasing 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 continue participation in key industry trade shows, the World Clinical Laser Institute® (“WCLI®”) (which we founded in 2002), dental schools, and other educational forums. We also intend to continue marketing our systems to dental practitioners through our laser specialists and advertising. Our technologies are also available for clinical research which may lead to publications from which we may benefit. We continue to explore marketing directly to patients and have embraced a number of social media platforms to deliver informative and entertaining content to this audience.
- Expanding sales and distribution capabilities. In the United States and Canada, we primarily distribute our products directly to dental practitioners utilizing a direct sales force. During 2012, we augmented our outside direct sales force by establishing an inside sales organization. The inside sales force is located at our corporate headquarters and is comprised of sales representatives and lead generators who work in partnership with the outside sales team to maximize sales by leveraging the existing installed customer base. In 2013, we also added regional imaging specialists to provide technical and clinical expertise in coordination with our laser sales representatives. In addition to our direct sales force in North America, we also have distribution agreements with various independent distributors to distribute our products in the United States, Canada, and various countries in Europe, the Middle East, Latin America, and Asia-Pacific. We continue to develop an infrastructure to support growth in sales and marketing both domestically and internationally. 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 non-exclusive distributors.
- Expanding product platform and applications. We plan to expand our product line and product applications by developing product enhancements and new laser technologies including new products for use in the medical community. To this end, we launched the Epic V-Series and Epic 10S in 2013 which improves and expands on certain capabilities previously offered by the Epic which was launched in late 2012 for use in the medical specialty markets, including sports medicine, orthopedics, podiatry, physical therapy, and chiropractics. 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 are continuing to explore collaborations to bring new products to other medical markets utilizing our proprietary laser technologies and we may strategically acquire complementary products and technologies.
- Expanding our Er,Cr:YSGG and 940 nm diode technologies into the medical field. Our WaterLase and Diode lasers and their delivery systems and accessories have applications in many other medical and veterinary specialties, including ophthalmology, orthopedics, sports medicine, dermatology, and podiatry. We currently hold a strong patent position which is complemented by our FDA-cleared general indications for use of our lasers with ocular tissue. Our patented Er,Cr:YSGG WaterLase technology has the potential to address several areas in ophthalmology including dry eye, glaucoma, and presbyopia, as well as several other major medical applications in dermatology, cosmetic surgery, orthopedics, and urology. During 2011 we established Occulase, Inc., a wholly owned subsidiary, for the purpose of consolidating our ophthalmologic-specific intellectual property, which includes over 35 U.S. and international patents and pending patents, as we continue our efforts to expand in this area. In 2013 we launched our Occulase website at www.occulase.com to further our marketing efforts of this laser technology. We plan to commercialize or license these applications in the future and may use distribution partners or other strategic partnerships to enter into these markets. During 2013 we also entered into collaborative arrangements with Valam, resulting in the introduction of the Epic 10S, and with Auris Surgical Robotics, Inc. (“Auris”), to utilize our lasers in a robotic system.

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Continuing 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 both 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 markets within and beyond North America.

- Strengthening and defending technology leadership. We believe our proprietary WaterLase system and YSGG Laser 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.
- Strengthening training and development of our laser users. In 2012 we opened our technology and training center at corporate headquarters. The center provides introductory and specialized training sessions for dental professionals seeking proficiency and certification training utilizing our products, and will also be used for ongoing training and clinical education for both outside and inside sales teams and our service professionals. We also have established access to several training facilities around the U.S. through our network of key-opinion leaders and trainers.

- Expanding our Total Technology Solution to dental practitioners. In 2013 we unveiled the Galaxy BioMill CAD/CAM system which enables dental practitioners to complete scanning, designing, milling, and finishing crowns, inlays, and veneers in the dental office in a single appointment. We anticipate to begin shipping these systems in the second quarter of 2014. We also expanded the imaging systems under distribution by adding the VG3, a readily upgradeable 2-D/3-D hybrid system. In February 2014 we added several 3-D printers in order to enable dentists to fabricate stone models, orthodontic appliances, delivery and positioning trays, models for clear aligners, retainers and surgical guides on their desktop

Products

Our WaterLase Dentistry consists of two principal product lines: WaterLase systems and Diode systems. We developed the WaterLase and Diode systems through our own research and development, as well as intellectual property obtained through various acquisitions. During the second half of 2012, we introduced the Epic diode laser system which increases our customer base by providing an exceptional laser at an attractive value proposition. During the second half of 2011, we introduced the Biolase DaVinci Imaging line of imaging products which enabled us to offer high quality digital diagnostic solutions to complement the minimally invasive dental treatment solutions offered by our WaterLase and Diode dental systems. In 2012, we added the distribution of the NewTom 3-D cone beam and Trios intra-oral CAD/CAM scanning system which expanded our imaging product line and provides dental customers with a wider and more comprehensive choice of configurations and range of performance. The integration of our laser products with imaging offers dental professionals the Total Technology Solution which provides imaging capabilities for early diagnosis and minimally invasive treatment with our WaterLase and Diode laser technologies.

WaterLase systems. Our all-tissue WaterLase dental laser systems currently consist of the WaterLase iPlus, the WaterLase MD Turbo, and the WaterLase MDX 300 and 450, both introduced in February 2012. Each of these systems is designed around our patented YSGG Laser technology that refers to the unique laser crystal used in the WaterLase system, which contains the elements erbium and chromium doped yttrium, scandium, and gallium garnet crystal (Er,Cr: YSGG). This unique crystal laser produces energy with specific absorption and tissue interaction characteristics optimized for dental applications. HydroPhotonics refers to the interaction of YSGG lasers with water to produce energy to cut tissue. It is minimally invasive and can precisely cut hard tissue, such as bone and teeth, and soft tissue, such as gums or skin, 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 methods of treatment.

The 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 laser energy, air, and water, as well as the pulse rate. Each system also has been designed to be easily moved from operatory to operatory within a practice office.

The original WaterLase MD released in 2005 features white light-emitting diode (“LED”) handpiece illumination, a full color touch screen improving user friendliness (with a built in user “Help” system), a refined water spray that improves cutting, and a Windows CE operating system. In 2008, we introduced a new clinical procedure for endodontic root canal disinfection with radial firing tips. The WaterLase MD Turbo All-Tissue Dental Laser System was introduced in the first quarter of 2009 and increased the cutting speed compared to the original WaterLase MD. In 2009, we also obtained FDA clearance for a new treatment protocol called Deep Pocket Therapy with New Attachment using the WaterLase MD and the patented Radial Firing Perio Tip. This is a non-surgical alternative treatment for moderate to advanced gum disease, the leading cause of tooth loss for adults over 35 and a condition impacting more than half of Americans over age 55. The procedure assists in new attachment and subgingival calculus removal, and in most cases provides deep pocket treatments in a single visit without the use of a scalpel, stitches, or the conventional cutting of the gums. The WaterLase iPlus, introduced in January 2011, is our most advanced and powerful, yet most intuitive, dual-wavelength all-tissue dental laser system. It delivers all the benefits of our other WaterLases, but with more power, versatility, and ease of use, including an intuitive user interface and a significant increase in cutting speed that is comparable to a high speed drill. The WaterLase iPlus also incorporates the iLase wireless diode laser that can be utilized for unexpected soft-tissue cases in an adjacent treatment room, controlling bleeding, and temporary pain

relief.

Diode systems. Our Diode laser systems in dentistry currently consist of the Epic and iLase, semiconductor diode lasers that perform soft tissue, hygiene, cosmetic procedures, teeth whitening, and temporary pain relief.

In February 2010, we introduced our iLase diode laser system, the first wireless, affordable dental diode laser that provides minimally invasive solutions for the most common everyday soft tissue surgical and hygiene procedures. Featuring patent-pending finger switch activation, battery power, our unique 940 nm wavelength, and ComfortPulse® cutting modality, we believe the wireless and highly portable iLase is a perfect complement for every dental operatory. In September 2012, we introduced our new Epic diode laser system, a portable touch screen system with applications in soft tissue surgery, dental hygiene, teeth whitening, and temporary pain relief. The iLase and Epic are FDA cleared in the United States and CE mark-approved in Europe.

Imaging systems. Our imaging systems include licensed state-of-the-art extra-oral and intra-oral dental digital imaging devices. Our expansion into digital imaging systems enables us to offer high quality diagnostic solutions to complement the minimally invasive dental treatment solutions offered by our WaterLase and Diode systems. We now provide both high-precision intuitive diagnosis and treatment planning solutions, fundamental to the delivery of quality dentistry, together with truly advanced laser treatment solutions thereby delivering, we believe, the best biological and therapeutic results for dentists and patients. Our Imaging systems include the CEFLA NewTom VGi and VG3, Biolase DaVinci D3D, 3-D Cone Beam Computed Tomography ("CBCT") devices. We are currently selling these products as a distributor under the manufacturer's FDA 510(k) clearance. Our 3-D CBCT devices produce stable and high quality 3-D images with low levels of radiation – critical features in dental implant, endodontic, orthodontic, and oral surgery cases.

The first CBCT system introduced to the dental market in 1996 was a NewTom. Since that time, the NewTom brand has been synonymous with providing the clearest, sharpest, and highest quality three-dimensional images. The NewTom VGi is a small-footprint CBCT system that offers medical grade imaging technology at a fraction of the cost and radiation exposure typically associated with medical CT equipment. In addition to producing up to 50% higher image resolution with medical grade rotating anode technology, its proprietary SafeBeam™ technology automatically adjusts radiation dosage to ensure patient safety. In 2013, we introduced the NewTom VG3, a readily upgradeable two-dimensional 2-D/3-D hybrid system to complement the VGi and to expand the range of features and price points to meet the needs of growing practices.

3Shape Trios CAD/CAM imaging systems. 3Shape unveiled this system at the International Dental Show in Germany in 2011. We immediately recognized this system as an advanced dental imaging product designed with technical solutions for the dental practitioner and comfort for patients. The 3Shape system offers a spray-free scanning device for optimal accuracy and patient comfort, high speed technology with accurate digital impression-taking with up to 1000 3-D pictures, a touchscreen interface with live 3-D visualization, online communication capability with labs, and additional benefits. We are currently selling this product as a distributor under the manufacturer's regulatory market clearances.

In-office milling system. The Galaxy BioMill CAD/CAM system enables dental practitioners to complete scanning, designing, milling, and finishing crowns, inlays, and veneers in the dental office in a single appointment. We anticipate beginning to ship these systems in the second quarter of 2014.

3-D Printers. In February 2014, we agreed to distribute Stratasys' Objet30 OrthoDesk and a number of their Design Series High End 3-D printers. The Objet30 OrthoDesk combines accurate and precise 3-D printing technology with a small footprint. It is easy to use, and includes specialized dental printing materials in convenient sealed cartridges. 3-D printers allow dentists to fabricate stone models, orthodontic appliances, delivery and positioning trays, models for clear aligners, retainers and surgical guides on their desktop. We anticipate beginning to ship these systems in the second quarter of 2014.

