BIOLASE, INC
Form 10-K
March 06, 2015

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, 2014

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 001-36385

BIOLASE, INC.

(Exact Name of Registrant as Specified in Its Charter)

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

4 Cromwell

Irvine, California 92618

(Address of Principal Executive Offices, including zip code)

(949) 361-1200

(Registrant's Telephone Number, Including Area Code)

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

(Title of each class)	(Name of each exchange on which registered)
Common Stock, par value $0.001 per share	The NASDAQ Stock Market LLC (NASDAQ 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 ¨	Non-accelerated filer ¨ (Do not check if a smaller reporting company)	Smaller Reporting Company x

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 $65,540,168 based on the last sale price of common stock on June 30, 2014.

As of February 27, 2015, there were 58,152,792 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 2015 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, 2014, 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, 2014

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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 from those expressed or implied by such forward-looking statements. Examples of forward-looking statements include, but are not limited to any statements, predictions or expectations regarding our strategy, the number of hard tissue and periodontal procedures for 2015, future demand for improved dental care, earnings, revenue, sales and operations, operating expenses, sales and marketing expenses, legal expenses and professional fees, planned investments in engineering and development, excise tax 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, plans to expand our direct sales force, intentions to implement new software, 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 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," "expect," "believe," "anticipate," "estimate," "predic "seek" and similar expressions.

These forward-looking statements are based on the expectations, estimates, projections, beliefs and assumptions of our management based on information available to management as of the date on which this Form 10-K was filed with the Securities and Exchange Commission (the "SEC") or as of the date on which the information incorporated by reference was filed with the SEC, as applicable, all of which are subject to change. 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:

- global economic uncertainty and volatility in financial markets;
- inability to raise additional capital on terms acceptable to us;
- our relationships with, and the efforts of, third-party distributors;
- our inability to overcome the hesitation of dentists and patients to adopt laser technologies;
- failure in our efforts to train dental practitioners;
- inconsistencies between future data and our clinical results;
- competition from other companies, including those with greater resources;
- our inability to successfully develop and commercialize enhanced or new products that remain competitive with products or alternative technologies developed by others;
- the inability of our customers to obtain third-party reimbursement for their use of our products;
- limitations on our ability to use net operating loss carryforwards;
- failure of our intellectual property rights to adequately protect our technologies;
- potential third-party claims that our products infringe their intellectual property rights;
- our failure to comply with existing or new laws and regulations, including fraud and abuse and health information privacy and security laws;
- delays or cancellation of our product sales or introductions as a result of the Food and Drug Administration ("FDA") regulatory process;
- recall of our products, even after receiving FDA clearance or approval;
- problems in manufacturing our products;
- warranty obligations if our products are defective;

- adverse publicity regarding our technology or products;
- litigation, including product liability claims against us;

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- failure of our suppliers to supply us with a sufficient amount or adequate quality of materials;
- rapidly changing standards and competing technologies;
- our inability to effectively manage and implement our growth strategies;
- risks associated with operating in international markets, including potential liabilities under the Foreign Corrupt Practices Act ("FCPA");
- breaches of our information technology systems;
- seasonality;
- disruptions to our operations at our primary facility;
- loss of our key management personnel or our inability to attract or retain qualified personnel;
- risks and uncertainties relating to acquisitions, including difficulties integrating acquired businesses successfully into our existing operations and risks of discovering previously undisclosed liabilities; and
- failure to comply with the reporting obligations of the Exchange Act and Section 404 of the Sarbanes Oxley Act of 2002 or maintain adequate internal control over financial reporting.

Further information about factors that could materially affect the Company, including our results of operations and financial condition, is contained under "Risk Factors" in Item 1A in this Form 10-K. Except as required by law, we undertake no obligation to revise or update any forward-looking statements to reflect changed assumptions, the occurrence of anticipated or unanticipated events, new information or changes to future results over time or otherwise.

PART I

Item 1. Business

Overview

BIOLASE, Inc. ("BIOLASE" and, together with its consolidated subsidiaries, the "Company," "we," "our" or "us") is medical device company that develops, manufactures, markets, and sells laser systems in dentistry and medicine and also markets, sells, and distributes dental imaging equipment, including cone beam digital x-rays and CAD/CAM intra-oral scanners, in-office, chair-side milling machines and three-dimensional ("3-D") printers. Our products advance the practice of dentistry and medicine for patients and health care professionals. Our proprietary dental laser systems allow dentists, periodontists, endodontists, oral surgeons, and other dental specialists to perform a broad range of minimally invasive dental procedures, including cosmetic, restorative, and complex surgical applications. Our laser systems are designed to provide clinically superior results for many types of dental procedures compared to those achieved with drills, scalpels, and other conventional instruments. We have clearance from the U.S. Food and Drug Administration (the "FDA") to market and sell our laser systems in the United States and also have the necessary registrations to market and sell our laser systems in Canada, the European Union, and many other countries outside the U.S. Additionally, our in-licensed imaging equipment and related products improve diagnoses, applications, and procedures in dentistry and medicine.

We offer two categories of laser system products: WaterLase (all-tissue) systems and Diode (soft tissue) systems. Our flagship brand, WaterLase, uses a patented combination of water and laser energy to perform most procedures currently performed using 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 have approximately 250 issued and 100 pending U.S. and international patents, the majority of which are related to WaterLase technology. From 1998 through December 31, 2014, we sold approximately 27,600 laser systems in over 80 countries around the world. Contained in this total are over 10,600 WaterLase systems, including more than 6,600 WaterLase MD and WaterLase iPlus systems. 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 in 2012, we changed our name to BIOLASE, Inc. Since 1998, we have been the global leading innovator, manufacturer, and marketer of dental laser systems.

We currently operate in a single reportable business segment. We had net revenues of $47.7 million, $56.4 million, and $57.4 million in 2014, 2013, and 2012, respectively, and we had net losses of $18.9 million, $11.5 million, and $3.1 million for the same periods.

Recent Developments

Significant Leadership Changes and Capital Infusions

Beginning in the second half of 2014, we appointed new key personnel to management to lead our sales and marketing department, including a new Vice President of Worldwide Sales and Account Management as well as a new Vice President and Chief Marketing Officer. Furthermore, in the fourth quarter of 2014, we enhanced our sales force domestically and internationally. We have also formed a new Dental Professional Advisory Board, made up of four founding members, who have made significant contributions to the specialties of periodontics, implantology, oral surgery, multi-stage restorative therapy, and peri-implantitis therapy. Our goal is to refocus our energies on strengthening leadership, worldwide competitiveness and attention to our professional customers and their patients.

We completed two private placements in the latter half of 2014 totaling approximately $46.3 million in net proceeds after offering expenses. We used a portion of the proceeds to pay off our lines of credit in July 2014. The remainder of the proceeds is being used for working capital and general corporate purposes.

New Product Offerings

In February 2015, we launched the WaterLase iPlus 2.0 and introduced Practice Growth Guarantee, a guarantee to assure growth in dental practices. The WaterLase iPlus 2.0 includes innovations and improvements designed to enhance patient experience and generate practice growth for dental practitioners through routine use. WaterLase iPlus 2.0 also marks the debut of the SureFire YSGG Delivery System which ensures greater uptime and routine use for dentists.

In December 2014, we introduced the EPIC X diode laser, an enhanced soft-tissue laser system featuring upgrades and improvements from our EPIC 10, that was released in 2012. EPIC X includes enhancements to nearly every system component to optimize treatment speed and efficiency, including pre-initiated diode tips, allowing dentists to significantly reduce procedure time.

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.

In the most recent update, a 2007 American Dental Association ("ADA") Survey of Dental Services Rendered (the "ADA Study") 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. Moreover, iData Research, an international market research group that specializes in medical devices, projects 391 million hard tissue procedures for 2015.

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 cosmetic smile design, gingivectomies and frenectomies. According to the ADA 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. iData Research estimates 1.7 million periodontal procedures will be performed in 2015.

The ADA estimated that the demand for dental services in the United States continues to grow due to population growth, aging demographics, the Patient Protection and Affordable Care Act (the "Affordable Care Act") and increased awareness of the benefits of preventive dentistry in reducing the incidence of oral and systemic disease.

We believe there is a growing awareness among consumers of the value and importance of oral health and its connections to overall systemic health and wellness. Studies indicate a link between periodontitis and other health conditions such as heart disease, diabetes, and stroke. According to the 2013 Distribution of Dentists in the U.S. by Region and State, there are 177,625 active private practitioners in the U.S. According to the World Health Organization in 2012, there were 1.8 million dentists worldwide. As many developing nations continue to experience fiscal growth, we believe those nations will also experience higher demand for improved dental care. Corresponding growth resulting from dental practices competing for patients could create further demand for clinical solutions that enable dentists to perform minimally invasive dental procedures with less trauma, improved patient acceptance, and clinically superior results. We believe our product offerings align with this trend.

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 desired results.

High Speed Drills. Most dentists use conventional high speed drills for hard tissue procedures, such as preparing cavities for filling, gaining access for performing root canals, and shaving or 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, such as micro-fractures, to the patient's teeth. The trauma can lead to longer 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 and are often the source of patient anxiety and fear. Because many dentists do not recommend anesthetizing more than one or two sections of the mouth in a single appointment, patients may need to return several times to complete their treatment plan.

Cutting Instruments. Soft tissue procedures are typically performed by oral surgeons or periodontists using scalpels, scissors, and other surgical tools. Due to the pain, bleeding, post-operative swelling and discomfort associated with these instruments, most soft tissue procedures require the use of local anesthetic which may result in numbness and

longer recovery time, and often require stitches. 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 for patients taking blood-thinning medications.

Film Radiography Equipment. Dentists have traditionally 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, 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 ability 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.

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 systems are generally less precise than lasers and can damage surrounding tissue. Electrosurge systems are also not suitable for hard tissue procedures and, due to the depth of penetration, generally require anesthesia and a lengthy healing process. Electrosurge systems generally cannot be used in areas near metal fillings and dental implants. Finally, electrosurge systems generally cannot be used to 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, but are not optimally designed to perform common dental procedures. Most dental lasers use thermal energy to cut tissue and are used primarily for soft tissue procedures.

Products

Combining our laser system products with imaging solutions provides dental professionals capabilities for early diagnosis and minimally invasive treatment. Our product offering consists of the following:

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. Each of these systems features our patented YSGG Laser technology with a proprietary laser crystal, which contains the elements erbium and chromium doped with yttrium, scandium, gallium, and garnet (Er, Cr: YSGG). This unique crystal laser produces energy with specific absorption and tissue interaction characteristics specifically designed for dental applications. It is minimally invasive and can precisely cut hard tissue, such as bone and teeth, and soft tissue, such as gums and skin, without the heat, vibration, bleeding or pressure associated with traditional dental treatments. By combining the YSGG laser light and water, our WaterLase systems may eliminate the need for anesthesia and also result in faster healing times compared to traditional methods of treatment.

The WaterLase systems incorporate an ergonomic hand-piece and a user-friendly digital interface with clinical applications 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. We developed the WaterLase systems using internally developed intellectual property, as well as intellectual property obtained through various acquisitions. The WaterLase systems are FDA cleared in the United States and CE mark-approved in Europe.

Diode systems. Our Diode (soft tissue) laser systems currently consist of the EPIC and iLase, semiconductor diode lasers that perform soft tissue, hygiene, cosmetic procedures, teeth whitening, and temporary pain relief. Each of these laser systems features our unique 940nm diode wavelength to deliver successful clinical outcomes for common surgical procedures. EPIC and iLase feature our proprietary pulse technology called ComfortPulse, which is designed for added patient comfort. iLase, released in 2010, was the first “personal” laser with no wires, footswitch, or cumbersome cables to manage. EPIC, released in 2012, is a portable, powerful diode laser that facilitates clinical versatility with surgical, pain therapy and whitening capabilities and provides an exceptional laser with an attractive value proposition. We developed the Diode systems using internally developed intellectual property, as well as intellectual property obtained through acquisitions. The iLase and Epic are FDA cleared in the United States and CE mark-approved in Europe.

Imaging systems. Our imaging systems include in-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. Our imaging systems provide both high-precision intuitive diagnosis and treatment planning solutions, which help dental practitioners to deliver the best clinical outcomes for patients. Our imaging systems include the CEFLA NewTom VGi and VG3, 3-D Cone Beam Computed Tomography devices. We distribute these products under the manufacturer's FDA 510(k) clearance.

3Shape Trios CAD/CAM digital impression systems. The 3Shape system offers a spray-free scanning device for enhanced accuracy and patient comfort, high speed technology with accurate digital impression-taking with up to 1,000 3-D pictures, a touchscreen interface with live 3-D visualization, online communication capability with labs, and practitioner efficiency and convenience. We distribute this product under the manufacturer's FDA 510(k) clearance.

In-office milling system. The Galaxy BioMill CAD/CAM system enables dental practitioners to complete scanning, designing, milling, and finishing of crowns, inlays, and veneers in the dental office in a single appointment.

3-D Printers. We distribute Stratasys' 3-D printers, which 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. 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.

Related Accessories and Consumable Products

We also manufacture and sell consumable products and accessories for our laser systems. Our WaterLase and Diode systems use disposable laser tips of differing sizes and shapes depending on the procedure being performed. We also market flexible fibers and hand pieces that dental practitioners replace at some point after initially purchasing laser systems. For our EPIC and ezLase systems, we sell teeth whitening gel kits.