Medical systems. Our Medical systems include the Diolase 10™ Diode Laser for which we received FDA 510(k) clearance in April 2009 to use in our ezlase platform for both dental and medical pain relief applications. In late 2009 we broadened our product scope to include the use of lasers in a variety of health care and therapeutic markets outside of dentistry. The Diolase 10 was launched with a patented handpiece for therapeutic applications, including temporary pain relief, topical heating for the purpose of temporarily relieving minor muscle and joint pain and stiffness, minor arthritis pain, muscle spasm, minor sprains and strains, and minor muscular back pain; temporarily increasing local blood circulation; and temporarily relaxing muscles. The Diolase 10 was our first strategic expansion into the medical market (which includes sports medicine, orthopedics, podiatry, physical therapy, and chiropractics). We initially focused on the chiropractic market and in 2010 we expanded into physical therapy and sports medicine and introduced the Deep Tissue Handpiece. A continuation of our expansion into the medical market is also realized in our Epic diode laser, which was launched in late 2012 and has improved portability and value proposition with applications including temporary pain relief. The Epic V-Series launching in 2013 is based on the Epic platform with software and delivery

adaptations enabling a wide range of veterinary applications, including surgical, dental, and pain therapy procedures. We anticipate further expansion of the Epic diode laser into additional medical markets in 2013.

Related Accessories and Disposable Products

We also manufacture and sell disposable products and accessories for our laser systems. Our WaterLase and Diode 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 dental practitioners will replace at some point after initially purchasing laser systems. For our Epic and ezlase systems, we sell teeth whitening gel kits.

Warranties

Our WaterLase laser systems sold domestically are covered by a warranty against defects in material and workmanship for a period of up to one-year while our Diode systems warranty is for a period of up to two years from the date of sale to the end-user by us or a distributor. WaterLase systems sold internationally are generally covered by a warranty against defects in material and workmanship for a period of sixteen months while our Diode systems warranty period is up to twenty eight months from date of sale to the international distributor. Our warranty covers parts and service for sales in our North American territories and parts only for international distributor sales. In North America and select international locations, 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. Products or accessories remanufactured, refurbished, or sold by authorized parties, voids all warranties in place for such products and exempts us from liability issues relating to the use of such products. We offer extended warranties on certain products that we distribute, including our digital radiography products. All products that we distribute are initially covered by manufacturer's warranties.

Insurance

We maintain product liability insurance on a claims-made-and-reported basis with a limit of $10 million per occurrence and $10 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 strategy is to manufacture products in-house when it is efficient for us to do so. We currently manufacture, assemble, and test all of our WaterLase products and diode lasers at our corporate headquarters facility in Irvine, California. The 57,000 square foot facility has approximately 20,000 square feet dedicated to manufacturing and warehousing. The facility is ISO 13485 certified. ISO 13485 certification provides guidelines for our quality management system associated with the design, manufacturing, installation, and servicing of our products. In addition, our U.S. facility is registered with the FDA and is compliant with the FDA's Quality System Regulation.

We use an integrated approach to manufacturing, including the assembly of tips, laser hand pieces, fiber assemblies, laser heads, electro-mechanical subassembly, final assembly, and testing. We obtain components and subassemblies for our products from third party suppliers, the majority of which are located in the United States. We generally purchase components and subassemblies from a limited group of suppliers through purchase orders. In general, we rely on these 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, including but not limited to those noted above. 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, educational events, individual meetings, the internet, 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 2010, we introduced the Biolase Store for online purchase of lasers, consumables, accessories, and service contracts in North America. In 2002, we founded the World Clinical Laser Institute (the "WCLI") to formalize our efforts to educate and train dental practitioners in laser dentistry. The WCLI 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 2012, the organization was expanded to include digital imaging. 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. In 2012 we formalized a 5 year agreement with Professor Norbert Gutknecht and the Aachen Center for Laser Dentistry ("AALZ"), the acknowledged leader in dental laser education since its founding in 1992. We expect the AALZ and related World Academy for Laser Education in Dentistry Network ("WALED") to continue expanding the availability of postgraduate advanced wavelength clinical laser education while also taking major steps toward standardizing laser dental education for all our owners worldwide.

Chiropractors, Sports Medicine. We market to chiropractors, physical therapists, and other pain management specialists through trade advertising, seminars, and trade shows. Our marketing activities are primarily executed by our network of independent sales representatives who are managed by our internal sales management team.

Patients. We market the benefits of our laser systems directly to patients through marketing and advertising programs, including the internet, social networks, 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. We can be found online at www.biolase.com, Facebook at www.facebook.com/biolase, Twitter at www.twitter.com/biolaseinc, Pinterest at www.pinterest.com/biolase, LinkedIn at www.linkedin.com/company/biolase, Google+ at www.google.com/+BIOLASEIrvine, Instagram at www.instagram.com/biolaseinc, and YouTube at www.youtube.com/biolasevideos.

Sales

We currently sell our products primarily to dentists in general practice through our direct sales force and our distributor network. The majority of the dentists in the United States and the majority of our end-user customers are sole practitioners. We expect our laser systems to continue 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. Sales to dental specialists will also benefit from the introduction of our NewTom, 3Shape, Galaxy, and Stratasys products into our Total Technology Solution. Outside of the dental market, we expect that our initial sales of lasers will be to pain management specialists, which include chiropractors and physical therapists, otolaryngologists, those who work with the ear, nose, and throat ("ENT"), and the veterinary market.

The following table summarizes our net revenues by category for the years ended December 31, 2013, 2012, and 2011 (dollars in thousands):

	Years Ended December 31,								
	2013			2012			2011		
Laser systems	$38,736	69	%	$42,348	74	%	$38,460	79	%
Imaging systems	4,632	8	%	3,365	6	%	238	—	%

Consumables and other	6,458	12 %	5,954	10 %	5,236	11 %
Services revenue	6,360	11 %	5,524	10 %	4,485	9 %
Products and services revenue	56,186	100%	57,191	100%	48,419	99 %
License fees and royalties	244	— %	165	— %	439	1 %
Net revenue	$56,430	100%	$57,356	100%	$48,858	100%

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

	Years Ended December 31,		
	2013	2012	2011
United States	$35,653	$40,524	$32,782
International	20,777	16,832	16,076
	$56,430	$57,356	$48,858

International revenue accounts for a significant portion of our total revenue and accounted for approximately 37%, 29%, and 33% of our net revenue in 2013, 2012, and 2011, respectively. No individual country outside the United States represented more than 10% of net revenue during the years ended December 31, 2013, 2012, and 2011.

For financial information about our long-lived assets, see Note 2 and Note 9 to the Notes to the Consolidated Financial Statements — Summary of Significant Accounting Policies and — Segment Information.

North American Sales. In the United States and Canada, we primarily sell our products directly to dental practitioners utilizing a direct sales force consisting of laser sales representatives, imaging specialists, and regional managers. During 2012, we augmented our outside direct sales force by establishing an inside sales organization. The inside sales force is located at our corporate headquarters and is comprised of sales representatives and lead generators who work in partnership with the outside sales team to maximize sales by leveraging the existing installed customer base.

International Sales. Our distributors purchase laser 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 their exclusivity. In 2011, we began selling our products directly to end users in Germany and other countries where we have non-exclusive distribution arrangements. In 2012, we began selling our products directly to end users in India and neighboring countries.

Customer Concentration. We sell our products through our direct sales force and non-exclusive distributor relationships. For the years ended December 31, 2013, 2012, and 2011, sales to our largest distributor worldwide accounted for approximately 5%, 3%, and 19%, respectively, of our net revenue.

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 maintain a network of service technicians 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 provide parts to distributors at no additional charge for products covered under warranty.

Financing Options. Many dentists finance their purchases through third-party financial institutions, including leasing companies and banks. In the United States and Canada, third-party customers enter into a financing agreement with a financial institution who purchases the product from us or one of our distributors. We are not party to these financing agreements, so if the customer agrees to pay the financial institution in installments we do not bear the credit risk that the dentist might not make payments. The financial institutions do not have recourse to us for a customer’s failure to make payments, nor do we have any obligation to take back the product.

Seasonality. 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. We believe that this trend exists because a significant number of dentists purchase their capital equipment towards the end of the calendar year in order to maximize their practice earnings while seeking to minimize their taxes. This can be accomplished by utilizing certain tax incentives, such as accelerated depreciation methods for purchasing capital equipment, as part of their year-end tax planning. 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. Our historical seasonal fluctuations may also be impacted by sales procedures employed by large dental distributors that encourage end-of-quarter and end-of-year buying in our industry. Because of these seasonal fluctuations, historically we have often used less cash in operations for the six months ended December 31 as compared to the six months ended June 30.

Engineering and Product Development

Engineering and product development activities are essential to maintaining and enhancing our business. We believe our engineering and product development team has demonstrated its ability to develop innovative products that meet evolving market needs. Our research and product development group consists of approximately 14 individuals with medical device and laser development experience, including two Ph.Ds. During the years ended December 31, 2013, 2012, and 2011, our engineering and product development expenses totaled approximately $4.0 million, $4.7 million, and $4.3 million, respectively. Our current engineering and product 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. Some examples of the improvements we are pursuing for our dental lasers include faster cutting speed, ease of use, less need for anesthesia injections, interconnectivity, and an expanded portfolio of consumable products for use with our laser systems.

We also devote engineering and development 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 several other medical markets, including ophthalmology, otolaryngology, orthopedics, podiatry, pain management, aesthetics/dermatology, veterinary, and consumer products. We have already started to enter the otolaryngology, pain management, and veterinary markets to varying degrees.

We have a non-exclusive license agreement with Procter & Gamble Company ("P&G"), granting P&G non-exclusive license rights to certain of our patents, enabling P&G to develop certain products aimed at the consumer market, and requiring P&G to pay royalties based on sales of products developed with such intellectual property. The term of the arrangement continues until the underlying patents expire unless terminated earlier by either party. We are exploring alternative product development opportunities.

Intellectual Property and Proprietary Rights

We believe that in order to maintain a competitive advantage in the marketplace, we must develop and maintain protection of the proprietary aspects of our technology. We rely on a combination of patents, trademarks, trade secrets, copyrights and other intellectual property rights to protect our intellectual property. We have developed a patent portfolio internally, and to a lesser extent through acquisitions and licensing, that covers many aspects of our product offerings. As of December 31, 2013, we had approximately 180 issued patents and 120 pending patent applications in the United States, Europe and other countries around the world. While we hold a variety of patents that cover a broad range of technologies and methods, the majority of these patents provide market protection for our core technologies incorporated in our laser systems and related accessories. Existing patents related to our core technology, which are at various stages of being incorporated into our products, are scheduled to expire as follows: four in 2014, 18 in 2015, nine in 2016, two in 2017, and 18 in 2018, with the majority having expiration dates ranging from 2019 to 2032. With approximately 120 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 adverse effect on our business.

There are risks related to our intellectual property rights. For further details on these risks, see Item 1A — "Risk Factors."

Competition

We operate under highly competitive market conditions. We believe that the principal competitive factors for companies that market technologies in dental and other medical markets include acceptance by leading dental and medical practitioners, product performance, product pricing, intellectual property protection, customer education and support, timing of new product research, and development of successful national and international distribution channels.

Our competitors vary by product and location. There are companies that market some, but not all, of the same types of products as those marketed by us. Our laser systems compete with other lasers, as well as with scalpels, scissors, air abrasion systems, and a variety of other cutting tools that are used to perform dental and medical cutting procedures. We believe our products have key differentiating performance features; for example, we market diode lasers which have FDA clearance for use in both pain management therapy and teeth whitening, in addition to a full range of soft tissue indications, and we know of no other laser in this diode category with this range of capabilities. Our teeth whitening technology competes with other in-office whitening products and high intensity lights used by dentists, as well as teeth whitening strips, and other over-the-counter products. Our pain management technology competes with a variety of traditional, advanced, and pharmaceutical pain management products and services. The dental imaging equipment and in-office milling machines that we offer also competes with traditional and advanced products and services.

Traditional tools could be less expensive for performing similar procedures. For example, a high speed handpiece or an electrosurge device, not including the cost of replacement disposables, can be purchased for less than $2,500 each. In addition, though our systems are superior to drills in many ways, they are not intended to replace all of the applications of the high speed drill, such as cutting metal fillings and certain polishing and grinding functions.

Some of our competitors have significantly greater financial, marketing, and/or 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 products. 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 which 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, loss of market share, or may render our products obsolete.

Government Regulation

FDA's Premarket Clearance and Approval Requirements

Unless an exemption applies, each medical device that we wish to market in the U.S. must first receive either 510(k) clearance, by filing a 510(k) pre-market notification, or PMA approval, by filing a Premarket Approval Application ("PMA") from the FDA pursuant to the Federal Food, Drug, and Cosmetic Act. The FDA's 510(k) clearance process usually takes from four to twelve months, but it can take longer. The process of obtaining PMA approval is much more costly, lengthy, and uncertain. It generally takes from one to three years or even longer. We cannot be sure that 510(k) clearance or PMA approval will ever be obtained for any product we propose to market.

The FDA decides whether a device must undergo either the 510(k) clearance or PMA approval process based upon statutory criteria. These criteria include the level of risk that the agency perceives is associated with the device and a determination of whether the product is a type of device that is similar to devices that are already legally marketed. Devices deemed to pose relatively less risk are placed in either Class I or II, which generally requires the manufacturer to submit a pre-market notification requesting 510(k) clearance, unless an exemption applies.

Class I devices are those for which safety and effectiveness can be assured by adherence to the FDA's general regulatory controls ("General Controls") for medical devices, which include compliance with the applicable portions of the FDA's Quality System Regulation ("QSR") facility registration and product listing, reporting of adverse medical events, and appropriate, truthful and non-misleading labeling, advertising, and promotional materials. Some Class I devices also require premarket clearance by the FDA through the 510(k) premarket notification process.

Class II devices are subject to the FDA's General Controls, and any other special controls as deemed necessary by the FDA to ensure the safety and effectiveness of the device. Premarket review and clearance by the FDA for Class II devices is accomplished through the 510(k) premarket notification procedure. All of our current regulated devices are Class II devices and all have qualified for 510(k) clearance.

Class III devices are those devices deemed by the FDA to pose the greatest risk, such as life-sustaining, life-supporting, or implantable devices, or deemed not substantially equivalent to a legally marketed predicate device. The safety and effectiveness of Class III devices cannot be assured solely by the General Controls and the other requirements described above. These devices almost always require formal clinical studies to demonstrate safety and effectiveness and must be approved through the premarket approval process described below. Premarket approval applications, and supplemental premarket approval applications, are subject to significantly higher user fees under Medical Device User Fee and Modernization Act of 2002, or MDUFMA, than are 510(k) premarket notifications, and generally take much longer for the FDA to review.

To obtain 510(k) clearance, a company must submit a premarket notification demonstrating that the proposed device is "substantially equivalent" in intended use and in technological and performance characteristics to a legally marketed "predicate device" that is either in Class I, Class II, or is a Class III device that was in commercial distribution before May 28, 1976, for which the FDA has not yet called for submission of a PMA application. Pursuant to the MDUFMA and the MDUFMA II provisions of the Food and Drug Amendments Act of 2007, unless a specific exemption applies, 510(k) premarket notification submissions are subject to user fees. 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, requires a new 510(k) clearance or could require a PMA approval. The FDA requires each manufacturer to make this determination in the first instance, but the FDA can review any decision. If the FDA disagrees with a manufacturer's decision not to seek a new 510(k) clearance, the agency may retroactively require the manufacturer to seek 510(k) clearance or PMA approval. The FDA also can require the manufacturer to cease marketing and/or recall the modified device until 510(k) clearance or PMA approval is obtained. We have made and plan to continue to make additional product enhancements to our laser systems that we believe will not require new 510(k) clearances. We cannot assure you that the FDA would agree with any of our decisions not to seek additional 510(k) clearances or

even PMA approval for these or future device modifications. If the FDA requires us to seek 510(k) clearance or PMA approval for any modification, we also may be required to cease marketing and/or recall the modified device until we obtain a new 510(k) clearance or PMA approval.

Class III devices are required to undergo the PMA approval process in which the manufacturer must establish the safety and effectiveness of the device to the FDA's satisfaction. A PMA application must provide extensive preclinical and clinical trial data as well as information about the device and its components regarding, among other things, device design, manufacturing and labeling. Also during the review period, an advisory panel of experts from outside the FDA may be convened to review and evaluate the application and provide recommendations to the FDA as to the approvability of the device. In addition, the FDA will conduct a preapproval inspection of the manufacturing facility to ensure compliance with the QSR. A new PMA or a PMA Supplement is required for modifications that affect the safety or effectiveness of the device, including, for example, certain types of modifications to the device's indications for use, manufacturing process, manufacturing facility, labeling and design. PMA Supplements often require submission of the same type of information as an original PMA application, except that the supplement is limited to information needed to support any changes from the device covered by the original PMA application, and may not require as extensive clinical data or the convening of an advisory panel. None of our products are currently approved under a PMA.

A clinical trial may be required in support of a 510(k) submission and generally is required for a PMA application. These trials generally require an Investigational Device Exemption ("IDE") application approved in advance by the FDA for a specified number of patients, unless the product is deemed a non-significant risk device eligible for certain exemptions from the IDE requirements. The IDE application must be supported by appropriate data, such as animal and laboratory testing results. Clinical trials may begin if the IDE application is approved by the FDA and the appropriate institutional review boards at the clinical trial sites. Even if a trial is completed, the results of clinical testing may not adequately demonstrate the safety and efficacy of the device or may otherwise not be sufficient to obtain FDA clearance to market the product in the U.S.

In the future, we may be required to make additional 510(k) submissions to the FDA to address new claims, uses, or products. We cannot assure you that the FDA will not deem one or more of our future products, or those of our OEM partners, to be a Class III device subject to the more burdensome PMA approval process. The FDA also may not approve or clear these products for the indications that are necessary or desirable for successful commercialization. Indeed, the FDA may refuse our requests for 510(k) clearance or PMA of new products, new intended uses or modifications to existing products.

Pervasive and Continuing FDA Regulation

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

device listing and establishment registration, which helps facilitate FDA inspections and other regulatory action;
QSR, which requires manufacturers, including third-party manufacturers, to follow stringent design control, testing, change control, documentation, and other quality assurance procedures during all aspects of the manufacturing process;
labeling control and advertising regulations which include FDA prohibitions against the promotion of products for uncleared, unapproved, or off-label uses or indications;
clearance of product modifications that could significantly affect safety or efficacy or that would constitute a major change in intended use of one of our cleared devices;
approval of product modifications that affect the safety or effectiveness of one of our future approved devices;
medical device reporting ("MDR"), regulations, which require that manufacturers comply with FDA requirements to report if their device may have caused or contributed to a death or serious injury, or has malfunctioned in a way that would likely cause or contribute to a death or serious injury if the malfunction of the device or a similar device were to recur;
post-approval restrictions or conditions, including post-approval study commitments;
post-market surveillance requirements, which apply when necessary to protect the public health or to provide additional safety and effectiveness data for the device;

the FDA's recall authority, whereby it can ask, or under certain conditions order, device manufacturers to recall from the market a product that is in violation of governing laws or regulations or other conditions under which the product was approved;
regulations pertaining to voluntary recalls; and
notices of corrections or removals.

We will need to invest significant time and other resources to ensure ongoing compliance with FDA QSR 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. As a manufacturer, we are subject to announced and unannounced facility inspections by the FDA and the California Department of Health Services to determine our compliance with various regulations. Our subcontractors' manufacturing facilities are also subject to inspection.

If the FDA finds that we have failed to comply, the agency can institute a wide variety of enforcement actions, ranging from a public warning letter to more severe sanctions such as:

fines and civil penalties;
unanticipated expenditures to address or defend such actions;
delays in clearing or approving, or refusal to clear or approve, our products;
withdrawal or suspension of approval of our products or those of our third-party suppliers by the FDA or other regulatory bodies;
product recall or seizure;
interruption of production;
operating restrictions;
injunctions; and
criminal prosecution.

The FDA also has the authority to request repair, replacement, or refund of the cost of any medical device manufactured or distributed by us. Our failure, or the failure of our subcontractors, to comply with applicable requirements could lead to an enforcement action that may have an adverse effect on our business, financial condition, and results of operations.

Advertising and promotion of medical devices, in addition to being regulated by the FDA, are also regulated by the Federal Trade Commission ("FTC") and by state regulatory and enforcement authorities. Recently, promotional activities for FDA-regulated products of other companies have been the subject of enforcement action brought under healthcare reimbursement laws and consumer protection statutes. In addition, under the federal Lanham Act and similar state laws, competitors and others can initiate litigation relating to advertising claims. If the FDA determines that our promotional materials or training constitutes promotion of an uncleared or unapproved use, it could request that we modify our training or promotional materials or subject us to regulatory or enforcement actions, including the issuance of an untitled letter, a notice of violation, a warning letter, injunction, seizure, civil fine, or criminal penalties. In that event, our reputation could be damaged and adoption of the products could be impaired.

We are also subject to regulation under the Radiation Control for Safety and Health Act of 1968 (the "Safety Act"), which is 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.