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 outcomes, help reduce 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, bone, and soft tissue with minimal or no damage to surrounding tissue and dental structures. Our Diode systems are designed to complement our WaterLase systems, and are used only 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 in-licensed Cefla NewTom products are state-of-the-art digital imaging 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 high quality images while exposing patients to minimal amounts of radiation.

The in-licensed 3Shape Trios ("Trios") intra-oral CAD/CAM scanner 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 utilizes the 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 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. Using the Stratasys 3-D printers, dentists and dental laboratories can fabricate stone models, orthodontic appliances, delivery and positioning trays, models for clear aligners, retainers and surgical guides.

We believe that by combining high-end digital imaging, laser systems, intra-oral scanning, CAD/CAM design, chair-side milling, and 3-D printing, dental offices can accurately and rapidly address a variety of unmet patient needs conveniently.

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Benefits to Dental Professionals

- Expanded range of procedures and revenue opportunities. Our laser systems allow general dentists to perform surgical and cosmetic procedures that they are unable or unwilling to perform using conventional methods, and that would typically be referred to a specialist. Our laser systems allow dentists to perform these procedures easily and efficiently, increasing their range of skills, professional satisfaction, patient retention and attraction, 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 or other 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. The WaterLase and Diode systems cut soft tissue 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 REPair, our proprietary periodontal treatment or protocol and subgingival calculus removal using the WaterLase system and patented Radial Firing Perio Tips. This is a minimally invasive 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, our EPIC system can be used to quickly perform in-office teeth whitening with our proprietary whitening gel and to provide temporary pain relief. The Galaxy BioMill System and Stratasys 3-D printers allow for same-day crowns.
- 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 helps improve patient retention, attract new patients, and increase revenue per patient, demand for elective procedures, acceptance of treatment plans, and word-of-mouth referrals.
- Improved clinical outcomes. 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 improved clinical outcomes and less follow-up treatment. In addition, our laser systems may reduce the risk of cross-contamination that can occur with traditional dental tools. The Galaxy BioMill System and Stratasys 3-D printers further expand treatment options available to patients and allow for same-day crowns. Thus, our products make it possible for practitioners to devote time to new cases, rather than treating complications.

Benefits to Patients

- Comfort. Our WaterLase systems allow dentists to perform minimally invasive dental procedures without anesthesia in many cases and patients recover more comfortably, faster, and with less pain than when treated with conventional instruments. The heat, vibration, microfractures, trauma, or pressure associated with traditional dental methods are largely avoided.
- Convenience. Our WaterLase systems do not require anesthesia in many cases, which allows dental practitioners to perform multiple procedures in one appointment, which saves patients time. Digital images are available almost immediately, so patients do not have to spend extra time in the dental chair waiting for film to be developed. Further, the Galaxy BioMill System and Stratasys 3-D printers allow for same-day crowns.
- Reduced trauma. WaterLase systems allow for a faster and more pleasant patient recovery with less swelling, bleeding, and general discomfort than when treated with conventional instruments.
- Broader range of available procedures. Due to the comfort and convenience of our WaterLase system, patients may be more likely to consider cosmetic and other elective procedures resulting in better smiles and oral health. Since digital images are displayed on computer monitors, doctors can make treatment planning a more personal experience for patients. Further, the Galaxy BioMill System and Stratasys 3-D printers offer patients the benefits of same day crowns. We believe that these factors will lead to greater patient case acceptance.

Business Strategy

Our business strategy includes the following key elements:

- Increasing awareness of and demand for our products among dental practitioners. We intend to increase demand for our products by educating dental practitioners and patients about the clinical benefits of our product suite. 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. Our products are also used for clinical research, which often leads to published articles that can garner attention from dental practitioners.
- Increasing awareness of and demand for our laser systems among patients. We also intend to increase demand for our products by educating patients about the clinical benefits of the WaterLase and Diode systems. We believe that patients will understand the clinical benefits and seek out dental practitioners that offer the WaterLase and Diode systems, which, in turn, will result in increased demand for our systems from dental practitioners. Consequently, we are testing methods of marketing directly to patients, utilizing a number of social and other media channels.
- Creating value through innovation and leveraging existing technologies into adjacent medical applications. We plan to expand our product line and clinical applications by developing enhancements and transformational innovations, including new clinical solutions for dental applications and for other adjacent medical applications. In particular, we believe that our existing technologies can provide significant improvements over existing standards of care in fields, 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 plan to continue to explore potential collaborations to bring our proprietary laser technologies to other medical applications. In addition or alternatively, we may acquire complementary products and technologies. We also aim to increase our consumables revenue by selling more single-use accessories used by dental practitioners when performing procedures using our dental laser systems.
- Improving product quality. We plan to achieve the industry's highest rate of defect-free delivery of products, adopt high quality standards, and address and timely resolve customer complaints. In connection with our initiative to measure, improve, and increase customer satisfaction and confidence, in 2014, we extended the warranty for WaterLase systems from one to two years for systems purchased in 2014 or later. In the U.S., we provide maintenance and support services to customers through our support hotline and dedicated staff of in-house and field service personnel. Outside the U.S., we maintain a network of factory-certified service technicians to provide maintenance and support services to customers.
- Strengthening sales and distribution capabilities. In the U.S. and Canada, we primarily distribute our products directly to dental practitioners via an outside direct sales force. During 2012, we augmented our outside direct sales force by establishing an inside sales organization. The inside sales organization 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 the inside sales organization to provide technical and clinical expertise in coordination with our laser sales representatives. In addition to our outside direct sales force in North America, we also use various independent distributors to sell and support our products throughout Europe, the Middle East, Latin America, and Asia-Pacific. We plan to continue to build out the infrastructure to support our customers and to drive revenue and profit growth, both domestically and internationally. This includes expanding our sales presence with respect to the rapidly growing group practices, group purchasing organizations, and government channels.
- Strengthening and defending technology leadership. We plan to continue protecting our intellectual property rights by expanding our existing patent portfolio in the United States and internationally. We strategically enforce our intellectual property rights worldwide.
- Strengthening customer training and clinical education. We provide introductory, advanced, and specialized training for dental practitioners to increase their proficiency and to certify them. Our goal is to provide our customers world class training that is accessible and can be executed with a practical technique.

Expanding our product portfolio to dental practitioners. By combining our digital imaging, intra-oral scanners, CAD/CAM design, chair-side milling, and 3-D printing, dental offices can accurately and timely address unmet patient needs with convenience. In 2014, we began shipping our Galaxy BioMill and 3-D printers. We plan to continue to evaluate how to optimize the manner in which we market and sell additional products to our WaterLase and Diode systems customers.

Warranties

Our WaterLase laser systems and Diode systems sold domestically are covered by a warranty against defects in material and workmanship for a period of up to two years from the date of sale to the end-user by us or a distributor. In 2014, we extended the warranty for WaterLase systems sold domestically from one to two years for systems purchased in 2014 or later. WaterLase systems and Diode systems sold internationally in 2014 are covered by a warranty against defects in material and workmanship for a period of up to twenty eight months from date of sale to the international distributor. Our laser systems 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 laser systems 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 imaging products that we distribute, including our digital radiography products. However, all imaging 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 the 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 laser systems 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, manufacture, installation, and servicing of our products. In addition, our U.S. facility is registered with the FDA and complies in all material respects 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 (hand pieces, 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. As of the date on which this Form 10-K was filed with the SEC, we were 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 worldwide. Our marketing efforts are focused on increasing brand awareness and demand among dental practitioners. We also continue to test methods to increase awareness of our brands' benefits by marketing directly to patients.

Dental Practitioners. We market our laser systems to dental practitioners through regional, national, and international trade publications, educational events, industry tradeshows, the internet, direct sales forces (in North America and Canada), agents and distributors, and seminars. We also use brochures, direct mail, public relations, and other promotional tools and materials. In 2010, we introduced the Biolase Store for online purchase of laser systems, 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 that use our products for clinical research and in-clinical training. We believe these relationships will increase awareness of and demand for our products. In 2012 we formalized a five-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, to continue expanding the availability of postgraduate advanced wavelength clinical laser education while also taking major steps toward standardizing laser dental education for all of our owners worldwide.

Patients. We plan to continue to test ways to effectively market the benefits of our laser systems directly to patients through marketing and advertising programs, including the internet, search engine optimization, social media, print and broadcast media, and point-of-sale materials in dental practitioners' offices. We believe that making patients aware of our laser systems and their benefits will motivate them to request from dental practitioners laser procedures and their outcomes thereby increasing demand for our brands. We can be found online at www.biolase.com, on Facebook at www.facebook.com/biolase, on Twitter at www.twitter.com/biolaseinc, on Pinterest at www.pinterest.com/biolase, on LinkedIn at www.linkedin.com/company/biolase, on Google+ at www.google.com/+BIOLASEIrvine, on Instagram at www.instagram.com/biolaseinc, and on YouTube at www.youtube.com/biolasevideos. Unless specifically stated otherwise, none of the information contained on any of these sites online is incorporated in this Form 10-K by reference.

Sales

We sell our products primarily to dentists in general practice through our direct sales force and our distributor network. We expect our laser systems to continue to gain acceptance among periodontists, endodontists, oral surgeons, pediatric dentists, and other dental specialists as they become aware of the clinical benefits and minimally invasive treatment options available by using our laser systems. We also sell our NewTom, 3Shape, Galaxy, and Stratasys products to dental specialists. Outside of the dental market, we expect that our initial sales of lasers will be in a regional test to ear, nose, and throat ("ENT") physicians (otolaryngologists) and we are exploring other medical adjacencies for other opportunities to expand.

The following table summarizes our net revenues by category for the years ended December 31, 2014, 2013, and 2012 (dollars in thousands):

	Years Ended December 31,								
	2014			2013			2012		
Laser systems	$29,490	61.9	%	$38,736	68.6	%	$42,348	73.8	%
Imaging systems	4,286	9.0	%	4,632	8.2	%	3,365	5.9	%
Consumables and other	6,524	13.7	%	6,458	11.5	%	5,954	10.4	%
Services revenue	7,211	15.1	%	6,360	11.3	%	5,524	9.6	%
Products and services revenue	47,511	99.7	%	56,186	99.6	%	57,191	99.7	%
License fees and royalties	145	0.3	%	244	0.4	%	165	0.3	%
Net revenue	$47,656	100.0	%	$56,430	100.0	%	$57,356	100.0	%

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

	Years Ended December 31,		
	2014	2013	2012
United States	$29,848	$35,653	$40,524
International	17,808	20,777	16,832
	$47,656	$56,430	$57,356

International revenue accounts for a significant portion of our total revenue and accounted for approximately 37%, 37%, and 29% of our net revenue in 2014, 2013, and 2012, respectively. No individual country outside the United States represented more than 10% of our net revenue during the years ended December 31, 2014, 2013, and 2012.

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, agents, and distributors for cause or non-performance. We have granted certain distributors the right to be our exclusive distributor in select territories. 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. 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, agents, and distributors. For the years ended December 31, 2014, 2013, and 2012, sales to our largest distributor worldwide accounted for approximately 6%, 5%, and 3%, respectively, of our net revenue.

Customer Service. We provide high quality maintenance and support services in the United States through our support hotline and dedicated staff of in-house and field service personnel. Outside the United States, we maintain a network of factory-certified service technicians to provide maintenance and support services to customers. 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. Most customers (other than distributors) 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 that 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. 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. Typically, we experience 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 practitioners. 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. They often use 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 promotions used 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 engineering and product development group consists of 14 individuals with medical

device and laser development experience, including two Ph.Ds. During the years ended December 31, 2014, 2013, and 2012, our engineering and product development expenses totaled approximately $4.6 million, $4.0 million, and $4.7 million, respectively. Our current engineering and product development activities are focused on developing new product platforms, 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 laser systems include faster cutting speed, improved ease of use, less need for anesthesia injections, interconnectivity, and an expanded portfolio of consumable products for use with our laser systems. Our engineering and product development activities encompass both fundamental and applied fields. We seek to improve methods to perform clinical procedures through the use of new laser wavelengths, laser operation modes and accessories.

We also devote engineering and product development resources toward markets outside of dentistry in which we might exploit our technology platform and capabilities. We believe our laser technology and development capabilities could address unmet needs in several other medical applications, 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.

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, 2014, we had approximately 250 issued patents and 100 pending patent applications in the United States, Europe and other countries. 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: 18 in 2015, 22 in 2016, four in 2017, and 20 in 2018, with the majority having expiration dates ranging from 2025 to 2038. With approximately 100 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, financial condition or results of operations.

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

Competition

We operate under relatively competitive market conditions. We believe that the principal competitive factors for companies that market technologies in dental and other medical applications 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 ours. Our laser systems compete with other lasers, mostly with other wavelengths, patient outcomes and benefit profiles, as well as with drills, scalpels, scissors, air abrasion systems, and a variety of other tools that are used to perform dental and medical procedures. We believe our products have key differentiating performance features. For example, we market diode lasers which also have FDA clearance for use in both pain management therapy and teeth whitening. 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 compete with traditional dental laboratories, imaging centers and products and services.