Foreign Regulation

Many foreign countries in which we market or may market our products have regulatory bodies and restrictions similar to those of the FDA. International sales are subject to foreign government regulation, the requirements of which vary substantially from country to country. The time required to obtain approval by a foreign country may be longer or shorter than that required for FDA clearance and the requirements may differ. Companies are now required to obtain the CE Mark prior to sale of medical devices within the European Union. During this process, the sponsor must demonstrate compliance with the International Organization for Standardization's manufacturing and quality requirements. We have received CE Marking for our WaterLase and Diode laser systems. Additionally, foreign

countries in which the Company markets its products may subject the Company to regulations affecting, among other things, product standards and specifications, packaging requirements, labeling requirements, quality system requirements, import restrictions, tariffs, duties, and tax requirements. We cannot assure you that we will be able to obtain necessary foreign government approvals or successfully comply with foreign regulations. Our failure to do so could hurt our business, financial condition, and results of operations.

Other U.S. Regulation

We and subcontractors also must comply with numerous federal, state and local laws relating to matters such as safe working conditions, manufacturing practices, environmental protection, fire hazard control, and hazardous substance disposal. We are also subject to various reporting requirements including those prescribed by the Patient Protection and Affordable Care Act (the "Affordable Care Act") and Dodd-Frank Wall Street Reform and Consumer Protection Act. We cannot be sure that we will not be required to incur significant costs to comply with these laws and regulations in the future or that these laws or regulations will not hurt our business, financial condition, and results of operations. Unanticipated changes in existing regulatory requirements or adoption of new requirements could hurt our business, financial condition, and results of operations.

Environmental

Our manufacturing processes involve the use, generation, and disposal of hazardous materials and wastes, including alcohol, adhesives, and cleaning materials. As such, we are subject to stringent federal, state, and local laws relating to the protection of the environment, including those governing the use, handling, and disposal of hazardous materials and wastes. Future environmental laws may require us to alter our manufacturing processes, thereby increasing our manufacturing costs. We believe that our products and manufacturing processes at our facilities comply in all material respects with applicable environmental laws and worker health and safety laws; however, the risk of environmental liabilities cannot be completely eliminated.

Health Care Fraud and Abuse

In the U.S., there are federal and state anti-kickback laws that generally prohibit the payment or receipt of kickbacks, bribes, or other remuneration in exchange for the referral of patients or other health-related business. For example, the Federal Health Care Programs' Anti-Kickback Law (42 U.S.C. § 1320a-7b(b)) prohibits anyone from, among other things, knowingly and willfully offering, paying, soliciting, or receiving any bribe, kickback, or other remuneration intended to induce the referral of patients for, or the purchase order, or recommendation of, health care products and services reimbursed by a federal health care program, including Medicare and Medicaid. Recognizing that the federal anti-kickback law is broad and potentially applicable to many commonplace arrangements, Congress and the Office of Inspector General within the Department of Health and Human Services ("OIG") has created statutory "exceptions" and regulatory "safe harbors." Exceptions and safe harbors exist for a number of arrangements relevant to our business, including, among other things, payments to bona fide employees, certain discount and rebate arrangements, and certain payment arrangements. Although an arrangement that fits into one or more of these exceptions or safe harbors is immune from prosecution, arrangements that do not fit squarely within an exception or safe harbor do not necessarily violate the law and the OIG or other government enforcement authorities will examine the practice to determine whether it involves the sorts of abuses that the statute was designed to combat. Violations of this federal law can result in significant penalties, including imprisonment, monetary fines and assessments, and exclusion from Medicare, Medicaid, and other federal health care programs. Exclusion of a manufacturer, like us, would preclude any federal health care program from paying for its products. In addition to the federal anti-kickback law, many states have their own laws that parallel and implicate anti-kickback restrictions analogous to the federal anti-kickback law, but may apply regardless of whether any federal health care program business is involved. Federal and state anti-kickback laws may affect our sales, marketing and promotional activities, educational programs, pricing and discount practices and policies, and relationships with dental and medical providers by limiting the kinds of arrangements we may have with hospitals, alternate care market providers, physicians, dentists, and others in a position to purchase or recommend our products.

Federal and state false claims laws prohibit anyone from presenting, or causing to be presented, claims for payment to third-party payers that are false or fraudulent. For example, the federal Civil False Claims Act (31 U.S.C. § 3729 et seq.) imposes liability on any person or entity who, among other things, knowingly and willfully presents, or causes to be presented, a false or fraudulent claim for payment by a federal health care program, including Medicaid and

Medicare. Some suits filed under the False Claims Act, known as “qui tam” actions, can be brought by a “whistleblower”, or “relater” on behalf of the government and such individuals may share in any amounts paid by the entity to the government in fines or settlement. Manufacturers, like us, can be held liable under false claims laws, even if they do not submit claims to the government, where they are found to have caused submission of false claims by, among other things, providing incorrect coding or billing advice about their products to customers that file claims, or by engaging in kickback arrangements with customers that file claims. A number of states also have false claims laws, and some of these laws may apply to claims for items or services reimbursed under Medicaid and/or commercial insurance. Sanctions under these federal and state laws may include civil monetary penalties, exclusion of a manufacturer’s products from reimbursement under government programs, and imprisonment.

The Health Insurance Portability and Accountability Act of 1996 (“HIPAA”) created two new federal crimes: health care fraud and false statements related to health care matters. The health care fraud statute prohibits, among other things, knowingly and willfully executing a scheme to defraud any health care benefit program, including private payers. A violation of this statute is a felony and may result in fines, imprisonment, or exclusion from government sponsored programs. The false statements statute prohibits, among other things, knowingly and willfully falsifying, concealing or covering up a material fact, or making any materially false, fictitious, or fraudulent statement in connection with the delivery of or payment for health care benefits, items, or services. A violation of this statute is a felony and may result in fines and imprisonment.

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.

The Foreign Corrupt Practices Act and similar worldwide anti-bribery laws in non-U.S. jurisdictions generally prohibit companies and their intermediaries from making improper payments to non-U.S. officials for the purpose of obtaining or retaining business.

Due to the breadth of some of these laws, it is possible that some of our current or future practices might be challenged under one or more of these laws. In addition, there can be no assurance that we would not be required to alter one or more of our practices to be in compliance with these laws. Evolving interpretations of current laws or the adoption of new federal or state laws or regulations could adversely affect many of the arrangements we have with customers and physicians. Our risk of being found in violation of these laws is increased by the fact that some of these laws are broad and open to interpretation. If our past or present operations are found to be in violation of any of these laws, we could be subject to civil and criminal penalties, which could hurt our business, financial condition, and results of operations.

Privacy and Security of Health Information

Numerous federal, state, and international laws and regulations govern the collection, use, and disclosure of patient-identifiable health information, including HIPAA. HIPAA applies to covered entities, which include most healthcare (including dental) facilities that purchase and use our products. The HIPAA Privacy Rule restricts the use and disclosure of patient information, and requires covered entities to safeguard that information and to provide certain rights to individuals with respect to that information. The HIPAA Security Rule establishes elaborate requirements for safeguarding patient information transmitted or stored electronically. We are not a covered entity but due to activities that we perform for or on behalf of covered entities, we are sometimes deemed to be a business associate of covered entities.

In certain circumstances, the HIPAA rules require covered entities to contractually bind us, as a business associate, to protect the privacy and security of health information we may encounter during activities like training customers on the use of our products or investigating product performance. The Health Information Technology for Economic and Clinical Health Act (“HITECH”) enacted in February 2009, made significant amendments to the HIPAA Privacy and Security Rules. Most provisions of HITECH were effective February 17, 2010; however, the new federal health data breach notice provision which requires business associates to notify covered entities of any breach of unsecured health information went into effect in September 2009. Prior to February 17, 2010, our business was not directly subject to the HIPAA Privacy and Security Rules. As a business associate, our privacy and security related obligations were solely contractual in nature and governed by the terms of each business associate agreement. HITECH fundamentally changed a business associate’s obligations by imposing a number of HIPAA Privacy Rule requirements and a majority of HIPAA Security Rule provisions directly on business associates and making business associates directly subject to

HIPAA civil and criminal enforcement and the associated penalties for violation of the Privacy and Security Rule requirements. HITECH increased civil penalty amounts for violations of HIPAA by either covered entities or business associates and requires the U.S. Department of Health and Human Services to conduct periodic audits to confirm compliance. In addition, HITECH authorizes state attorneys general to bring civil actions in response to violations of HIPAA Privacy and Security Rules that threaten the privacy of state residents. Due to the very recent enactment of HITECH and expected implementing regulations, we are unable to predict what the extent of the impact on our business will be, but these new HITECH requirements may require us to incur additional costs and may restrict our business operations.

The HIPAA standards also apply to the use and disclosure of health information for research, and require the covered entity performing the research to obtain the written authorization of the research subject (or an appropriate waiver) before providing that subject's health information to sponsors like us for purposes related to the research. These covered entities also typically impose contractual limitations on our use and disclosure of the health information they disclose to us. We may be required to make costly system modifications to comply with the privacy and security requirements that will be imposed on us and our failure to comply may result in liability and adversely affect our business.

Numerous other federal and state laws protect the confidentiality of patient information, including state medical privacy laws and federal and state consumer protection laws. These various laws in many cases are not preempted by the HIPAA rules and may be subject to varying interpretations by the courts and government agencies, creating complex compliance issues for us and our customers and potentially exposing us to additional expense, adverse publicity, and liability. Other countries also have, or are developing, laws governing the collection, use, and transmission of personal or patient information and these laws could create liability for us or increase our cost of doing business.

New health information standards, whether implemented pursuant to HIPAA, congressional action or otherwise, could have a significant effect on the manner in which we must handle health care related data, and the cost of complying with these standards could be significant. If we do not properly comply with existing or new laws and regulations related to patient health information we could be subject to criminal or civil sanctions.

Third Party Reimbursement

Dentists and other healthcare providers that purchase our products generally rely on third-party payers, including the Medicare and Medicaid programs and private payers, such as indemnity insurers and managed care plans, to cover and reimburse all or part of the cost of the products and the procedures in which they are used. As a result, demand for our products is dependent in part on the coverage and reimbursement policies of these payers. No uniform coverage or reimbursement policy for medical technology exists among all third-party payers, and coverage and reimbursement can differ significantly from payer to payer.

The Affordable Care Act, enacted in March 2010, is intended to expand health insurance coverage to uninsured persons in the U.S. The impact of this expansion of coverage on the sales of our products is currently unknown. The Affordable Care Act includes Medicare reimbursement policy, payment and health care delivery system, and coverage reforms, including development, implementation, and revision to prospective payment systems, any of which may adversely impact third-party reimbursements received by our end-user customers. Centers for Medicare and Medicaid Services (“CMS”), the federal agency responsible for administering the Medicare program, along with its contractors, establish coverage and reimbursement policies for the Medicare program. In addition, private payers, whom often follow the coverage and reimbursement policies of Medicare, and employer-sponsored health care plans, are subject to rules and penalties under the Affordable Care Act which may also adversely impact third-party reimbursements received by our end-user customers. We cannot assure you that government or private third-party payers will cover and reimburse the procedures using our products in whole or in part in the future or that payment rates will be adequate and we continue to assess the impact of the Affordable Care Act on our business.

In general, we expect Medicare will continue to cover a medical product or procedure when the product or procedure is reasonable and necessary for the diagnosis or treatment of an illness or injury, or to improve the functioning of a malformed body part. Even if the medical product or procedure is considered medically necessary and coverage is available, Medicare may place restrictions on the circumstances where it provides coverage.

Medicare payments also are frequently made under a prospective payment system based on the ambulatory payment classifications (“APCs”), under which individual items and procedures are categorized. Providers of outpatient services typically receive reimbursement the applicable APC payment rate for a procedure regardless of the actual cost for such treatment. Some outpatient services for which our products may be used do not receive separate reimbursement. Rather, their reimbursement is deemed packaged into the APC for an associated procedure, and the payment for that APC does not vary depending on whether the packaged procedure is performed. Some procedures also are paid through Composite APCs, which are APCs that establish a payment rate that applies when a specific combination of services is provided. We believe that most of the procedures being performed with our current products generally are reimbursable, with the exception of cosmetic applications, such as teeth whitening.

Because payments through the prospective payment system are based on predetermined rates and may be less than a provider's actual costs in furnishing care, providers have incentives to lower their operating costs by utilizing products that will decrease labor or otherwise lower their costs. We cannot be certain that dental and medical service providers will purchase our products, despite the clinical benefits and opportunity for cost savings that we believe can be derived from their use. If providers cannot obtain adequate coverage and reimbursement for our products, or the procedures in which they are used, our business, financial condition, and results of operations could suffer.

Employees

At December 31, 2013, the Company employed approximately 220 people. Our employees are not represented by any collective bargaining agreement and we believe our employee relations are good.

Executive Officers of the Registrant

The executive officers of the Company are elected each year at the organizational meeting of the Board of Directors ("Board"), which follows the annual meeting of stockholders, and at other Board meetings, as appropriate.

At March 17, 2014, the executive officers of the Company were as follows:

Name	Age	Position
Federico Pignatelli	61	Chief Executive Officer and Chairman of the Board
Alexander K. Arrow, MD	43	President and Chief Operating Officer
Frederick D. Furry	46	Chief Financial Officer

Federico Pignatelli has served as our Chief Executive Officer ("CEO") since August 2010 and Chairman of the Board since September 2010. Mr. Pignatelli served as Chairman of our Board from 1994 until March 2006, at which point he resigned as Chairman of the Board and became Chairman Emeritus. Mr. Pignatelli served as our President from January 2008 until June 2010. From November 2007 to January 2008, Mr. Pignatelli served as interim CEO. Mr. Pignatelli has served as a director since 1991. Mr. Pignatelli is the Founder, and has served as President, of Art & Fashion Group since 1992. Art & Fashion Group is a holding company of an array of businesses providing services to the advertising industry, including the world's largest complex of digital and film still photography studios for production and post-production. Previously, Mr. Pignatelli was a Managing Director at Gruntal & Company, an investment banking and brokerage firm, and was a Managing Director of Ladenburg, Thalmann & Co., an investment banking and brokerage firm.

Alexander K. Arrow, MD, has served as our President and Chief Operating Officer since June. Dr. Arrow has also served on the Board of Rindex Medical, a cardiovascular device start-up, since June 2011. Dr. Arrow was the Chief Medical and Strategic Officer of Circuit Therapeutics, Inc., a Stanford-affiliated neurological device company seeking to commercialize optogenetics-enabled products, from 2012 until 2013. From 2007 through 2012, Dr. Arrow was the Chief Financial Officer and Medical Director of Arstasis, Inc., a 115-employee cardiology device manufacturer. From 2002 until 2007, Dr. Arrow headed medical technology equity research at the global investment bank Lazard. From 1999 through 2001, Dr. Arrow served as Chief Financial Officer of The Patent & License Exchange, Inc. Dr. Arrow holds a medical doctorate from Harvard Medical School and a bachelor's degree in biophysics, magna cum laude, from Cornell University.

Frederick D. Furry has served as our Chief Financial Officer since November 2010. From October 2011 to June 2013, Mr. Furry also served as our Chief Operating Officer. From July 2004 to December 2009, Mr. Furry served as an audit partner of Windes & McClaughry. Mr. Furry is a certified public accountant (inactive) and has significant experience working with manufacturing and high technology companies with more than 18 years with public accounting firms, including PricewaterhouseCoopers. Mr. Furry holds a master's of business administration and bachelor's of business administration from University of California, Riverside.

Available Information

Our Annual Report on Form 10-K, Quarterly Reports on Form 10-Q, Current Reports on Form 8-K and amendments to reports filed or furnished pursuant to Sections 13(a) and 15(d) of the Securities Exchange Act of 1934, as amended, are available free of charge on our website at http://www.biolase.com, as soon as reasonably practicable after the Company electronically files such reports with, or furnishes those reports to, the Securities and Exchange Commission. We are providing our internet site solely for the information of investors. We do not intend the address to be an active link or to otherwise incorporate the contents of the website into this report.

Additional Information

BIOLASE®, ZipTip®, ezlase®, eztips®, MD Flow®, Comfortpulse®, WaterLase®, iLase®, iPlus®, WCLI®, World Clinical Laser Institute®, WaterLase MD®, WaterLase Dentistry®, Proprietary MD®, and EZLase It's So Easy® are registered trademarks of Biolase, Inc., and Diolase™, HydroPhotonics™, LaserPal™, HydroBeam™, Occulase™, Diolase 10™ Body Contour™, Radial Firing Perio Tips™, Deep Pocket Therapy with New Attachment™, 2R™ , Comfortpulse™, Rapidprep™, Bondprep™, Occulase iPlus™, Flavorflow™, Occulase MD™, Epic Laser™, Epic™, Dermalase™, Deltalaser™, Delta™, iStar iStar™, Biolase DaVinci Imaging™, Oculase™, WaterLase MDX™, Total Technology Solution™, Geyserlaser™, Geyser™, elase™, and Galaxy BioMill™ are trademarks of BIOLASE, Inc. All other product and company names are registered trademarks or trademarks of their respective owners.

Item 1A. Risk Factors

The following risk factors and other information included in this Form 10-K should be carefully considered. The risks and uncertainties described below are not the only ones we face. Additional risks and uncertainties not presently known to us or that we presently deem less significant may also impair our business operations. If any of the following risks come to fruition, our business, financial condition, results of operations and future growth prospects would likely be materially and adversely affected. In these circumstances, the market price of our stock could decline, and you could lose all or part of your investment.

Risks Related to Our Revenue

Although our financial statements have been prepared assuming the Company will continue as a going concern, our management and our independent registered public accounting firm, in its report accompanying our consolidated financial statements as of and for the year ended December 31, 2013, believe that our recurring losses from operations and other factors have raised substantial doubt about our ability to continue as a going concern as of December 31, 2013.

Our audited financial statements for the fiscal year ended December 31, 2013, were prepared on a going concern basis in accordance with United States generally accepted accounting principles. The going concern basis of presentation assumes that we will continue in operation for the next twelve months and will be able to realize our assets and discharge our liabilities and commitments in the normal course of business and do not include any adjustments to reflect the possible future effects on the recoverability and classification of assets or the amounts and classification of liabilities that may result from our inability to continue as a going concern. Our need for additional capital and the uncertainties surrounding our ability to raise such funding, raises substantial doubt about our ability to continue as a going concern. In order for us to continue operations beyond the next twelve months and be able to discharge our liabilities and commitments in the normal course of business, we must sell our products directly to end-users and through distributors; establish profitable operations through increased sales and a reduction of operating expenses; and potentially raise additional funds, principally through the additional sales of our securities or debt financings to meet our working capital needs. We intend to increase sales by increasing our product offerings, expanding our direct sales force and expanding our distributor relationships both domestically and internationally. However, we cannot guarantee that we will be able to increase sales, reduce expenses or obtain additional funds when needed or that such funds, if available, will be obtainable on terms satisfactory to us. If we are unable to increase sales, reduce expenses or raise sufficient additional capital we may be unable to continue to fund our operations, develop our products or realize value from our assets and discharge our liabilities in the normal course of business. These uncertainties raise substantial doubt about our ability to continue as a going concern. If we become unable to continue as a going concern, we may have to liquidate our assets, and might realize significantly less than the values at which they are carried on our financial statements, and stockholders may lose all or part of their investment in our common stock.

Continued global economic uncertainty and volatility in financial markets may continue to adversely affect our liquidity, operating results, and financial condition.

Our business is highly sensitive to changes in general economic conditions as a seller of capital equipment to end users in dental professional practices. Financial markets inside the United States and internationally have experienced extreme disruption in recent times, 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;

increase price competition in our served markets; and
result in supply interruptions, which could disrupt our ability to produce our products.

We have experienced net losses for each of the past three years and we may experience additional losses and have difficulty achieving profitability in the future.

We had an accumulated deficit of approximately $123.8 million at December 31, 2013. We recorded net losses of approximately $11.5 million, $3.1 million, and $4.5 million for the years ended December 31, 2013, 2012, and 2011, 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.

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. If cash generated from our operations is insufficient to fund such growth, we may be required to raise additional funds through further debt or equity financings, which may dilute 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 through debt financing, 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 dental or medical device industries;
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 distributors may cancel, reduce or delay orders of our products, any of which could reduce our revenue.

We rely on exclusive and non-exclusive independent distributors for a portion of our sales in North America and a majority of our sales in countries outside of the United States and Canada. For the fiscal years ended December 31, 2013, 2012, and 2011 revenue from distributors accounted for approximately 30%, 23%, and 42% of our total net revenue, respectively. Our ability to maintain or increase our revenue will depend in large part on our success in developing and maintaining relationships with our current distributors and developing relationships with new distributors. Our distributors have significant discretion in determining the efforts and resources they apply to the sale of our products. Our distributors may not commit 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. From time to time, we may face competition or pricing pressure from one or more of our non-exclusive distributors in certain geographic areas where those distributors are selling inventory to the same customer base as us. Additionally, most of our distributor agreements can be terminated with limited notice, and we may not be able to replace any terminating distributor in a timely manner or on terms agreeable to us, if at all. If we are not able 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.

Dentists and patients have been hesitant in adopting laser technologies and our inability to overcome this hesitancy could limit the market acceptance of our products and market share.

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 dentists 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. In order to invest in a WaterLase system, a dentist generally needs to invest time to understand the technology, consider how patients may respond to the new technology, assess the financial impact the investment may have on the dentist's practice and become comfortable performing procedures with our products. 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. Dentists may not accept or adopt our products until they see additional clinical evidence supporting the safety and efficiency of our products or recommendations supporting our laser systems by influential dental practitioners. 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.

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 users of our laser systems. It is critical to the success of our sales efforts to adequately train a sufficient number of dental practitioners. 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 may be less likely to appreciate 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.