Traditional tools are generally less expensive than our laser systems for performing similar procedures. For example, a high speed drill or an electrosurge device can be purchased for less than $2,500 each. In addition, though our systems are superior to traditional tools in many ways, they are not intended to replace all of the applications of traditional tools, such as removing 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 that could prove to be more effective, safer, or less costly than procedures using our laser systems. The introduction of new products, procedures, or clinical solutions by competitors may result in price reductions, reduced margins, or loss of market share, 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 are subject to significantly higher user fees under the FDA Safety and Innovation Act (the "FDASIA"), which includes the Medical Device User Fee Amendments of 2012 (the "MDUFA III") as well as other medical device provisions, 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 or 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 FDASIA, which includes the MDUFA III as well as other medical device provisions, 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 will 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 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. 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 original equipment manufacturer 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, 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 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.

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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. Promotional activities for FDA-regulated products of other companies have been the subject of enforcement actions brought under health care 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, the FDA 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, an injunction, a seizure, a 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. 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, tax requirements and interactions with health care providers and/or government officials (e.g. UK Anti-Bribery Act). 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 adversely affect our business, financial condition, and results of operations.

Other U.S. Regulation

We and our 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 Affordable Care Act and the 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 adversely affect our business, financial condition, and results of operations. Unanticipated changes in existing regulatory requirements or the adoption of new requirements could adversely affect 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

As a medical device manufacturer, our operations and interactions with health care providers, including dentists, are subject to extensive laws and regulations imposed at the federal, state, and local level in the U.S., including, but not limited to, those discussed in this Form 10-K. For example, 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 Anti-Kickback Law is a criminal statute that prohibits anyone from, among other things, knowingly and willfully offering, paying, soliciting, or receiving any bribe, kickback, or other remuneration intended to induce a referral for the furnishing of, or the purchase, order, or recommendation of, any item or service reimbursable under the Federal health care programs ("FHCPs"), including Medicare, Medicaid, and TRICARE. Recognizing that the federal Anti-Kickback Law is broad and potentially applicable to many commonplace arrangements, the U.S. Congress and the Office of Inspector General ("OIG") within the Department of Health and Human Services ("HHS") have created statutory "exceptions" and regulatory "safe harbors" to the Anti-Kickback Law. Exceptions and safe harbors exist for a number of arrangements relevant to our business, including, among other things, certain payments to bona fide employees, certain discount and rebate arrangements, and certain payment arrangements with health care providers, assuming all elements of the relevant exception/safe harbor have been satisfied. Although an arrangement that fits squarely into one or more of these exceptions or safe harbors generally will not be subject to prosecution, OIG has also cautioned in various contexts that even where each component of an arrangement has been structured to satisfy a safe harbor, the components, as part of an overall arrangement, may still violate the Anti-Kickback Law. However, arrangements that do not fit squarely within an exception or safe harbor do not necessarily violate the Anti-Kickback Law. Rather, OIG and/or other government enforcement authorities will examine the facts and circumstances relevant to the specific arrangement to determine whether it involves the sorts of abuses that the statute was designed to combat. Violations of this federal law constitute a felony offense punishable by imprisonment, criminal fines of up to $25,000, civil fines of up to $50,000 per violation and three times the amount of the unlawful remuneration, and exclusion from Medicare, Medicaid, and other FHCPs. Exclusion of a manufacturer, like us, would preclude any FHCP from paying for the manufacturer's products. In addition, pursuant to the changes made by the Affordable Care Act, a claim resulting from a violation of the Anti-Kickback Law may serve as the basis for a false claim under the federal Civil False Claims Act. Many states also have their own laws that parallel and implicate anti-kickback restrictions, but may apply regardless of whether any FHCP 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 imposes liability on any person or entity that knowingly presents, or causes to be presented, a false or fraudulent claim for payment to the government, including FHCPs. Some suits filed under the Civil False Claims Act can be brought by a "whistleblower" or a "relator" 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 violation of the Civil False Claims Act could result in fines ranging from $5,500 to $11,000 (as adjusted for inflation) for each false claim, plus up to three times the amount of damages sustained by the government. A Civil False Claims Act violation may also provide the basis for the imposition of administrative penalties and exclusion from participation in FHCPs. In addition to the Civil False Claims Act, the federal government also can use several criminal statutes to prosecute persons who are alleged to have submitted false or fraudulent claims for payment to the federal government, or improperly retained funds received which were not due. Moreover, 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.

In addition to the general fraud statutes mentioned above, there are a variety of other fraud and abuse laws specific to health care. For example, the Health Insurance Portability and Accountability Act of 1996 ("HIPAA") created several new federal crimes, including 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, up to ten years imprisonment (assuming no serious bodily injury or death results), or exclusion from FHCPs. 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 items or services under a health care benefit program. A violation of this statute is a felony and may result in fines and imprisonment and could potentially result in the government's pursuit of exclusion from FHCPs. Additionally, a person who offers or transfers to a Medicare or Medicaid beneficiary any remuneration that the person knows or should know is likely to influence the beneficiary's selection of a particular provider, practitioner, or supplier of items or services payable by Medicare or Medicaid may be liable for civil money penalties of up to $10,000 for each item or service and potential exclusion from FHCPs.

The Physician Payments Sunshine Act requires us to report annually to the Centers for Medicare and Medicaid Services ("CMS") certain payments and other transfers of value we make to U.S.-licensed physicians, dentists, and teaching hospitals. These annual reports are publicly available, which could impact the number of health care providers who are willing to work with us on the research and development of our products. In addition, several states have implemented similar transparency and disclosure laws applicable to medical device manufacturers, some of which require reporting of transfers of value made to a wider variety of health care professionals and institutions.

The federal physician self-referral prohibition ("Stark Law") is a strict liability statute, which, in the absence of a statutory or regulatory exception, prohibits: (i) the referral of Medicare and Medicaid patients by a physician to an entity for the provision of designated health care 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 (ii) the submission of a bill to Medicare or Medicaid for services rendered pursuant to a prohibited referral. Penalties for violations of the Stark Law include denial of payment for the service, required refund of payments received pursuant to the prohibited referral, and civil monetary penalties for knowing violations of up to $15,000 per claim, up to $100,000 for circumvention schemes, and up to $10,000 per day for failing to report information concerning the entity's ownership, investment, and compensation arrangements upon HHS' request. Stark Law violations also may lead to False Claims Act liability and possible exclusion from FHCPs.

The Foreign Corrupt Practices Act ("FCPA") generally prohibits companies and their intermediaries from offering to pay, promising to pay, or authorizing the payment of money or anything of value to non-U.S. officials for the purpose of influencing any act or decision of the foreign official in his/her capacity or to secure any other improper advantage to obtain or retain business. Violation of the anti-bribery provisions of the FCPA can result in criminal fines of up to $2 million and civil penalties of up to $16,000 for each violation. Individuals, including officers, directors, stockholders, and agents of companies, can be subject to a criminal fine of up to $250,000 and imprisonment, in addition to civil penalties of up to $16,000, per violation.

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 some of the arrangements we have with customers, physicians, and dentists. 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, among other entities, a "health care provider" that transmits health information in electronic form in connection with certain transactions regulated under HIPAA. HIPAA also applies to "business associates," meaning persons or entities that create, receive, maintain, or transmit protected health information ("PHI") to perform a function on behalf of, or provide a service to, a covered entity. Although we are not a covered entity, most health care (including dental) facilities that purchase our products are covered entities under HIPAA. Due to activities that we perform for or on behalf of covered entities, we may sometimes act as a business associate, or our customers may ask us to enter Business Associate Agreements and assume business associate responsibilities.

Various implementing regulations have been promulgated under HIPAA. The HIPAA Security Rule requires implementation of certain administrative, physical, and technical safeguards to ensure the confidentiality, integrity, and availability of electronic PHI. The HIPAA Privacy Rule governs the use and disclosure of PHI and provides certain rights to individuals with respect to that information. For example, for most uses and disclosures of PHI, other than for treatment, payment, health care operations, and certain public policy purposes, the HIPAA Privacy Rule

generally requires obtaining valid written authorization from the individual, including in the research context. With certain limited exceptions, the covered entity performing the research must obtain valid authorization from the research subject (or an appropriate waiver) before providing that subject's PHI to sponsors like us. Furthermore, in most cases, the HIPAA Privacy Rule requires that use or disclosure of PHI be limited to the minimum necessary to achieve the purpose of the use or disclosure.

The HIPAA Privacy and Security Rules require covered entities to contractually bind us, where we are acting as a business associate, to protect the privacy and security of individually identifiable health information that we may use, access, or disclose for purposes of services we may provide. Moreover, the Health Information Technology for Economic and Clinical Health Act ("HITECH") enacted in February 2009, made certain provisions of the HIPAA Privacy and Security Rules directly applicable to business associates.

HITECH also established new breach notification requirements, increased civil penalty amounts for HIPAA violations, and requires HHS to conduct periodic audits of covered entities and business associates to confirm compliance. In addition, HITECH authorizes state attorneys general to bring civil actions in response to HIPAA violations committed against residents of their respective states.

On January 17, 2013, the Office for Civil Rights ("OCR") of HHS released an omnibus final rule ("Final Rule"), implementing HITECH. Among other provisions, the Final Rule made certain changes to the breach notification regulations, including requiring business associates to notify covered entities if a breach occurs at or by the business associate. Following a breach of unsecured PHI, covered entities must provide notification of the breach to affected individuals, the HHS Secretary, and, for breaches affecting more than 500 residents of a state or jurisdiction, prominent media outlets serving that state/jurisdiction. Breaches of health information can also give rise to class actions by affected individuals and result in significant reputational damage to the covered entity and/or business associates or other parties involved in the breach.

The Final Rule also provides for heightened governmental investigations of potential non-compliance. However, the Final Rule did not address accounting of disclosures, although such regulations are forthcoming. The proposed rule addressing accounting of disclosures, if finalized, could impose a significant burden on us, as it would require covered entities and their business associates to develop systems to monitor (1) which employees access an individual's electronic PHI contained in a designated record set, (2) the time and date such access occurs, and (3) the action taken during the access session (e.g., modification, deletion, viewing).

Failure to comply with HIPAA may result in civil and criminal penalties. Civil penalties for a single violation of the regulations occurring on or after February 18, 2009 range from $100 to more than $50,000 per violation, with a maximum penalty of $1.5 million per year for violations of an identical provision of the regulations. Criminal penalties of up to $250,000 and imprisonment may also be imposed for certain knowing violations of HIPAA. We may be required to make costly system modifications, which may restrict our business operations, to comply with HIPAA, to the extent we act as a business associate. Our failure to comply may result in liability and adversely affect our business, financial condition, and results of operations.

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 state laws may be similar to or possibly more stringent than the federal provisions. These 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, which could create liability for us or increase our cost of doing business.

New health information standards, whether implemented pursuant to HIPAA, future Congressional action, or otherwise, could have a significant effect on the manner in which we handle health information, 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 health care providers that purchase our products may rely on third-party payers, including the Medicare, Medicaid, and private payers to cover and reimburse all or part of the cost of the clinical procedures performed using our products. As a result, demand for our products is dependent in part on the coverage and reimbursement policies of these payers. 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.

No uniform coverage or reimbursement policy for dental and medical treatment exists among third-party payers, and coverage and reimbursement can differ significantly from payer to payer. Under Medicaid, for example, states are required to cover basic dental services for children, but retain discretion as to whether to provide coverage for dental services for adults. Under the Early Periodic Screening, Diagnostic, and Treatment benefit available to children, dental services determined to be “medically necessary” and provided at intervals that meet reasonable standards of dental practice are generally covered by Medicaid. Although not required to cover dental services for adults, a majority of state Medicaid programs still provide some degree of coverage for dental services.

Medicare covers dental services only in certain limited circumstances. For instance, Medicare will pay for certain dental services when provided in the inpatient hospital setting. Medicare will also pay for certain dental services that are an integral part of a covered procedure (e.g., jaw reconstruction following accidental injury), extractions done in preparation for certain radiation treatments, and oral examinations preceding kidney transplantation or heart valve replacement, under certain circumstances.

Future legislation, regulation or coverage and reimbursement policies of third-party payers may adversely affect the demand for our products. For example, the Affordable Care Act included various reforms impacting Medicare reimbursement and coverage, including revision to prospective payment systems, any of which may adversely impact any Medicare reimbursements received by our end-user customers. Moreover, the Budget Control Act of 2011, enacted on August 2, 2011, established a process to reduce federal budget deficits through an automatic "sequestration" process if deficit reductions targets are not otherwise reached. Under the terms of the Budget Control Act, sequestration imposes cuts to a wide range of federal programs, including Medicare, which is subject to a two percent cut. The Bipartisan Budget Act of 2013 extended the two percent sequestration cut for Medicare through fiscal year 2023, and a bill signed by President Obama on February 15, 2014 further extended this cut for an additional year, through fiscal year 2024. The Protecting Access to Medicare Act of 2014 realigned the fiscal year 2024 Medicare sequestration amounts so that there will be a four percent sequester for the first six months and a zero percent sequester for the second six months, instead of a two percent sequester for the full 12-month period.

In addition, private payers and employer-sponsored health care plans became subject to various rules and potential penalties under the Affordable Care Act. For example, health plans in the individual and small group markets were required to begin providing a core package of health care services, known as "essential health benefits." Essential health benefits include ten general categories of care, including pediatric services, which requires coverage of dental and vision care, among other medical services, for children. The Affordable Care Act also required employers with fifty or more employees to offer health insurance coverage to full-time workers or pay a penalty, which could potentially increase the availability of third-party reimbursement for some medical procedures using our products, although we continue to assess the impact of the Affordable Care Act on our business.

We cannot be sure 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.

Because third-party payments 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. However, 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, 2014, the Company employed approximately 210 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 meeting of the board of directors (our "Board"), which follows the annual meeting of stockholders, and at other Board meetings, as appropriate.

At March 6, 2015, the executive officers of the Company were as follows:

Name	Age	Position
Jeffrey M. Nugent	68	President and Chief Executive Officer
Brendan O'Connell	38	Vice President of Finance and Corporate Controller
Clark Barousse	49	Senior Vice President of Worldwide Sales and Account Management
Orlando Rodrigues	53	Vice President and Chief Marketing Officer

Dmitri Boutoussov	51	Vice President of Research and Development

Jeffrey M. Nugent has served as our President and Chief Executive Officer (“CEO”) since September 2014, Acting CEO since June 2014 and a Biolase director since August 2014. In December 2010, Mr. Nugent founded Precision Dermatology, Inc., a multi-channel skin care company, and he served as its President and Chief Executive Officer from December 2010 until it was acquired by Valeant Pharmaceuticals International, Inc. in February 2014. From 2008 until he founded Precision Dermatology, Inc., Mr. Nugent was Chairman and Chief Executive Officer of Ascension Orthopedics, a maker of joint replacement implants. Mr. Nugent began his career with Johnson & Johnson and progressed in increasing responsibilities in finance, operations, marketing, research and development as well as becoming corporate Vice President for Global Quality. He led the acquisition of Neutrogena and became worldwide President and CEO from 1995 to 1999. From 1999 to 2002, Mr. Nugent served as the President and Chief Executive Officer of Revlon, Inc. Mr. Nugent holds an M.B.A. in Marketing and Finance from Loyola University in Chicago and a B.S. degree in Mathematics from St. Joseph’s College.

Brendan O'Connell was appointed Vice President of Finance and Corporate Controller in January 2015. Mr. O'Connell began his career with Biolase as our Assistant Controller in May 2007 and was promoted to serve as our Corporate Controller effective February 2009. Mr. O'Connell earned a Bachelor of Science in Accounting and an M.B.A. from University of California, Riverside.

Clark Barousse joined Biolase in August 2014 and as the Senior Vice President for Worldwide Sales and Account Management. Before joining Biolase, Mr. Barousse served as President of Hybridge, a leading group of dental practices focus on implant procedures, from August 2012 to August 2014. Prior to Hybridge, Mr. Barousse was Senior Vice President of Global Sales & Marketing for Biohorizons Implant Systems, a dental implant and biologics company, from June 2008 until July 2012. Mr. Barousse earned his M.B.A. from Georgia State University and holds a Bachelor of Arts degree in Economics and Spanish from Hampden-Sydney College in Hampden-Sydney, Virginia.

Orlando Rodrigues joined Biolase in July 2014 as Vice President and Chief Marketing Officer. Prior to Biolase, Mr. Rodrigues was Principal and Senior Consultant at COR Communications, where he assisted various medical device and life sciences company's in the areas of marketing and sales, fundraising and business development from February 2013 to June 2014. He was Vice President, Global Sales and Marketing for SynergEyes, a privately-held specialty contact lens company from October 2011 to January 2013. Mr. Rodrigues was Interim President for K1 Speed, an upscale consumer entertainment concept from June 2010 to May 2011. He was Vice President of Marketing for I-Flow Corporation, a NASDAQ-traded medical device company focused on delivering a unique pain relief solution for post-surgical care, from January 2002 to May 2010. Mr. Rodrigues earned Bachelor of Arts degrees in Managerial Studies and Biochemistry from Rice University.

Dmitri Boutoussov, Ph.D. became our Vice President of Research and Development in July, 2013. Mr. Boutoussov has been with the Company since 2000 and initially joined as the Director of Engineering. He held this position from June, 2000 through April, 2005 when he became the Vice President of Engineering. He held that position until October 2010, when he was appointed Chief Technology Officer. He held the position of Chief Technology Officer until July 2013. Mr. Boutoussov holds a Doctorate Degree in Philosophy and a Master's of Science Degree in Physics from Polytechnic University in St. Petersburg, Russia.

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 (the "Exchange Act"), 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 SEC. 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

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 consider to be immaterial may also adversely affect us. If any of the following risks come to fruition, our business, financial condition, results of operations, cash flows, 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 Business and Operations

We are vulnerable to continued global economic uncertainty and volatility in financial markets.

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 $142.7 million at December 31, 2014. We recorded net losses of approximately $18.9 million, $11.5 million, and $3.1 million for the years ended December 31, 2014, 2013, and 2012, 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.

We may need to raise additional capital in the future, and if we are unable to secure adequate funds on terms acceptable to us, we may be unable to execute our business plan.

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 the issuance of equity or debt securities in the public or private markets, or through a collaborative arrangement or sale of assets. Additional financing opportunities may not be available to us, or if available, may not be on favorable terms. The availability of financing opportunities will depend, in part, on market conditions, and the outlook for our business. Any future issuance of equity securities or securities convertible into equity securities could result in substantial dilution to our stockholders, and the securities issued in such a financing may have rights, preferences or privileges senior to those of our common stock. In addition, if we raise additional funds through debt financing, we may be subject to debt covenants that 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, we may lose revenue and market share and we may have to curtail our

capital expenditures. 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 success depends, in part, on our relationships with, and the efforts of, third-party distributors.

We rely on exclusive and non-exclusive third-party distributors for a portion of our sales in North America and a majority of our sales in countries outside of the U.S. and Canada. For the fiscal years ended December 31, 2014, 2013, and 2012, revenue from distributors accounted for approximately 30%, 30%, and 23% of our total net revenue, respectively. Our distributors have significant discretion in determining the efforts and resources they apply to the sale of our products, and we face significant challenges and risks in expanding, training, and managing our third-party distributors, particularly given that their geographically dispersed operations. 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 hesitation could limit the market acceptance of our products and our market share.

Our dental laser systems represent relatively new technologies in the dental market. 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 to a broad spectrum of dentists and patients the potential performance advantages of our laser systems over traditional methods of treatment and over competitive laser systems. 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 health care 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 the relative effectiveness, safety, reliability and comfort of our systems as compared to other instruments and methods for performing dental procedures.

Any failure in our efforts to train dental practitioners could result in the misuse of our products and reduce the market acceptance of our products.

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, dental practitioners may choose not to purchase our laser systems until they receive additional published long-term clinical evidence and recommendations from prominent dental practitioners 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 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 health care 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, improving our customer support, accurately timing the introduction of new products, and developing sustainable distribution channels worldwide; and (ii) develop and successfully commercialize new products, new or improved technologies, and additional applications for our laser systems.

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 payers, such as private insurance or government programs. In the United States, third-party payers review and frequently challenge the prices charged for medical products and/or services. In many foreign countries, the prices for dental services are predetermined through government regulation. Payers may deny coverage and reimbursement on various grounds, including if they determine that the procedure was not medically necessary or that the device used in the procedure was investigational. Accordingly, both coverage and reimbursement can vary significantly from payer to payer. 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 that future health care reforms or changes in financing for health and dental plans may have on our business. Any such changes could have an adverse effect on the ability of a dental or medical professional to generate a profit using our current or future products. In addition, such changes could act as disincentives for capital investments by dental and medical professionals.

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, 2014, approximately $93.2 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.

We may incur problems in manufacturing our products.

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 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 addressing 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. Our future success depends on our ability to manufacture 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.

We may be subject to significant warranty obligations if our products are defective.

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 engineering and development departments into our service department; and
- legal action.

Adverse publicity regarding our technology or products could negatively impact us.

Adverse publicity regarding any of our products or similar products marketed or sold by others could negatively affect us. If any studies raise or substantiate concerns regarding the efficacy or safety of our products or other concerns, our reputation could be harmed and demand for our products could diminish.

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, we cannot assure you 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 or adequate quality of materials.

Our business depends on our ability to obtain timely deliveries of materials, components, and subassemblies of acceptable quality and in acceptable quantities from third-party suppliers. We generally purchase components and subassemblies from a limited group of suppliers through purchase orders, rather than written supply contracts. Consequently, many of our suppliers have no obligation to continue to supply us on a long-term basis. In addition, 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. Moreover, 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 satisfy our requirements.

Certain components of our products, particularly specialized components used in our laser systems, 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 of our suppliers ceases to provide us with sufficient quantities of our components in a timely manner or on terms acceptable to us, or ceases to manufacture components of acceptable quality, we could incur manufacturing delays and sales disruptions while we locate and engage alternative qualified suppliers, and we might be unable to engage acceptable alternative suppliers on favorable terms. In addition, we may need to reengineer our components, which may require product redesign and submission to the FDA of a 510(k) application, which could significantly delay production. 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. As of the date on which this Form 10-K was filed with the SEC, we were 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, or at all.

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 that 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.

We may be unable to effectively manage and implement our growth strategies.

Our growth strategy includes expanding our product line and clinical applications by developing enhancements and transformational innovations, including new clinical solutions for dental applications and for other adjacent medical applications. Expansion of our existing product line and entry into new medical applications 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. We may be unable to increase our sales and earnings by expanding our product offerings in a cost-effective manner, and we may fail to accurately predict future customer needs and preferences or to produce viable technologies. In addition, we may invest heavily in research and development of products that do not lead to significant revenue. Even if we successfully innovate and develop new products and product enhancements, we may incur substantial costs in doing so. 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.

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, 2014, 2013, and 2012, international sales accounted for approximately 37%, 37%, and 29% 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. However, we may do so in the future.

We may be subject to breaches of our information technology systems, which could damage our reputation and customer relationships. Such breaches could subject us to significant reputational, financial, legal, and operational consequences.

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.

- Such an attack may result in the theft, destruction, loss, misappropriation or release of confidential data and intellectual property;
- operational or business delays; and
- liability for a breach of personal financial and health information belonging to our customers and their patients. In the event of an attack, we would be exposed to a risk of loss or litigation and possible liability.

Our revenue and operating results fluctuate due to seasonality and other factors, so you should not rely on quarter-to-quarter comparisons of our operating results as an indication of our future performance.

Our revenue typically fluctuates from quarter to quarter due to a number of factors, many of which are beyond our control. 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 practitioners. 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. They often use 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 promotions used by large dental distributors that encourage end-of-quarter and end-of-year buying in our industry. Other factors that might cause quarterly fluctuations in our revenue and operating results include the following:

- variation in demand for our products;
- 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 expected net revenue. Accordingly, you should not rely on quarter-to-quarter comparisons of our operating results as an indication of our future performance.

Litigation against us could be costly and time-consuming to defend

We are from time to time involved in various claims, litigation matters and regulatory proceedings 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 as compensatory damages. The defense of these lawsuits may divert our management’s attention, and we may incur significant expenses in defending these lawsuits. In addition, we may be required to pay damage awards or settlements or become subject to unfavorable equitable remedies. Moreover, any insurance or indemnification rights that we may have may be insufficient or unavailable to protect us against potential loss exposures.

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

Substantially all of our administrative operations and our manufacturing operations are located at our facility in Irvine, California, which is near known earthquake fault zones. We have taken precautions to safeguard our facilities including disaster recovery planning and off-site backup of computer data. However, a natural disaster such as an earthquake, fire, or flood, could seriously harm our facility and significantly disrupt our operations. Additionally, labor disputes, maintenance requirements, power outages, equipment failures, civil unrest, or terrorist attacks affecting our Irvine, California facility may significantly disrupt our operations. Our business interruption insurance coverage may not cover all or any of our losses from natural disasters or other disruptions.

If we lose our key management personnel, or are unable to attract or retain qualified personnel, it could adversely affect our ability to execute our growth strategy.

Our success is dependent, in part, upon our ability to hire and retain management, engineers, marketing and sales personnel, technical, research and other personnel who are in high demand and are often subject to competing employment opportunities. Our success will depend on our ability to retain our current management, engineers, marketing and sales, technical, research and other 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. If we lose the services of any executive officers or key employees, our ability to achieve our business objectives could be harmed. In general, our officers may terminate their employment at any time without notice for any reason.

Acquisitions involve risks and uncertainties, including difficulties integrating acquired businesses successfully into our existing operations and risks of discovering 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.

In addition, an acquisition could cause us to incur debt or issue shares, resulting in dilution to existing shareholders. 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 Exchange Act 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 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 Exchange Act 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 that may change from time to time due to the influence of availability, pricing, or other factors in their purchasing decisions. On an annual basis, 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 of our supply chain will be willing or able to provide this information or further identify their sources of supply or notify us timely of changes by May 31 subsequent to year-end.

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 control 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 compliance with 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, 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 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 depends, 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 the patent laws and rules of the U.S. Patent and Trademark Office, and there may be future proposed changes that, 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 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 dental and other medical laser applications. 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 we 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.

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.

If 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. 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 PMA 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 the European Union. 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 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.

Changes in health care regulations 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 for health plans, and create insurance pooling mechanisms and other expanded public health care measures. In general, an expansion of 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, and reduce volumes for dental and medical procedures. 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, and 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 we could face substantial penalties if we are unable to fully comply with such regulations.