If future data proves to be inconsistent with our clinical results or if competitors' products present more favorable 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. Additionally, if future studies indicate that our competitors' products are more effective or safer than ours, 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.

We face competition from other companies, many of which have substantially greater resources than we do. If we do not successfully develop and commercialize enhanced or new products that remain competitive with products or alternative technologies developed by others, we could lose revenue opportunities and customers and our ability to grow our business would be impaired.

A number of competitors have substantially greater capital resources, larger customer bases, larger technical, sales and marketing forces and have established stronger reputations with target customers than ours. 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. The marketplace is highly fragmented and very competitive. We expect that the rapid technological changes occurring in the healthcare industry may lead to the entry of new competitors, particularly if dental and medical lasers gain increasing market acceptance. If we do not compete successfully, our revenue and market share may decline.

Our long-term success depends upon our ability to (i) 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; and (ii) develop and successful commercialize new products, new or improved technologies, and additional applications for our existing dental and medical lasers.

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 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 teeth 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.

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

Section 382 of the Internal Revenue Code (“IRC”) 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 IRC 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, 2013, approximately $77.9 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 an IRC Section 382 limitation. In addition, any ownership changes qualifying under IRC Section 382, including changes resulting from or affected by public offerings or stock repurchase plans, 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.

Risks Related to Our Intellectual Property

If the patents that we own or license, or our other intellectual property rights, do not adequately protect our technologies, we may lose market share to our competitors and be unable to operate our business profitably.

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 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 or more desirable products, duplicate our products, or design products that circumvent our patents. 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 have been recent changes in patent laws and rules of the U.S. Patent and Trademark Office, and there may be future proposed changes which, if enacted, may have a significant impact on our ability to protect our technology and enforce our intellectual property rights. If we fail to protect our intellectual property rights adequately, our competitive position and financial condition may be adversely affected.

If third parties claim that we infringe their intellectual property rights, we may incur liabilities and costs and may have to redesign or discontinue selling certain products.

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 affect our business.

Risks Related to Our Regulatory Environment

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 control testing, labeling control, 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 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.

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 FDA 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 or region. 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.

Changes in the health care industry in the U.S. and elsewhere could adversely affect the demand for our products as well as the way in which we conduct our business. Significantly, President Obama signed health care reform legislation into law that will require most individuals to have health insurance, establish new regulations on health plans, and create insurance pooling mechanisms and other expanded public health care measures. In general, an expansion in government's role in the U.S. health care industry may lower reimbursements for our products or the procedures for which our products are used, reduce demand for innovative products, reduce volumes for dental and medical procedures, and adversely affect our business and results of operations, possibly materially. In addition, as a result of the focus on health care reform, there is risk that Congress may implement changes in laws and regulations governing health care service providers, including measures to control costs, or reductions in reimbursement levels.

We may be subject to or otherwise affected by federal and state health care laws, including fraud and abuse and health information privacy and security laws, and could face penalties 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;
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;
federal provisions of HIPAA that established federal crimes for knowingly and willfully executing a scheme to defraud any health care benefit program or making false statements in connection with the delivery of or payment for health care benefits, items or services;
federal and state false claims laws that prohibit anyone from presenting, or causing to be presented, claims for payment to third-party payers that are false or fraudulent;
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, or 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.

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.

Our products are subject to recall even after receiving FDA clearance or approval; any recalls 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 would be particularly harmful to our business and financial results because the laser systems compose such an important part of our portfolio of products.

Our business and results of operations may be adversely affected by provisions of the Affordable Care Act.

Under the Affordable Care Act, we are subject to a 2.3% excise tax payable semi-monthly on U.S. revenues of certain medical devices beginning in January 2013. A significant portion of our revenue is generated from medical devices sold in the U.S. and these taxes are imposed on us whether or not we earn a profit. The Affordable Care Act also contains reporting requirements of certain payments made by us to medical and dental practitioners and teaching hospitals (the "Physician Payment Sunshine Act") which will be published on a publicly available website annually beginning in 2014. This requirement is expected to increase the administrative costs for both manufacturers and health care providers and may result in a decline in our collaborative efforts. A decline in these collaborations may adversely affect advances in our laser technology or may reduce attendance at events at which our technology is demonstrated, which could reduce demand for our products and lead to sales price pressures.

Additionally, the Affordable Care Act may adversely impact third-party reimbursements received by our end-user customers, which may reduce demand for our products. There may be other provisions in the law that could adversely affect our business, and we cannot predict with any certainty the full impact this legislation may have on our business.

Risks Related to Our Business and Operations

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

We currently handle a significant portion of the marketing, distribution, and sales of our products. We also utilize our relationships with domestic and international distributors to market, distribute, and sell our products. We face significant challenges and risks in expanding, training, managing, and retaining our sales and marketing teams, including managing geographically dispersed operations. 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 our distribution partners 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.

We may incur problems in manufacturing our products which 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 the 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 ensure our manufacturing facilities, processes, and quality systems, and the manufacture of our laser systems comply with FDA regulations governing 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 QSR 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 with acceptable manufacturing costs, while at the same time maintaining good quality control and complying with applicable regulatory requirements, our business could be harmed.

Components used in our products are complex in design and any defects may not be discovered prior to shipment to customers. These defects could result in warranty obligations which would increase our cost and may negatively affect our operating results and our reputation.

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 non-compliance in the future, which could lead to higher costs and 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.

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

The sale of dental and medical devices involves the risk of product liability claims against us. Claims could exceed our product liability insurance coverage limits. Our insurance policies are 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 suppliers may not supply us with a sufficient amount of materials and components or materials and components of adequate quality.

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 involves 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 acceptable 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.

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.

Failure to effectively manage and implement our growth strategies could negatively affect our business, financial condition, and results of operations.

Our growth strategy includes adding new vendors and products to further expand our offerings within existing product markets and developing new product offerings leveraging our patented laser technologies and strategic relationships for entry into new product markets. Expansion of our existing product markets and entry into new product markets divert the use of our resources and systems, require additional resources that might not be available (or available on acceptable terms), require additional country-specific regulatory approvals, result in new or increasing competition, may require longer implementation times or greater start-up expenditures than anticipated, and may otherwise fail to achieve the desired results in a timely fashion, if at all. These efforts may also require that we successfully commercialize new technologies in a timely manner, price them competitively and cost-effectively, and manufacture and deliver sufficient volumes of new products of appropriate quality on time. If we are unable to increase our sales and earnings by expanding our product offerings in a cost effective manner, if we fail to accurately predict future customer needs and preferences, or if we fail to produce viable technologies, then our revenues may not grow, which would adversely affect our profitability. In addition, we may invest heavily in research and development of products that do not lead to significant revenue, which would adversely affect our profitability. Even if we successfully innovate and develop new products and product enhancements, we may incur substantial costs in doing so, and our profitability may suffer. In addition, promising new products may fail to reach the market or realize only limited commercial success because of efficacy or safety concerns, failure to achieve positive clinical outcomes, or uncertainty over third-party reimbursement, which could also adversely affect our profitability.

Our failure to effectively manage our growth could have an adverse effect on our business, financial condition, or results of operations. Additionally, our growth may increase our working capital requirements and as a result, we may require additional equity or debt financing. Such financing may not be available on terms that are favorable to us, if at all.

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 years ended December 31, 2013, 2012, and 2011, international sales

accounted for approximately 37%, 29%, and 33% of our net revenue, respectively. 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 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. 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. 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.

Risks generally associated with our information systems could adversely affect our results of operations.

We rely on information systems ("IS") in our business to obtain, rapidly process, analyze and manage data to, among other things:

facilitate the purchase and distribution of thousands of inventory items through numerous distributors;
receive, process and ship orders on a timely basis;
accurately bill and collect from thousands of customers;
process payments to suppliers; and
provide technical support to our customers.

A cyber-attack that bypasses our IS security causing an IS security breach may lead to a material disruption of our IS and/or the loss of business information, which could adversely affect our business. These risks may include, among others, the following:

future results could be adversely affected due to the theft, destruction, loss, misappropriation or release of confidential data or intellectual property;
operational or business delays resulting from the disruption of IS and subsequent clean-up and mitigation activities; and
liability for a breach of personal financial and health information belonging to our customers and their patients.

Our results of operations could be adversely affected if our IS are interrupted, damaged by unforeseen events, incur cyber-attacks or fail for any extended period of time.

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. We believe that this trend exists because a significant number of dentists purchase their capital equipment towards the end of the calendar year in order to maximize their practice earnings while seeking to minimize their taxes. This can be accomplished by utilizing certain tax incentives, such as accelerated depreciation methods for purchasing capital equipment, as part of their year-end tax planning. 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. Our historical seasonal fluctuations may also be impacted by sales procedures employed by large dental distributors that encourage end-of-quarter and end-of-year buying in our industry. 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. Other factors that might cause quarterly fluctuations in our revenue and operating results include 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;
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;
legal expenses, particularly related to litigation matters;
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 carry-forwards under the provisions of IRC 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.

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

The credit availability and liquidity of our customers and suppliers may be materially affected by the ongoing credit 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. The recent recession made, and may continue to make, such funding less readily available. Any reduction in the sales of our products would cause our business to suffer.

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, 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 settlements or become subject to equitable remedies that could adversely affect our business, financial condition, 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.

Our operations are consolidated primarily in one facility. A disruption at this facility could result in a prolonged interruption of our business and adversely affect our results of operation and financial condition.

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. Additionally, labor disputes, maintenance requirements, power outages, equipment failures, civil unrest, or terrorist attacks affecting our Irvine, California facility may materially and adversely affect our operating results. Our business interruption insurance coverage may not cover all or any of our losses from natural disasters or other disruptions.

If we lose the services of our key personnel, or if we are unable to attract other key personnel, we may not be able to manage our operations or meet our growth objectives.

We are highly dependent on our senior management, especially Federico Pignatelli, our Chief Executive Officer, Fred Furry, our Chief Financial Officer, and other key employees. We are also heavily dependent on our engineers, sales and marketing personnel, and other highly skilled technical personnel. Our success will depend on our ability to retain our current management, engineers, marketing and sales team, and other technical personnel and to attract and retain qualified like personnel in the future. Competition for senior management, engineers, marketing and sales personnel, and other specialized technicians is intense and we may not be able to retain our personnel. The loss of the services of members of our key personnel could prevent the implementation and completion of our objectives, including the development and introduction of our products. In general, our officers may terminate their employment at any time without notice for any reason.

Existing or future acquisitions of businesses could negatively affect our business, financial condition, and results of operations if we fail to integrate the acquired businesses successfully into our existing operations or if we discover previously undisclosed liabilities.

Successful acquisitions depend upon our ability to identify, negotiate, complete, and integrate suitable acquisitions and to obtain any necessary financing. 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. Even if we complete acquisitions, we may experience:

difficulties in integrating any acquired companies, personnel, products, and other assets into our existing business;
delays in realizing the benefits of the acquired company, product, or other assets;
diversion of our management’s time and attention from other business concerns;
limited or no direct prior experience in new markets or countries we may enter;
higher costs of integration than we anticipated; and
Difficulties in retaining key employees of the acquired business who are necessary to manage these acquisitions.