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, to induce the referral for the furnishing of, or the purchase, order, or recommendation of, a good or service, for which payment may be made under FHCPs such as Medicare, Medicaid, and TRICARE;
- state law equivalents to the Anti-Kickback Law, which may not be limited to government reimbursed items;
- state laws that prohibit fee-splitting arrangements;
- the federal Civil False Claims Act, which imposes liability on any person or entity that knowingly presents, or causes to be presented, a false or fraudulent claim for payment to the government, including FHCPs;
- 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;
-

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 items or services under a health care benefit program;

- federal law prohibiting offering remuneration to a Medicare or Medicaid beneficiary to influence the beneficiary's selection of a particular provider, practitioner, or supplier;
- the federal Stark Law, which, in the absence of a statutory or regulatory exception, prohibits: (i) the referral of Medicare or Medicaid patients by a physician to an entity for the provision of designated health care 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 (ii) submitting a bill to Medicare or Medicaid for services rendered pursuant to a prohibited referral;

- state law equivalents to the Stark Law, which may not be limited to government reimbursed items
- the Physician Payments Sunshine Act, which requires us to report annually to CMS certain payments and other transfers of value we make to U.S.-licensed physicians, dentists, and teaching hospitals;
- the FCPA, which generally prohibits companies and their intermediaries from paying anything of value to foreign officials to influence any decision of the foreign official in his/her official capacity or to secure any other improper advantage to obtain or retain business;
- HIPAA and HITECH and their implementing regulations, which govern the use, disclosure, and safeguarding of PHI;
- state privacy laws that protect the confidentiality of patient information;
- Medicare and Medicaid laws and regulations that prescribe the requirements for coverage and payment, including the amount of such payment; state laws that prohibit the practice of medicine by non-physicians; 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 laws or regulations to which we or our customers are subject, we may be subject to the applicable penalty associated with the violation, which may include civil and criminal penalties, damages, fines, exclusion from FHCPs, 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 could be significant. The risk of potential non-compliance is increased by the fact that many of these laws 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.

We may be exposed to liabilities under the Foreign Corrupt Practices Act, and any determination that we violated the Foreign Corrupt Practices Act could have a material adverse effect on our business, financial condition, and result of operations.

In light of our operations outside the United States, we are subject to the FCPA, which generally prohibits companies and their intermediaries from offering to pay, promising to pay, or authorizing the payment of money or anything of value to non-U.S. officials for the purpose of influencing any act or decision of the foreign official in his/her capacity or to secure any other improper advantage to obtain or retain business. Violation of the anti-bribery provisions of the FCPA can result in criminal fines of up to $2 million and civil penalties of up to $16,000 for each violation. Individuals, including officers, directors, stockholders, and agents of companies, can be subject to a criminal fine of up to $250,000 and imprisonment, in addition to civil penalties of up to $16,000, per violation. We may be held liable for actions taken by our distributors in violation of the FCPA, even though such partners are foreign companies that may not be subject to the FCPA. Any determination that we violated the FCPA could result in sanctions that could have a material adverse effect on our business, financial condition, and result of operations.

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.

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 us, because our laser systems comprise such an important part of our portfolio of products.

We 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. 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 is published on a publicly available website annually. This requirement increases 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.

Risks Related to Our Stock

The liquidity and trading volume of our common stock may be low, and our ownership is concentrated.

The liquidity and trading volume of our common stock has at times been low in the past and may again be low in the future. If the liquidity and trading volume of our common stock is low, this could adversely impact the trading price of our shares, our ability to issue stock and our stockholders' ability to obtain liquidity in their shares. The issuance of common stock by us in 2013 and 2014 involved a significant issuance of stock to a limited number of investors, significantly increasing the concentration of our share ownership in a few holders.

Our stock price has been, and may continue to be volatile.

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 or other factors. Some factors, in addition to the other risk factors identified above, that may have a significant effect on our stock market price include but are not limited to the following:

- 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 warrants and options, 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 warrants and outstanding options issued as compensation for services performed by employees, directors, consultants, and others, future sales of our equity, or the grant of future equity-based awards. As of December 31, 2014, an aggregate of 9,250,000 shares of common stock were reserved for future issuance under our equity incentive plan, 3,475,000 of which were subject to options outstanding as of that date at a weighted average exercise price of $3.03 per share. In addition, as of December 31, 2014, 10,094,000 shares of our common stock were subject to warrants at a weighted average exercise price of $4.18 per share. Of the 3,475,000 stock options outstanding at December 31, 2014, 2,627,000 stock options were vested and exercisable. To the extent that outstanding warrants or options are exercised, our existing stockholders may experience 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 interests in the Company. During 2014, we sold approximately 22.4 million shares of common stock in private placements with gross proceeds totaling approximately $52.0 million. During 2013, we sold approximately 2.7 million shares of common stock in a private placement with 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. Our Board declared a 0.5% stock dividend in the first quarter of 2014 and each of the four quarters in 2013 and 2012 which resulted in the issuance of 187,224 shares, 667,342 shares and 634,162 shares in 2014, 2013 and 2012, respectively.

Anti-takeover provisions in our charter, bylaws, other agreements, and under Delaware law could discourage, delay, or prevent a change in control of our company.

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. These provisions include but are not limited to the right of our Board to issue preferred stock without stockholder approval, no stockholder ability to fill director vacancies, elimination of the rights of our stockholders to act by written consent and call special stockholder meetings, super-majority vote requirements for certain amendments to our certificate of incorporation and stockholder proposals for amendments to our bylaws, prohibition against stockholders from removing directors other than “for cause” and rules regarding how stockholders may present proposals or nominate directors for election at stockholder meetings.

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, 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 our 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 the consummation of an unsolicited tender offer for shares of our common stock 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.

Because we do not intend to pay dividends, our stockholders will benefit from an investment in our common stock only if it appreciates in value.

We intend to retain our future earnings, if any, to finance the expansion of our business and do not expect to pay any cash dividends in the foreseeable future. As a result, the success of an investment in our common stock will depend entirely upon any future appreciation. There is no guarantee that our common stock will appreciate in value or even maintain the price at which our stockholders purchased their shares.

The ownership of our common stock is highly concentrated.

Three of our stockholders beneficially own of approximately 42% of our outstanding common stock, in the aggregate, as of February 27, 2015, as determined based on a review of their reports on Schedule 13D/A and Schedule 13G. As a result, these stockholders will be able to affect the outcome of, or exert significant influence over, all matters requiring stockholder approval, including the election and removal of directors and any change in control. In particular, this concentration of ownership of our common stock could have the effect of delaying or preventing a change in control of us or otherwise discouraging or preventing a potential acquirer from attempting to obtain control of us. This, in turn, could have a negative effect on the market price of our common stock. It could also prevent our stockholders from realizing a premium over the market prices for their shares of common stock. Moreover, the interests of this concentration of ownership may not always coincide with our interests or the interests of other stockholders. The concentration of ownership also contributes to the low trading volume and volatility of our common stock.

Item 1B. Unresolved Staff Comments

None.

Item 2. Properties

As of December 31, 2014, we owned or leased a total of approximately 74,000 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

From time to time, we are involved in legal proceedings and regulatory proceedings arising out of our operations. We establish reserves for specific liabilities in connection with legal actions that we deem to be probable and 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 then Chief Executive Officer, Federico Pignatelli, and its then Chief Financial Officer, 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 its then President and Chief Operating 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 Exchange Act. 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 the lead plaintiff's selection of lead counsel. On February 24, 2014, the 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 Exchange Act.

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

We believe that the claims contained in the lawsuits are without merit and we intend to vigorously defend against the claims. During the year ended December 31, 2013, we paid $250,000 for legal costs incurred in connection with these matters. No legal costs were incurred by us in connection with these matters during the year ended December 31, 2014.

The parties have reached an agreement in principle to settle the consolidated securities class action lawsuit, which is subject to the negotiation of a definitive settlement agreement and preliminary and final approval of the court. Although there can be no assurance that such agreement will be finalized, as of the date of the filing of this Form 10-K, management does not expect the Company to incur additional expenses related to this matter due to certain insurance coverage in place.

Intellectual Property Litigation

On April 24, 2012, CAO Group, Inc. ("CAO") filed a lawsuit against the Company in the District of Utah for patent infringement of U.S. Patent No. 7,485,116 (the "116 Patent") regarding the Company's 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 the Company 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 (the "USPTO") to consider the Company's 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 116 Patent while finding that other claims appeared to be patentable. The Company appealed the USPTO's findings on January 9, 2014 and 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. On March 17, 2014, the Company filed its brief in support of its appeal of the USPTO's decision not to reject certain claims of the 116 Patent. On March 24, 2014, CAO filed its brief in support of its appeal of the USPTO's decision to reject certain claims of the 116 patent. On April 18, 2014, the Company filed a respondent brief in opposition to the CAO's appeal arguments. On May 30, 2014, both parties filed rebuttal briefs in support of their appeals. On June 30, 2014, the Company requested an oral hearing before our Board. On July 1, 2014, our Board noted that request and docketed the case for consideration. A hearing on reconsideration was held in November 2014.

The Company filed a patent infringement lawsuit against Fotona dd. ("Fotona") in Düsseldorf District Court (the "Düsseldorf Court") on April 12, 2012 alleging infringement with respect to the Fotona Fidelis dental laser system. Fotona denies liability and seeks the reimbursement of statutory fees from the Company. 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, the Company filed its counterplea in the infringement proceedings and phrased its 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, the Company filed its response to the Patent Court. Fotona filed a rejoinder on February 3, 2014, including its counterplea on nullity.

On April 29, 2014, the Düsseldorf Court rendered a first instance decision whereby Fotona must cease and desist from selling its Fidelis and Lightwalker dental laser systems, render accounts on past sales, recall respective products, and pay damages on infringement. Additionally, the Company was awarded statutory fees, court costs, and attorney's fees. Preliminary enforcement against Fotona is possible if the Company posts a bond totaling €500,000, which is designed

to cover a portion of the potential damages, before a final instance decision is available. In Germany, damages can be calculated based on the profits made by the infringer after the formal announcement of the granting of a patent, in this case beginning January 1, 2009, without considering direct labor or any other operational costs. This could amount to several million euros. However, Fotona has yet to provide the details of its profits in order to allow the Company to calculate the damages. In the two additional first instance cases following the extension of the initial lawsuit against Fotona, the Düsseldorf Court also required the Company to provide a statutory bond totaling €146,000. Such bonds are traditionally imposed on foreign plaintiffs to cover all statutory, court, and attorney's fees. Fotona submitted its responses to the action and filed respective invalidation actions against the rights of the Company, which are now pending at the Patent Court and the Federal Patent and Trademark Office.

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:

	2014		2013	
	High	Low	High	Low
First Quarter	$3.36	$2.29	$4.46	$1.88
Second Quarter	$2.39	$1.76	$5.90	$3.57
Third Quarter	$2.72	$1.92	$4.02	$1.20
Fourth Quarter	$2.97	$2.28	$3.06	$1.51

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

As of February 27, 2015, the closing price of our common stock on the NASDAQ Capital Market was $2.17 per share, and the number of stockholders of record was 186. 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 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. Our dividend policy may be changed at any time, and from time to time, by our Board.

The following table sets forth certain information relating to our stock dividends declared during 2014, 2013, and 2012:

	Declaration Date	Record Date	Payment Date	Dividend per Share	Number of Shares Outstanding	Total Stock Dividends Declared
	(in thousands, except per share data)					
Calendar year 2014	Mar. 5, 2014	Mar. 14, 2014	Mar. 28, 2014	0.50%	37,422,753	187,224
Calendar year 2013	Dec. 5, 2013	Dec. 16, 2013	Dec. 30, 2013	0.50%	35,191,663	179,847
	Aug. 15, 2013	Aug. 30, 2013	Sept. 13, 2013	0.50%	31,999,465	164,026
	May 21, 2013	Jun. 14, 2013	Jun. 28, 2013	0.50%	31,831,732	162,933
	Feb. 28, 2013	Mar. 15, 2013	Mar. 29, 2013	0.50%	31,343,676	160,536
Calendar year 2012	Nov. 8, 2012	Dec. 14, 2012	Dec. 28, 2012	0.50%	31,283,974	159,490
	Aug. 22, 2012	Sept. 14, 2012	Sept. 28, 2012	0.50%	31,124,484	158,561
	May 10, 2012	Jun. 8, 2012	Jun. 25, 2012	0.50%	31,062,608	158,318
	Mar. 2, 2012	Mar. 15, 2012	Mar. 30, 2012	0.50%	30,805,300	157,793

In the first quarter of 2014, our Board announced a 2% annual stock dividend policy for 2014 and declared a one-half percent stock dividend (the “March Stock Dividend”) payable March 28, 2014 to stockholders of record on March 14, 2014. Although our Board expressed its desire to continue to declare stock dividends in each quarter, the March Stock Dividend was deemed to be a special dividend and there is no assurance, with respect to the amount or frequency, that any stock dividend will be declared in the future.

Equity Compensation Plan Information

The information set forth under the caption “Equity Compensation Plan Information” in the definitive proxy statement (the “Proxy Statement”) to be filed in connection with our 2015 Annual Meeting of Stockholders, is incorporated by reference herein.