In addition, an acquisition could materially impair our operating results by causing us to incur debt or requiring us to amortize expenses and acquired assets. We may also discover deficiencies in internal controls, data adequacy and integrity, product quality, regulatory compliance, and product liabilities that we did not uncover prior to our acquisition of such businesses, which could result in us becoming subject to penalties or other liabilities. Any difficulties in the integration of acquired businesses or unexpected penalties or liabilities in connection with such businesses could have a material adverse effect on our business, financial condition, and result of operations.

If we fail to comply with the reporting obligations of the Securities Exchange Act of 1934 and Section 404 of the Sarbanes Oxley Act of 2002, or if we fail to maintain adequate internal control over financial reporting, our business, results of operations and financial condition and investors’ confidence in us could be materially and adversely affected.

As a public company, we are required to comply with the periodic reporting obligations of the Securities Exchange Act of 1934, as amended, or the Exchange Act, including preparing annual reports, quarterly reports, and current reports. Our failure to prepare and disclose this information in a timely manner and meet our reporting obligations in their entirety could subject us to penalties under federal securities laws and regulations of The Nasdaq Stock Market LLC, expose us to lawsuits, and restrict our ability to access financing on favorable terms, or at all.

Section 1502 of the Dodd-Frank Wall Street Reform and Consumer Protection Act added Section 13(p) to the Securities Exchange Act of 1934 which requires us to disclose annually whether any conflict minerals, including tantalum, tin, gold, and tungsten, that are necessary to the functionality or production of a product manufactured by us originated in the Democratic Republic of the Congo or an adjoining country. Components of our products containing these minerals are sourced through various vendors who may have complex supply chains which may change from time to time due to the influence of availability, pricing, or other factors in their purchasing decisions. We are required to conduct a good faith and reasonable effort to determine the source of these materials; however, there can be no assurance that members in the supply chain will be willing or able to provide this information or further identify their sources of supply or notify us timely of changes. We must comply with the final rule for the calendar year beginning January 1, 2013 with the first reports due May 31, 2014.

In addition, pursuant to Section 404 of the Sarbanes Oxley Act of 2002, as amended (the "Sarbanes Oxley Act"), we are required to evaluate and provide a management report of our systems of internal control over financial reporting. During the course of the evaluation of our internal control over financial reporting, we may identify areas requiring improvement and may be required to design enhanced processes and controls to address issues identified through this review. This could result in significant delays and costs to us and require us to divert substantial resources, including management time, from other activities. In addition, if we fail to maintain the adequacy of our internal controls over financial reporting, we may not be able to ensure that we can conclude on an ongoing basis that we have effective internal control over financial reporting in accordance with the Sarbanes Oxley Act. Moreover, effective internal controls are necessary for us to produce reliable financial reports and are important to help prevent fraud. Any failure to maintain the requirements of Section 404 on a timely basis could result in the loss of investor confidence in the reliability of our financial statements, which in turn could harm our business, negatively impact the trading price of our stock, and adversely affect investors' confidence in our company and our ability to access capital markets for financing.

Climate change initiatives may materially and adversely affect our business.

Our manufacturing processes require that we purchase significant quantities of energy from third parties, which results in the generation of greenhouse gases, either directly on-site or indirectly at electric utilities. Both domestic and international legislation to address climate change by reducing greenhouse gas emissions and establishing a price on carbon could create increases in energy costs and price volatility. Considerable international attention is now focused on development of an international policy framework to address climate change. Proposed and existing legislative efforts to control or limit greenhouse gas emissions could affect our energy source and supply choices as well as increase the cost of energy and raw materials derived from sources that generate greenhouse gas emissions. If our suppliers are unable to obtain energy at a reasonable cost in the future, the cost of our raw materials may be negatively impacted which could result in increased manufacturing costs.

Risks Related to Our Stock

Our stock price may be volatile, and your investment in our stock could suffer a decline in value.

There has been significant volatility in the market price and trading volume of equity securities, which is often unrelated to the financial performance of the companies issuing the securities. These broad market fluctuations may negatively affect the market price of our stock. The market price and volume of our common stock may fluctuate, and in the past has fluctuated, more dramatically than the stock market in general. You may not be able to resell your shares at or above the price you paid for them due to fluctuations in the market price of our stock caused by changes in our operating performance or prospects and other factors. Some specific factors, in addition to the other risk factors identified above, that may have a significant effect on our stock market price, many of which we cannot control. These include but are not limited to:

actual or anticipated fluctuations in our operating results or future prospects;

our announcements or our competitors' announcements of new products;
the public's reaction to our press releases, our other public announcements, and our filings with the SEC;
strategic actions by us or our competitors, such as acquisitions or restructurings;
new laws or regulations or new interpretations of existing laws or regulations applicable to our business;
changes in accounting standards, policies, guidance, interpretations, or principles;
changes in our growth rates or our competitors' growth rates;
developments regarding our patents or proprietary rights or those of our competitors;
our inability to raise additional capital as needed;
concerns or allegations as to the safety or efficacy of our products;
changes in financial markets or general economic conditions;

sales of stock by us or members of our management team, our Board, or certain institutional stockholders; and changes in stock market analyst recommendations or earnings estimates regarding our stock, other comparable companies or our industry generally.

You could experience substantial dilution of your investment as a result of subsequent exercises of our outstanding convertible securities, future sales of our equity, or the future grant of equity by us.

You could experience substantial dilution of your investment as a result of subsequent exercises of outstanding options and warrants issued as incentive compensation for services performed by employees, directors, consultants, and others, future sales of our equity, or the grant of future equity awarded by us. As of December 31, 2013, an aggregate of 7,750,000 shares of common stock were reserved for future issuance under our equity incentive plan, 4,441,000 of which were subject to options outstanding as of that date at a weighted average exercise price of $3.51 per share. In addition, as of December 31, 2013, 1,598,000 shares of our common stock were subject to warrants at a weighted average exercise price of $5.66 per share. Of the 4,441,000 outstanding stock options at December 31, 2013, 2,688,000 stock options were exercisable. To the extent that outstanding options are exercised, our existing stockholders may incur dilution. We rely heavily on equity awards to motivate current employees and to attract new employees. The grant of future equity awards by us to our employees and other service providers may further dilute our stockholders. We also expect to issue additional shares of our equity securities to raise capital. During 2013, we sold approximately 2.7 million shares of common stock through a registered direct offering for gross proceeds totaling approximately $5.0 million, and sold 340,000 shares of common stock through an unregistered direct offering for gross proceed totaling approximately $612,000. During 2011, we sold approximately 2.5 million shares of common stock through a controlled equity offering for gross proceeds totaling approximately $9.3 million and we also sold an aggregate of 1.6 million shares in a private placement for gross proceeds totaling approximately $9 million. Our Board declared a 0.5% stock dividend in each of the four quarters in 2013 and 2012 and a 1% stock dividend in each of the four quarters in 2011 which resulted in the issuance of 667,342 shares, 634,162 shares, and 1,165,715 shares, respectively.

Our corporate documents and Delaware law contain provisions that could discourage, delay, or prevent a change in control of our company and reduce the market price of our stock.

Provisions in our restated certificate of incorporation and amended and restated bylaws may discourage, delay, or prevent a merger or acquisition involving us that our stockholders may consider favorable. For example, our restated certificate of incorporation authorizes our Board to issue up to 500,000 shares of “blank check” preferred stock. As a result, without further stockholder approval, the Board has the authority to attach special rights, including voting and dividend rights, to this preferred stock. With these rights, preferred stockholders could make it more difficult for a third party to acquire us.

We are also subject to the anti-takeover provisions of the Delaware General Corporation Law. Under these provisions, if anyone becomes an “interested stockholder,” we may not enter into a “business combination” with that person for three years without special approval, which could discourage a third party from making a takeover offer and could delay or prevent a change in control of us. An “interested stockholder” generally means (subject to certain exceptions as described in the Delaware General Corporation Law) someone owning 15% or more of our outstanding voting stock or an affiliate of ours that owned 15% or more of our outstanding voting stock during the past three years.

In addition, we have adopted a stockholder rights plan. Under the stockholder rights plan, if any party acquires 20% or more, as amended February 4, 2014, of our outstanding common stock while the stockholder rights plan remains in place, subject to a number of exceptions set forth in the plan, the holders of these rights, other than the party acquiring the 20% 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 20% position. Following the acquisition of 20% 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, if we are acquired by or merged with any other entity, holders of these rights, other than the party acquiring the 20% 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. Our stockholder rights plan could discourage a takeover attempt and make an unsolicited takeover of our company more difficult. As a result, without the approval of our Board, you may not have the opportunity to sell your shares to a potential acquirer of us at a premium over prevailing market prices. This could reduce the market price of our stock.

We may elect to not declare cash dividends on our stock, or may elect to only pay dividends on an infrequent or irregular basis, and any return on your investment may be limited to the value of our stock.

Our Board may from time to time declare, and we may pay, cash dividends on our outstanding shares of common stock in the manner and upon the terms and conditions provided by law. However, we may elect to retain all future earnings for the operation and expansion of our business, rather than paying cash dividends on our stock. Any payment of cash dividends on our stock will be at the discretion of our Board and will depend upon our results of operations, earnings, capital requirements, financial condition, business prospects, contractual restrictions, and other factors deemed relevant by our Board. In the event our Board declares any cash dividends, there is no assurance with respect to the amount, timing, or frequency of any such dividends.

We could be negatively affected as a result of a proxy fight and related litigation.

In March 2014, we received from Oracle Partners, L.P., Oracle Institutional Partners, L.P., Oracle Ten Fund Master, L.P., Oracle Associates, LLC, Oracle Investment, Inc., and Larry N. Feinberg (collectively "Oracle"), which reports that it owns 16% of our common stock, declared its intention to change the composition of our Board. Oracle nominated a majority opposition slate of individuals for election to replace our Board at the 2014 Annual Meeting of Stockholders and has stated its dissatisfaction with our performance and senior management. Oracle has filed a lawsuit against our Board with respect to the present composition of our Board and the operation of the Company until the Court determines the Board composition, see Item 3 — "Legal Proceedings." A proxy contest and related litigation could negatively affect us because:

- Responding to proxy contests, litigation, and other actions by dissident shareholders can be costly and time-consuming, disrupting our operations and diverting the attention of management and our employees;
- Perceived uncertainties as to our future direction may divert the attention of, damage morale, and create instability among our business partners, management, and employees, and adversely impact our existing and potential strategic and operational relationships and opportunities;
- We may experience difficulties in hiring, retaining, and motivating personnel during the resulting uncertain and turbulent times;
- If individuals are elected to our Board with a specific agenda, it may adversely affect our ability to effectively and timely implement our current business plan which could have a material adverse effect on our results of operations and financial condition;
- Increases in legal fees, administrative, and associated costs incurred in connection with responding to a proxy contest and related litigation could be substantial; and
- A proxy contest, or the threat of one, could cause our stock price to experience periods of volatility or stagnation.