Sale of Unregistered Common Stock

On November 7, 2014, we completed private placement with several institutional and individual investors, and certain of our directors and officers, under which we agreed to sell an aggregate of 14,162,873 unregistered shares of our common stock at the price of $2.39 per share, the closing price of our common stock on November 3, 2014, and warrants to purchase up to an aggregate of 9,205,862 unregistered shares of our common stock at an exercise price of $4.00 per share. Gross proceeds from the sale were $35.0 million, and net proceeds, after offering expenses of approximately $235,000, were approximately $34.8 million. The warrants become exercisable on May 7, 2015, six months after the closing of the private placement, and have a term of three years from the date of issuance. In connection with the transaction, we agreed to use commercially reasonable efforts to file within 30 days of the closing a registration statement with the SEC to register the resale of both the shares and the shares underlying the warrants issued at the closing. The proceeds will be used for working capital and general corporate purposes. These shares were issued and sold in reliance upon exemptions from registration under the Securities Act of 1933, as amended (the “Act”), afforded by Section 4(a)(2) of the Act and the rules promulgated thereunder and corresponding provisions of state securities laws. Each of the investors was either a "qualified institutional buyer" as defined in Rule 144A(a) under the Act or an "accredited investor" as defined in Rule 501(a) under the Act.

On July 22, 2014, we completed a private placement with several institutional and individual investors, and several of our directors and officers, in which we sold 6,250,000 unregistered shares of our common stock at a price of $1.92 per share (the closing price of our common stock on July 18, 2014). Gross proceeds from the sale totaled $12 million, and net proceeds, after offering expenses of approximately $462,000, were approximately $11.5 million. We used the proceeds to pay off our lines of credit with Comerica Bank and for working capital and general corporate purposes. These shares were issued and sold in reliance upon exemptions from registration under the Act, afforded by Section 4(a)(2) of the Act and the rules promulgated thereunder and corresponding provisions of state securities laws. Each of the investors was either a "qualified institutional buyer" as defined in Rule 144A(a) under the Act or an "accredited investor" as defined in Rule 501(a) under the Act.

On February 10, 2014, we entered into a subscription agreement with Oracle Partners L.P., Oracle Institutional Partners, L.P., and Oracle Ten Fund Master L.P., under which we 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 were $5.0 million, and net proceeds, after offering expenses of approximately $188,000, were approximately $4.8 million. We used the proceeds to repay our lines of credit and for working capital and general corporate purposes. These shares were issued and sold in reliance on Section 4(2) of the Act, and Rule 506 of Regulation D promulgated under the Act. These transactions qualified for exemption from registration because, among other things, the transactions did not involve a public offering, each investor was an accredited investor and/or qualified institutional buyer, each investor took our common stock for investment and not resale, and we took appropriate measures to restrict the transfer of the Common Stock. No registration rights were provided, and none of these shares of our 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.

On December 19, 2013, we entered into a 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, and net proceeds, after offering expenses of approximately $30,000, totaled approximately $582,000. We used the proceeds for working capital and general corporate purposes. 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.

Stock Performance Graph

The following stock performance graph and related information shall not be deemed “soliciting material” or to be “filed” with the SEC, nor shall such information be incorporated by reference into any future filing under the Securities Act or the Exchange Act, except to the extent that we specifically incorporate it by reference into such filing.

The stock performance graph below compares the cumulative total stockholder return for Biolase, Inc. on $100 invested, assuming the reinvestment of all dividends, on December 31, 2009, the last trading day before our 2010 fiscal year, through the end of fiscal 2014 with the cumulative total return on $100 invested for the same period in the NASDAQ Composite Index and the NASDAQ Medical Equipment Index. The historical stock performance shown on the graph below is not necessarily indicative of future price performance.

	Years Ended December 31,					
	2009	2010	2011	2012	2013	2014
Biolase, Inc.	$100.00	$91.62	$140.02	$102.82	$160.46	$149.87
NASDAQ Composite Index	100.00	117.61	118.70	139.00	196.83	223.74
NASDAQ Medical Equipment	100.00	105.75	118.61	131.64	155.38	175.37

Item 6. Selected Financial Data

The information set forth below is not necessarily indicative of future operations and should be read in conjunction with Item 7, “Management’s Discussion and Analysis of Financial Condition and Results of Operations,” and the Consolidated Financial Statements and notes thereto included in Item 8, “Financial Statements and Supplementary Data,” of this Form 10-K, in order to understand further the factors that may affect the comparability of the financial data presented below.

	Years Ended December 31,				
	2014	2013	2012	2011	2010
	(in thousands, except per share data)				
Consolidated Statements of Operations Data:					
Net revenue	$47,656	$56,430	$57,356	$48,858	$26,225
Net cost of revenue(1)	29,484	34,900	30,878	27,540	17,400
Gross profit	18,172	21,530	26,478	21,318	8,825
Operating expenses:					
Sales and marketing(1)	16,375	18,682	16,250	13,075	9,938
General and administrative(1)	14,854	9,377	8,075	7,936	6,557
Engineering and development(1)	4,577	4,029	4,684	4,311	3,790
Excise tax	307	438	—	—	—
Impairment of property, plant, and equipment(2)	—	—	—	—	35
Total operating expenses	36,113	32,526	29,009	25,322	20,320
Loss from operations	(17,941)	(10,996)	(2,531)	(4,004)	(11,495)
Non-operating loss	(873)	(650)	(414)	(393)	(468)
Loss before income taxes	(18,814)	(11,646)	(2,945)	(4,397)	(11,963)
Income tax provision (benefit)	112	(164)	111	89	58
Net loss as reported	$(18,926)	$(11,482)	$(3,056)	$(4,486)	$(12,021)
Net loss from operations per share:					
Basic	$(0.42)	$(0.34)	$(0.08)	$(0.13)	$(0.42)
Diluted	$(0.42)	$(0.34)	$(0.08)	$(0.13)	$(0.42)
Net loss per share:					
Basic	$(0.45)	$(0.35)	$(0.10)	$(0.15)	$(0.44)
Diluted	$(0.45)	$(0.35)	$(0.10)	$(0.15)	$(0.44)
Shares used in computing net loss from operations per share and net loss per share(3):					
Basic	42,232	32,768	32,162	30,762	27,105
Diluted	42,232	32,768	32,162	30,762	27,105
Consolidated Balance Sheet Data:					
Working capital (deficit)	$38,647	$3,915	$7,542	$9,044	$(5,717)
Total assets	$59,403	$31,038	$31,973	$29,807	$18,147
Long-term liabilities	$1,196	$618	$804	$956	$1,534
Stockholders' equity (deficit)	$42,056	$8,481	$11,794	$12,569	$(3,047)

(1) 2014, 2013, 2012, 2011, and 2010 include $1.2 million, $1.6 million, $1.6 million, $1.5 million, and $727,000, respectively, in total compensation cost related to stock options classified in cost of revenue, sales and marketing, general and administrative, and engineering and development expenses.

(2) In 2010, we wrote down the value of our land and building in Germany by $35,000 to reflect the market value of the asset.

(3) Shares used in computing net loss from operations per share and net loss per share have been adjusted to reflect the effects of stock dividends.

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

The following information should be read in conjunction with our consolidated financial statements and related notes included elsewhere in this Form 10-K. In addition to historical information, this discussion and analysis contains forward-looking statements that involve risks, uncertainties, and assumptions, which could cause actual results to differ materially from management's expectations. Please see the "Cautionary Statement Regarding Forward-Looking Statements" section immediately preceding Part I, Item 1 of this Form 10-K and the "Risk Factors" section in Part I, Item 1A of this Form 10-K.

Overview

We are a medical device company that develops, manufactures, markets and sells laser systems in dentistry and medicine and also markets, sells, 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 3-D printers. Our products advance the practice of dentistry and medicine for patients and health care professionals. Our proprietary dental laser systems allow dentists, periodontists, endodontists, oral surgeons, and other dental specialists to perform a broad range of minimally invasive dental procedures, including cosmetic, restorative, and complex surgical applications. Our laser systems are designed to provide clinically superior results for many types of dental procedures compared to those achieved with drills, scalpels, and other conventional instruments. We have clearance from the FDA to market and sell our laser systems in the United States and also have the necessary registration to market and sell our laser systems in Canada, the European Union, and many other countries outside the U.S. Additionally, our in-licensed imaging equipment and related products improve diagnoses, applications, and procedures in dentistry and medicine.

We offer two categories of laser system products: WaterLase (all-tissue) systems and Diode (soft-tissue) systems. Our flagship brand, the WaterLase, uses a patented combination of water and laser energy to perform most procedures currently performed using 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 have approximately 250 issued and 100 pending U.S. and international patents, the majority of which are related to WaterLase technology. From 1998 through December 31, 2014, we sold approximately 27,600 laser systems in over 80 countries around the world. Contained in this total are over 10,600 WaterLase systems, including more than 6,600 WaterLase MD and iPlus systems.

The shareholder litigation brought by Oracle to resolve the dispute over our corporate governance and the composition of our Board, as well as the proxy contest and new litigation, brought by the former Chairman and CEO in July 2014, which litigation was subsequently dismissed, have significantly and pervasively impacted all aspects of our organization. The litigation disrupted our daily operations, disrupted relationships with vendors and weakened employee morale. In addition, the legal expenses and professional fees associated with the litigation caused working capital strains. Externally in the marketplace, this litigation has impaired customer and investor perceptions of the Company, which resulted in a loss of overall confidence and has impacted us through the fourth quarter of 2014.

Beginning in the second half of 2014, we appointed new key personnel to management to lead our sales and marketing department, including a new Vice President of Worldwide Sales and Account Management as well as a new Senior Vice President and Chief Marketing Officer. Furthermore, in the fourth quarter of 2014, we enhanced our sales force domestically and internationally. We have also formed a new Dental Professional Advisory Board, made up of four founding members, who have made significant contributions to the specialties of periodontics, implantology, oral surgery, multi-stage restorative therapy, and peri-implantitis therapy. Our goal is to refocus our energies on strengthening leadership, worldwide competitiveness and our professional customers and their patients.

We completed two private placements in the latter half of 2014 totaling in net proceeds after offering expenses, of approximately $46.3 million. We used a portion of the proceeds to repay our lines of credit in July 2014. The remainder of the proceeds is being used for working capital and general corporate purposes. Prior to these infusions of

capital, the available borrowing capacity on our lines of credit with Comerica Bank and the net proceeds from the February 2014 equity transaction have been principal sources of liquidity during the first half of 2014. On April 10, 2014, we entered into a forbearance agreement that reduced our total aggregate available borrowings to $4.0 million. On May 5, 2014, June 3, 2014 and July 9, 2014, we amended the forbearance agreement to extend the forbearance periods and paid fees associated with such amendments. On July 28, 2014, we paid in full all amounts due under the revolving lines of credit, including principal, accrued interest, and fees which totaled, in the aggregate, approximately $2.9 million, and the Credit Agreements were terminated. Further discussion of the amendments is included in Note 5 to the Consolidated Financial Statements in Part IV, Item 15 of this Annual Report on Form 10-K, which is incorporated herein by reference.

Critical Accounting Policies

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

Revenue Recognition. We sell our products in North America directly to customers through our direct sales force and through non-exclusive distributors. We sell our products internationally through exclusive and non-exclusive distributors as well as directly to customers in certain countries. Sales are recorded upon shipment from our facility and payment of our invoices is generally due within 90 days or less. Internationally, we primarily sell products through independent distributors. We record revenue based on four basic criteria that must be met before revenue can be recognized: (i) persuasive evidence of an arrangement exists; (ii) delivery has occurred and title and the risks and rewards of ownership have been transferred to our customer, or services have been rendered; (iii) the price is fixed or determinable; and (iv) collectability is reasonably assured. Revenue is recorded for all sales upon shipment assuming all other revenue recognition criteria are met.

Sales of our laser systems include separate deliverables consisting of the product, disposables used with the laser systems, installation, and training. We apply the relative selling price method, which requires that arrangement consideration be allocated at the inception of the arrangement to all deliverables using the relative selling price method. This requires us to use estimated selling prices of each of the deliverables in the total arrangement. The sum of those prices is then compared to the arrangement, and any difference is applied to the separate deliverable ratably. This method also establishes a selling price hierarchy for determining the selling price of a deliverable, which includes: (i) vendor-specific objective evidence (“VSOE”), if available, (ii) third-party evidence if VSOE is not available, and (iii) estimated selling price if neither VSOE nor third-party evidence is available. VSOE is determined based on the value we sell the undelivered element to a customer as a stand-alone product. Revenue attributable to the undelivered elements is included in deferred revenue when the product is shipped and is recognized when the related service is performed. Disposables not shipped at time of sale and installation services are typically shipped or installed within 30 days. Training is included in deferred revenue when the product is shipped and is recognized when the related service is performed or upon the approximate expiration of time offered under the agreement. The adoption of the relative selling price method does not significantly change the value of revenue recognized.

Key judgments related to our revenue recognition include the collectability of payment from the customer, the satisfaction of all elements of the arrangement having been delivered, and that no additional customer credits and discounts are needed. We evaluate a customer’s credit-worthiness prior to the shipment of the product. Based on our assessment of the available credit information, we may determine the credit risk is higher than normally acceptable, and we will either decline the purchase or defer the revenue until payment is reasonably assured. Future obligations required at the time of sale may also cause us to defer the revenue until the obligation is satisfied.

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

Extended warranty contracts, which are sold to our laser and certain imaging customers, are recorded as revenue on a straight-line basis over the period of the contract, which is typically one year.

For sales transactions involving used laser trade-ins, we record the purchased trade-ins as inventory at the fair value of the asset surrendered with the offset to accounts receivable. In determining the estimated fair value of used laser trade-ins, we make an assessment of usable parts and key components and consider the ultimate resale value of the certified pre-owned (or “CPO”) laser with applicable margins. We sell these CPO laser trade-ins as refurbished lasers following our laser system revenue recognition policy. Trade-in rights are not established nor negotiated with

customers during the initial sales transaction of the original lasers. Trade-in rights are promotional events used at our discretion to encourage existing laser customers to purchase new lasers by offering perceived discounts in exchange for customers trading in original lasers. A customer is not required to trade-in a laser nor are we required to accept a trade-in, however, the promotional value offered in exchange for the trade-in laser is not offered without a laser trade-in. The transaction is treated as a monetary transaction as each sale transaction involving a customer trade-in includes significant boot of greater than 25% of the fair value of the exchange. As a monetary transaction, the sale is recognized following our laser system revenue recognition policy. There have been no sales transactions in which the cash consideration was less than 25% of the total transaction value.

We recognize revenue for royalties under licensing agreements for our patented technology when the product using our technology is sold. We estimate and recognize the amount earned based on historical performance and current knowledge about the business operations of our licensees. Historically, our estimates have been consistent with amounts historically reported by the licensees. Licensing revenue related to exclusive licensing arrangements is recognized concurrent with the related exclusivity period.

From time to time, we may offer sales incentives and promotions on our products. We recognize the cost of sales incentives at the date at which the related revenue is recognized as a reduction in revenue, an increase in cost of revenue, or a selling expense, as applicable, or later, in the case of incentives offered after the initial sale has occurred.

Accounting for Stock-Based Payments. We recognize compensation cost related to all stock-based payments based on the grant-date fair value using the Black-Scholes option valuation model, taking into consideration the probability of vesting and estimated forfeitures.

Valuation of Accounts Receivable. We maintain an allowance for uncollectible accounts receivable to estimate the risk of extending credit to customers. We evaluate our allowance for doubtful accounts based upon our knowledge of customers and their compliance with credit terms. The evaluation process includes a review of customers' accounts on a regular basis which incorporates input from sales, service, and finance personnel. The review process evaluates all account balances with amounts outstanding 90 days from the due date and other specific amounts for which information obtained indicates that the balance may be uncollectible. The allowance for doubtful accounts is adjusted based on such evaluation, with a corresponding provision included in general and administrative expenses. Account balances are charged off against the allowance when we believe it is probable the receivable will not be recovered. We do not have any off-balance-sheet credit exposure related to our customers.

Valuation of Inventory. Inventory is valued at the lower of cost, determined using the first-in, first-out method, or market. We periodically evaluate the carrying value of inventory and maintain an allowance for excess and obsolete inventory to adjust the carrying value as necessary to the lower of cost or market. We evaluate quantities on hand, physical condition and technical functionality, as these characteristics may be impacted by anticipated customer demand for current products and new product introductions. Unfavorable changes in estimates of excess and obsolete inventory would result in an increase in cost of revenue and a decrease in gross profit.

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

Valuation of Goodwill and Other Intangible Assets. Goodwill and other intangible assets with indefinite lives are not amortized but are evaluated for impairment annually or whenever events or changes in circumstances indicate that the asset might be impaired. We conducted our annual impairment analysis of our goodwill as of June 30, 2014 and concluded there had been no impairment in goodwill. We closely monitor our stock price and market capitalization and perform such analysis when events or circumstances indicate that there may have been a change to the carrying value of those assets.

Warranty Cost. We provide warranties against defects in materials and workmanship of our laser systems for specified periods of time. For the year ended December 31, 2014, WaterLase and Diode systems sold domestically are covered by our warranty for a period of two years. For the years ended December 31, 2013 and 2012, WaterLase systems sold domestically were covered by our warranty for a period of one year while our Diode systems warranty period was for two years from date of sale by us or the distributor to the end-user. For the year ended December 31, 2014, WaterLase and Diode systems sold internationally are covered by our warranty for a period of twenty-eight months from the date of sale to the international distributor. For the years ended December 31, 2013 and 2012, WaterLase systems sold internationally were covered by our warranty for a period of sixteen months while our Diode systems warranty period was up to twenty-eight months from the date of sale to the international distributor. Estimated warranty expenses are recorded as an accrued liability with a corresponding provision to cost of revenue. This estimate is recognized concurrent with the recognition of revenue on the sale to the distributor or end-user. Warranty expenses expected to be incurred after one year from the time of sale to the distributor are classified as a

long-term warranty accrual. Our overall accrual is based on our historical experience and our expectation of future conditions, taking into consideration the location and type of customer and the type of laser, which directly correlate to the materials and components under warranty, the duration of the warranty period, and the logistical costs to service the warranty. Additional factors that may impact our warranty accrual include changes in the quality of materials, leadership and training of the production and services departments, knowledge of the lasers and workmanship, training of customers, and adherence to the warranty policies. Additionally, an increase in warranty claims or in the costs associated with servicing those claims would likely result in an increase in the accrual and a decrease in gross profit. We offer extended warranties on certain imaging products. However, all imaging products are initially covered by the manufacturer’s warranties.

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

Income Taxes. Based upon our operating losses during 2014, 2013, and 2012 and the available evidence, management has determined that it is more likely than not that the deferred tax assets as of December 31, 2014 will not be realized in the near term. Consequently, we have established a valuation allowance against our net deferred tax asset totaling approximately $42.1 million and $35.6 million as of December 31, 2014 and 2013, respectively. In this determination, we considered factors such as our earnings history, future projected earnings, and tax planning strategies. If sufficient evidence of our ability to generate sufficient future taxable income tax benefits becomes apparent, we may reduce our valuation allowance, resulting in tax benefits in our statement of operations and in additional paid-in-capital. Management evaluates the potential realization of our deferred tax assets and assesses the need for reducing the valuation allowance periodically.

Fair Value of Financial Instruments

Our financial instruments, consisting of cash and cash equivalents, accounts receivable, accounts payable, and accrued liabilities, approximate fair value because of the short maturity of these items. Financial instruments consisting of lines of credit approximate fair value, as the interest rates associated with the lines of credit approximate the market rates for debt securities with similar terms and risk characteristics.

Fair value is defined as the price that would be received to sell an asset or paid to transfer a liability in an orderly transaction between market participants in the principal market or, if none exists, the most advantageous market, for the specific asset or liability at the measurement date (referred to as the “exit price”). The fair value should be based on assumptions that market participants would use, including a consideration of nonperformance risk. Level 1 measurement of fair value is quoted prices in active markets for identical assets or liabilities.

Results of Operations

The following table sets forth certain data from our operating results for each of the years ended December 31, 2014, 2013, and 2012, expressed as percentages of revenue:

	Years Ended December 31,		
	2014	2013	2012
Products and services	99.7 %	99.6 %	99.7 %
License fees and royalty	0.3	0.4	0.3
Net revenue	100.0	100.0	100.0
Cost of revenue	61.9	61.8	53.8
Gross profit	38.1	38.2	46.2
Operating expenses:			
Sales and marketing	34.4	33.1	28.3
General and administrative	31.2	16.6	14.1
Engineering and development	9.6	7.2	8.2
Excise tax	0.6	0.8	—

Total operating expenses	75.8	57.7	50.6
Loss from operations	(37.7)	(19.5)	(4.4)
Non-operating loss, net	(1.8)	(1.1)	(0.7)
Loss before income taxes	(39.5)	(20.6)	(5.1)
Income tax provision (benefit)	0.2	(0.3)	0.2
Net loss	(39.7)%	(20.3)%	(5.3)%

The following table summarizes our net revenues by category for the years ended December 31, 2014, 2013, and 2012 (dollars in thousands):

	Years Ended December 31,								
	2014			2013			2012		
Laser systems	$29,490	61.9	%	$38,736	68.6	%	$42,348	73.8	%
Imaging systems	4,286	9.0	%	4,632	8.2	%	3,365	5.9	%
Consumables and other	6,524	13.7	%	6,458	11.5	%	5,954	10.4	%
Services	7,211	15.1	%	6,360	11.3	%	5,524	9.6	%
Total products and services	47,511	99.7	%	56,186	99.6	%	57,191	99.7	%
License fees and royalty	145	0.3	%	244	0.4	%	165	0.3	%
Net revenue	$47,656	100.0	%	$56,430	100.0	%	$57,356	100.0	%

Non-GAAP Disclosure

In addition to the financial information prepared in conformity with generally accepted accounting principles in the United States (“GAAP”), we provide certain historical non-GAAP financial information. Management believes that these non-GAAP financial measures assist investors in making comparisons of period-to-period operating results and that, in some respects, these non-GAAP financial measures are more indicative of the Company’s on-going core operating performance than their GAAP equivalents.

Management believes that the presentation of this non-GAAP financial information provides investors with greater transparency and facilitates comparison of operating results across a broad spectrum of companies with varying capital structures, compensation strategies, derivative instruments, and amortization methods, which provides a more complete understanding of our financial performance, competitive position, and prospects for the future. However, the non-GAAP financial measures presented in this Form 10-K have certain limitations in that they do not reflect all of the costs associated with the operations of our business as determined in accordance with GAAP. Therefore, investors should consider non-GAAP financial measures in addition to, and not as a substitute for, or as superior to, measures of financial performance prepared in accordance with GAAP. Further, the non-GAAP financial measures presented by the Company may be different from similarly named non-GAAP financial measures used by other companies.

Non-GAAP Net Loss. Management uses non-GAAP net loss (defined as net loss before interest, taxes, depreciation and amortization, stock-based, other equity instruments, and other non-cash compensation) in its evaluation of the Company’s core results of operations and trends between fiscal periods and believes that these measures are important components of its internal performance measurement process. Management believes that this non-GAAP financial information reflects an additional way of viewing aspects of our business that, when viewed with our GAAP results, provides a more complete understanding of factors and trends affecting our business.

Non-GAAP net loss for the periods presented is as follows (in thousands):

	Years Ended December 31,		
	2014	2013	2012
GAAP net loss, as reported	$(18,926)	$(11,482)	$(3,056)
Adjustments:			
Interest expense	458	600	239
Income tax (benefit) provision	112	(164)	111

Depreciation and amortization	696	601	513
Stock-based, other equity instruments, and other non-cash compensation	1,356	1,965	1,873
Non-GAAP net loss	$(16,304)	$(8,480)	$(320)

Comparison of Results of Operations

Year Ended December 31, 2014 Compared with Year Ended December 31, 2013

Net Revenue. Net revenue for the year ended December 31, 2014 ("Fiscal 2014") was $47.7 million, a decrease of $8.7 million, or 15%, as compared with net revenue of $56.4 million for the year ended December 31, 2013 ("Fiscal 2013"). Domestic revenues were $29.8 million, or 63% of net revenue, for Fiscal 2014 compared to $35.6 million, or 63% of net revenue, for Fiscal 2013. International revenues for Fiscal 2014 were $17.8 million, or 37% of net revenue compared to $20.8 million, or 37% of net revenue for Fiscal 2013. The decrease in period-over-period net revenue resulted from decreases in domestic and international laser system revenue, imaging systems revenue, and license fees and royalties revenue, partially offset by increases in consumables and other and services revenue. We believe that our results for Fiscal 2014 were pervasively and negatively impacted by the significant distractions caused by our shareholder litigation and the related disruptions within both management and the marketplace, as well as a lack of sales management. Since the second half of 2014, our goal has been to refocus on strengthening our leadership, worldwide competitiveness and our professional customers and their patients. We have enhanced our management team with new key personnel and increased our sales force both domestically and internationally.

Laser system net revenues, as a result of the aforementioned reasons, decreased by approximately $9.2 million, or 24%, in Fiscal 2014 compared to Fiscal 2013. As expected, we experienced an improvement in sales of our core laser systems during the fourth quarter of Fiscal 2014 as compared with the third quarter of Fiscal 2014. Historically, revenue in the fourth quarter has typically been stronger than average due to the buying patterns of dental professionals. We believe that a significant number of dentists purchase capital equipment during the fourth quarter in order to maximize their practice earnings and minimize their taxes through the utilization of certain tax incentives, such as accelerated depreciation methods for purchased capital equipment, as part of their year-end tax planning.

Imaging system net revenue, also as a result of the aforementioned reasons, decreased by approximately $346,000, or 7%, in Fiscal 2014 compared to Fiscal 2013.

Consumables and other net revenue, which includes consumable products such as disposable tips and shipping revenue, increased approximately $66,000, or 1%, for Fiscal 2014, as compared to Fiscal 2013. This increase in consumables and other net revenue was primarily a result of auxiliary sales to our growing laser customer base.

Services net revenue, which consists of extended warranty service contracts, advanced training programs, and other services, increased by approximately $851,000, or 13%, for Fiscal 2014, as compared to Fiscal 2013. The increased revenue was mainly attributed to the impact from recognizing $708,000 in deferred training service revenues resulting from a change in estimate in the period over which deferred training service revenue was being recognized during the third quarter of 2014.

License fees and royalty revenue decreased by approximately $99,000, or 40%, to approximately $145,000 in Fiscal 2014 compared to $244,000 in Fiscal 2013. These license fees and royalty revenue were attributable to intellectual property related to our laser technologies.

Cost of Revenue. Cost of revenue in Fiscal 2014 decreased by $5.4 million, or 15%, to $29.5 million, or 62% of net revenue, compared with cost of revenue of $34.9 million, or 62% of net revenue, in Fiscal 2013. Our laser systems generally have significantly higher margins than our licensed imaging systems and our domestic sales generally have higher margins than our international sales. In connection with our initiative to measure and improve customer satisfaction, the warranty for WaterLase systems purchased after January 1, 2014 was extended from one year to two years, which added $519,000 to the cost of revenue during Fiscal 2014. In the third quarter of Fiscal 2013, we recorded a provision of $1.0 million for excess and obsolete inventory related to negative market trends for certain products and the decreased velocity of certain elements of our inventory at that time. As a result, cost of revenue as a percentage of net revenue, remained consistent between Fiscal 2014 and Fiscal 2013 despite the decline in sales.