Risks Related to Our Revolving Credit Facilities

The terms of our revolving credit facilities impose financial and operating restrictions on us and failure to comply may have an adverse effect on our business, liquidity, and financial position.

Our revolving credit facilities contain a number of negative covenants that limit our ability to engage in activities. These covenants limit or restrict, among other things, our ability to:

incur additional indebtedness and grant liens on assets;
make certain investments and restricted payments (including the ability to pay cash dividends and repurchase stock);
undertake certain acquisitions or sell certain assets;
enter into certain transactions with our affiliates; and
replace our Chief Executive Officer or Chief Financial Officer, unless our Board determines, in good faith, exigent circumstances require their prompt replacement.

These limitations and restrictions may adversely affect our ability to finance our future operations or capital needs or engage in other business activities that may be in our best interests. Further, the revolving credit facilities subject us to

various reporting covenants and financial covenants, including requirements to maintain certain levels of debt ratios and minimum earnings before income taxes, depreciation, and amortization (“EBITDA”).

The lockbox arrangements under the revolving bank facilities provide that substantially all of the income generated is deposited directly into lockbox accounts and then swept into cash management accounts for the benefit of the bank. Cash is disbursed to us only after payment of the applicable debt service and principal.

Our ability to borrow under the revolving bank facilities is subject to compliance with the negative and financial covenants. If we breach any of the covenants in our revolving credit facilities, we may be in default under our revolving credit facilities. If we default, our borrowings under the revolving credit facilities, plus accrued interest and other fees, could be declared due and payable.

Item 1B. Unresolved Staff Comments

None.

Item 2. Properties

As of December 31, 2013, we owned or leased a total of approximately 73,000 square feet of space worldwide. We lease our corporate headquarters and manufacturing facility which consists of approximately 57,000 square feet in Irvine, California. Our lease expires on April 20, 2015. We also own a 12,000 square foot manufacturing and administrative facility in Floss, Germany. See Note 3 to the Notes to the Consolidated Financial Statements – Property, Plant, and Equipment, Net.

We believe that our current facilities are sufficient for the current operations of our business and we believe that suitable additional space in various applicable local markets is available to accommodate any needs that may arise.

Item 3. Legal Proceedings

We disclose material loss contingencies deemed to be reasonably possible and accrue for loss contingencies when, in consultation with our legal advisors, we conclude that a loss is probable and reasonably estimable. The ability to predict the ultimate outcome of such matters involves judgments, estimates, and inherent uncertainties. The actual outcome of such matters could differ materially from management’s estimates.

Class Action Lawsuits

On August 23, 2013, a purported class action lawsuit entitled Brady Adams v. Biolase, Inc., et al., Case No. 13-CV-1300 JST (FFMx) was filed in the United States District Court for the Central District of California against BIOLASE and its current executive officers Federico Pignatelli and Frederick D. Furry. On August 26, 2013, a purported class action lawsuit entitled Ralph Divizio v. Biolase, Inc., et al., Case No. 13-CV-1317 DMG (MRWx) was filed in the same court against BIOLASE, Messrs. Pignatelli and Furry, and current executive officer Alexander K. Arrow. Each of the lawsuits alleges violations of the federal securities laws and asserts causes of action against the defendants under Sections 10(b) and 20(a) of the Securities Exchange Act of 1934. In accordance with the Private Securities Litigation Reform Act of 1995, on December 10, 2013, the court entered an order consolidating the lawsuits, appointing a lead plaintiff and approving lead plaintiff's selection of lead counsel. On February 24, 2014, lead plaintiff filed a consolidated complaint against BIOLASE and Messrs. Pignatelli, Furry, and Arrow, alleging violations of the federal securities laws and asserting causes of action against the defendants under Sections 10(b) and 20(a) of the Securities Exchange Act of 1934.

On November 19, 2013, our Board received a letter from attorneys for purported shareholder David T. Long, demanding that the Board investigate, institute litigation, and take measures to redress and prevent alleged wrongdoing concerning the dissemination of certain allegedly false and misleading public disclosures we made

between January 2013 and August 2013.

As of December 31, 2013, we paid $250,000 for legal costs expected to be incurred in connection with these matters. We believe that the claims contained in the lawsuits are without merit and intend to vigorously defend against the claims.

Director Dispute and Shareholder Litigation

On March 3 and 6, 2014, we disclosed that the Board had appointed Paul N. Clark and Jeffrey M. Nugent to the Board and Dr. Alexander K. Arrow and Dr. Sam Low had tendered their resignations. Subsequent to this disclosure, questions were raised as to whether these changes were effected.

On March 7, 2014, we received from Oracle, which reports that it is a 16% shareholder, a notice pursuant to our Bylaws, stating that Oracle intended to nominate four independent directors for election to the Board at our 2014 Annual Meeting of Stockholders. Oracle's nominees are Messrs. Clark and Nugent, Frederic H. Moll, and Eric Varma, M.D.

On March 11, 2014, Oracle filed a lawsuit in the Delaware Court of Chancery seeking a determination of the composition of our Board and a temporary restraining order that would preclude our Board from taking any action without the approval of four purported directors whose directorships Oracle claims to be undisputed.

We have reason to believe that Oracle and individuals who may be, depending on the outcome of the foregoing dispute, members of our Board will seek to make changes in our senior management and the composition of our Board and its committees.

Intellectual Property Litigation

On April 24, 2012, CAO Group, Inc. (“CAO”) filed a lawsuit against us in the District of Utah for patent infringement of U.S. Patent No. 7,485,116 regarding our EZlase dental laser. On September 9, 2012, CAO filed its First Amended Complaint, which added claims for (1) business disparagement/injurious falsehood under common law and (2) unfair competition under 15 U.S.C. Section 1125(a). The additional claims stem from a press release that we issued on April 30, 2012, which CAO claims contained false statements that are disparaging to CAO and its diode product. The First Amended Complaint seeks injunctive relief, treble damages, attorneys’ fees, punitive damages, and interest. On November 13, 2012, the Court stayed the lawsuit for 120 days to allow the United States Patent and Trademark Office (“USPTO”) to consider our request for reexamination of the patent-in-suit. The USPTO granted the request to reexamine the asserted claims of the patent-in-suit and, on February 28, 2013, the Court stayed the lawsuit until the termination of the reexamination proceedings. On April 23, 2013, the USPTO issued an office action rejecting all of the asserted claims over the prior art, and CAO responded to the office action. On August 28, 2013, the USPTO issued an Action Closing Procedure, rejecting all of CAO’s patent claims. CAO responded to the USPTO’s ruling and on December 10, 2013, the USPTO issued a Right of Appeal Notice, finally rejecting some claims of the patent while finding that other claims appeared to be patentable. Both parties are permitted to appeal the USPTO’s findings to the Patent Trial and Appeal Board. We appealed the USPTO’s findings on January 9, 2014. On January 27, 2014, the USPTO declined to reconsider the finding of certain claims as patentable and instructed the parties to proceed to appeal to the Patent Trial and Appeal Board.

We filed a patent infringement lawsuit against Fotona dd. (“Fotona”) in Düsseldorf District Court alleging infringement with respect to the Fotona Fidelis dental laser system. Oral proceedings are currently scheduled for March 2014. Fotona denies liability and seeks the reimbursement of statutory fees from us. Together with its response brief, Fotona also filed a nullity action against the patent in dispute, patent number EP 1 560 470. The nullity action is pending at the German Federal Patent Court (the “Patent Court”), Docket No. 1 Ni 58/13 (EP). On September 2, 2013, we filed our counterplea in the infringement proceedings and phrased our arguments defending the validity of the patent. These arguments were also the subject of the defense brief to the Patent Court in the parallel nullity action proceedings. On September 9, 2013, we filed our response to the Patent Court. Fotona filed a rejoinder on February 3, 2014, including our counterplea on nullity.

False Advertising Lawsuit

We filed a false advertising lawsuit against Fotona and Technology4Medicine L.L.C., two of our competitors (together "the Defendants") in United States District Court for the Central District of California. The lawsuit alleges six causes of action, and claims that the Defendants have made false and misleading statements regarding the Company's products, technology, and management. The lawsuit, filed on February 20, 2014, seeks both cash damages and injunctive relief.

Other Matters

In the normal course of business, we are subject to legal proceedings, lawsuits, and other claims. Although the ultimate aggregate amount of probable monetary liability or financial impact with respect to these matters is subject to many uncertainties and is therefore not predictable with assurance, management believes that any monetary liability or financial impact to us from these matters, individually and in the aggregate, would not be material to our financial condition, results of operations, or cash flows. However, there can be no assurance with respect to such results, and monetary liability or financial impact to us from these other matters could differ materially from those projected.

Item 4. Mine Safety Disclosures

Not applicable.

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 traded on the NASDAQ Capital Market under the symbol "BIOL."

The following table sets forth the high and low closing prices for our common stock for the periods indicated:

	2013		2012	
	High	Low	High	Low
First Quarter	$4.46	$1.88	$3.43	$2.44
Second Quarter	$5.90	$3.57	$2.99	$1.72
Third Quarter	$4.02	$1.20	$2.00	$1.50
Fourth Quarter	$3.06	$1.51	$2.37	$1.65

The above quotations reflect inter-dealer prices, without retail markup, markdown, or commission and may not necessarily represent actual transactions.

As of February 28, 2014, the closing price of our common stock on the NASDAQ Capital Market was $3.09 per share, and the number of stockholders of record was 169. We believe that the number of beneficial owners is substantially greater than the number of record holders because a large portion of our stock is held of record through brokerage firms in “street name.”

Dividend Policy

We currently intend to retain our available funds from earnings and other sources for future growth and, therefore, do not anticipate paying any cash dividends in the foreseeable future. Stock dividends are discussed quarterly by our Board and management. The actual declaration of future stock dividends, and the establishment of record and payment dates, is subject to final determination by our Board after its review of our financial performance, expected future operations and earnings, and any other factors as our Board may deem relevant. Our dividend policy may be changed at any time, and from time to time, by our Board.

Sale of Unregistered Common Stock

On December 19, 2013, we entered into a subscription agreement (the “December 2013 Subscription Agreement”) with Oracle Ten Fund Master, L.P. under which we sold an aggregate of 340,000 unregistered shares of common stock in a private placement at a price of $1.80 per share. Gross proceeds from the sale totaled $612,000. The common stock has not been registered under the Securities Act of 1933 (the "Act") and was offered pursuant to the exemptions from registration promulgated under the Act. No registration rights were provided and none of the common stock sold may be re-offered or resold absent either registration under the Act or the availability of an exemption from the registration requirements.

The following table sets forth certain information relating to our stock dividends declared during 2013, 2012, and 2011:

Declaration Date	Record Date