Gross Profit. Gross profit for Fiscal 2014 was $18.2 million, or 38% of net revenue, a decrease of approximately $3.4 million, or 16%, as compared with gross profit of $21.5 million, or 38% of net revenue, for Fiscal 2013. Gross profit for Fiscal 2014, as a percentage of net revenue, was consistent with Fiscal 2013.

Operating Expenses. Operating expenses for Fiscal 2014 were $36.1 million, or 76% of net revenue, an increase of approximately $3.6 million, or 11%, as compared with $32.5 million, or 58% of net revenue, for Fiscal 2013. We expect that operating expenses as a percentage of net revenue will decrease for the year ending December 31, 2015 (“Fiscal 2015”). The year-over-year increase in expense is explained in the following expense categories:

Sales and Marketing Expense. Sales and marketing expenses for Fiscal 2014 decreased by $2.3 million, or 12%, to $16.4 million, or 34% of net revenue, as compared with $18.7 million, or 33% of net revenue, for Fiscal 2013. The decrease was primarily a result of decreased convention related expenses of $1.3 million, decreased commission expenses of $938,000, and decreased media and advertising expenses of $923,000, partially offset by increased payroll and consulting related expenses of $699,000. The mid-year shareholder litigation brought distractions and disruptions within management and the marketplace in connection with such litigation, as well as a lack of sales management. Due to the working capital required for legal expenditures and professional fees in connection with the shareholder litigation, management made the decision to reduce sales and marketing expenditures. Beginning in the second half of 2014, we appointed new key personnel to lead our sales and marketing department, including a new Senior Vice President of Worldwide Sales and Account Management as well as a new Vice President and Chief Marketing Officer. Furthermore, in the fourth quarter of 2014, we enhanced our sales force domestically and internationally. As we continue to transform and sustain growth, we expect sales and marketing expenses to increase in Fiscal 2015.

General and Administrative Expense. General and administrative expenses for Fiscal 2014 increased by $5.5 million, or 58%, to $14.9 million, or 31% of net revenue, as compared with $9.4 million, or 17% of net revenue, for Fiscal 2013. The increase to general and administrative expenses was primarily due to increased legal expenses and professional fees of $4.2 million, increased payroll and consulting related expenses of $520,000, and an increase to our provision for doubtful accounts of $1.0 million, partially offset by decreased patent and patent defense costs of $297,000. We incurred legal expenses and professional fees of approximately $4.3 million at the direction of our former Chairman and CEO in the shareholder litigation brought by Oracle to resolve the dispute over our corporate governance and the composition of our Board, as well as the proxy contest and new litigation, brought by the former Chairman and CEO in July 2014, which litigation was subsequently dismissed. We believe that the legal expenses and professional fees we incurred in 2014 are atypical and expect these expenses to decrease in Fiscal 2015.

Engineering and Development Expense. Engineering and development expenses for Fiscal 2014 increased by $548,000, or 14%, to $4.6 million, or 10% of net revenue, as compared with $4.0 million, or 7% of net revenue, for Fiscal 2013. The increase was primarily related to increased payroll, consulting and temporary labor expenses of $524,000 resulting from our efforts to accelerate innovation of our products and technologies beginning in the third quarter of Fiscal 2014. We expect to increase our investment in engineering and development as we continue our efforts in new product development in the future.

Excise Tax Expense. Beginning in 2013, the Affordable Care Act imposed a 2.3% medical device excise tax on certain product sales to customers located in the U.S. Excise tax expenses for Fiscal 2014 was $307,000, or 1% of net revenue, as compared with $438,000, or 1% of net revenue, for Fiscal 2013. The decrease of $131,000, or 30%, was directly associated with our decreased sales in the U.S.

Non-Operating Income (Loss)

(Loss) Gain on Foreign Currency Transactions. We recognized a $415,000 loss on foreign currency transactions for Fiscal 2014 compared to a $50,000 loss for Fiscal 2013 due to exchange rate fluctuations primarily between the U.S. dollar and the Euro. During Fiscal 2014, the Euro fell approximately 12% in translation value against the U.S. dollar.

Interest Expense, Net. Interest expense consists primarily of interest on our revolving credit facilities, amortization of debt issuance costs and debt discount, and the financing of our business insurance premiums. Interest expense totaled approximately $458,000 and $600,000 for Fiscal 2014 and 2013, respectively. The decrease of $142,000 in interest expense, in Fiscal 2014 when compared to Fiscal 2013 was primarily due to the repayment and termination of our credit facilities with Comerica Bank on July 28, 2014.

Provision (benefit) for Income Taxes. Our provision for income taxes was $112,000 for Fiscal 2014, compared to provision for income tax benefit of $164,000 in Fiscal 2013. The year over year change was driven by reversals of tax

liabilities associated with expiring international unrecognized tax benefits of $138,000 in Fiscal 2013. In addition, we recognized deferred tax assets related to certain indefinite lived assets (federal alternative minimum tax credits and California R&D credits) that were used to offset deferred tax liabilities related to indefinite-lived intangible assets. This resulted in additional tax benefits of $107,000 for Fiscal 2013.

Net Loss. For the reasons stated above, our net loss was $18.9 million for Fiscal 2014 compared to a net loss of $11.5 million for Fiscal 2013. The increase in net loss of approximately $7.4 million, or 65%, was primarily due to decreased gross profit of $3.4 million, increased operating expenses of $3.6 million and increased foreign currency translation loss of $365,000.

Year Ended December 31, 2013 Compared With Year Ended December 31, 2012

Net Revenue. Net revenue for Fiscal 2013 was $56.4 million, a decrease of $926,000, or 2%, as compared with net revenue of $57.4 million for the year ended December 31, 2012 ("Fiscal 2012"). Domestic revenues were $35.6 million, or 63% of net revenue, for Fiscal 2013 compared to $40.6 million, or 71% of net revenue, for Fiscal 2012. International revenues for Fiscal 2013 were $20.8 million, or 37% of net revenue compared to $16.8 million, or 29% of net revenue for Fiscal 2012. The decrease in period-over-period net revenue resulted from decreases in domestic laser system revenue, partially offset by increases in imaging systems, consumables and other, services, and license fees and royalty revenue. We believe that these results were primarily due to our transition from primarily selling WaterLase dental lasers to selling a wide range of hard- and soft-tissue dental and medical lasers and other high-tech solutions for dentists, including digital radiography and CAD/CAM intra-oral scanners. In order to more effectively deploy our resources and improve overall revenue as well as our margins we changed our sales and marketing leadership during the fourth quarter of Fiscal 2013. Subsequent to our leadership change we hired 15 additional sales personnel of which 12 were to primarily focus on selling our core laser products.

Laser system net revenues, as a result of the aforementioned reasons, decreased by approximately $3.6 million, or 9%, in Fiscal 2013 compared to Fiscal 2012. As expected, we experienced an improvement in sales of our core laser systems during the quarter ending December 31, 2013 as compared with the quarter ending September 30, 2013. Historically, revenue in the fourth quarter has typically been stronger than average due to the buying patterns of dental professionals. We believe that a significant number of dentists purchase capital equipment during the fourth quarter in order to maximize their practice earnings and minimize their taxes through the utilization of certain tax incentives, such as accelerated depreciation methods for purchased capital equipment, as part of their year-end tax planning.

Imaging system net revenue increased by approximately $1.3 million, or 38%, in Fiscal 2013 compared to Fiscal 2012. The increase was driven by increased offerings at various value propositions, including the NewTom VG3.

Consumables and other net revenue, which includes consumable products such as disposable tips and shipping revenue, increased approximately $504,000, or 8%, for Fiscal 2013, as compared to Fiscal 2012. This increase in consumables and other net revenue was primarily a result of auxiliary sales to our growing laser customer base.

Services net revenue, which consists of extended warranty service contracts, advanced training programs, and other services, increased by approximately $836,000, or 15%, for Fiscal 2013, as compared to Fiscal 2012. The increased revenue was due largely to increased follow-on sales related to our growing laser customer base and increased sales and marketing efforts in this part of our business.

License fees and royalty revenue increased by approximately $79,000, or 48%, to approximately $244,000 in Fiscal 2013 compared to $165,000 in Fiscal 2012. These license fees and royalty revenue were attributable to intellectual property related to our laser technologies. We also have a non-exclusive license agreement with Proctor and Gamble Company ("P&G"), granting P&G non-exclusive license rights to certain of our patents. Although the term of the arrangement continues until the underlying patents expire unless terminated earlier by either party, we have not generated revenue under the arrangement since 2011 and we are exploring alternative product development opportunities.

Cost of Revenue. Cost of revenue in Fiscal 2013 increased by $4.0 million, or 13%, to $34.9 million, or 62% of net revenue, compared with cost of revenue of $30.9 million, or 54% of net revenue, in Fiscal 2012. The increased cost as a percentage of revenue is a result of lower laser system sales and increased imaging and international sales. Our laser systems generally have significantly higher margins than our licensed imaging systems and our domestic sales generally have higher margins than our international sales. We also recorded a provision of $1.0 million for excess and obsolete inventory during the third quarter 2013, related to negative market trends for certain products and the decreased velocity of certain elements of our inventory at that time.

Gross Profit. Gross profit for Fiscal 2013 was $21.5 million, or 38% of net revenue, a decrease of approximately $5.0 million, as compared with gross profit of $26.5 million, or 46% of net revenue, for Fiscal 2012. The decrease was primarily due to higher sales of licensed imaging systems, which generally carry lower margins than our laser products, increased international laser sales, which generally carry a lower margin than our domestic laser sales, and the increased provision for excess and obsolete inventory.

Operating Expenses. Operating expenses for Fiscal 2013 were $32.5 million, or 58% of net revenue, an increase of approximately $3.5 million as compared with $29.0 million, or 51% of net revenue, for Fiscal 2012. The year-over-year increase in expense is explained in the following expense categories:

Sales and Marketing Expense. Sales and marketing expenses for Fiscal 2013 increased by $2.4 million, or 15%, to $18.7 million, or 33% of net revenue, as compared with $16.3 million, or 28% of net revenue, for Fiscal 2012. The increase was primarily a result of increased payroll and consulting related expenses of $1.4 million, increased convention costs of $579,000, and increased media and advertising expenses of $471,000, offset by decreased commission expenses of $482,000 related to lower sales. The increased costs were related to the launch and integration of our Cefla NewTom and Biolase DaVinci 3-D Imaging product lines and our 3Shape Trios intra-oral scanners, the launch of our Epic V-Series and Epic 10S diode lasers in veterinary and otolaryngology, respectively, and the introduction of our Galaxy BioMill CAD/CAM chair-side milling system.

General and Administrative Expense. General and administrative expenses for Fiscal 2013 increased by $1.3 million, or 16%, to $9.4 million, or 17% of net revenue, as compared with $8.1 million, or 14% of net revenue, for Fiscal 2012. We experienced increased legal expenses of $615,000, of which $250,000 related to the defense of class action lawsuits (refer to Part I, Item 3 - Legal Proceedings), increased payroll and consulting related expenses of $536,000, and increased investor relations expenses of $220,000.

Engineering and Development Expense. Engineering and development expenses for Fiscal 2013 decreased by $655,000, or 14%, to $4.0 million, or 7% of net revenue, as compared with $4.7 million, or 8% of net revenue, for Fiscal 2012. The decrease was primarily related to decreased payroll and consulting related expenses of $295,000 and decreased supplies expenses of $463,000.

Excise Tax Expense. Beginning in 2013, the Affordable Care Act imposed a 2.3% medical device excise tax on certain product sales to customers located in the U.S. We incurred excise tax expenses of $438,000, or 1% of net revenue, for Fiscal 2013.

Non-Operating Income (Loss)

(Loss) Gain on Foreign Currency Transactions. We recognized a $50,000 loss on foreign currency transactions for Fiscal 2013 compared to a $175,000 loss for Fiscal 2012 due to exchange rate fluctuations between the U.S. dollar and other currencies.

Interest Expense, Net. Interest expense consists primarily of interest on our revolving credit facilities, amortization of debt issuance costs and debt discount, and the financing of our business insurance premiums. Interest expense totaled approximately $600,000 and $239,000 for Fiscal 2013 and 2012, respectively.

Provision (benefit) for Income Taxes. Our provision for income taxes was a benefit of $164,000 for Fiscal 2013, compared to provision of $111,000 in Fiscal 2012. During Fiscal 2013, we reversed certain tax liabilities associated with unrecognized tax benefits related to international operations due to expiring statutes and recognized tax benefits of $138,000. In addition, we recognized deferred tax assets related to certain indefinite lived assets (federal alternative minimum tax credits and California R&D credits) that were used to offset deferred tax liabilities related to indefinite-lived intangible assets. This resulted in additional tax benefits of $107,000. We also recorded an income tax expense of $81,000 for the current year tax provision in Fiscal 2013.

Net Loss. For the reasons stated above, our net loss was $11.5 million for Fiscal 2013 compared to a net loss of $3.1 million for Fiscal 2012.

Selected Quarterly Financial Data

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