BIOLASE, INC
Form 10-K
March 11, 2016

UNITED STATES

SECURITIES AND EXCHANGE COMMISSION

WASHINGTON, DC 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, 2015

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

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

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

The aggregate market value of the Registrant's common stock held by non-affiliates was $60,842,695 based on the last sale price of common stock on June 30, 2015.

As of February 29, 2016, there were 58,227,539 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 2016 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, 2015, 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, 2015

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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 do not materialize as expected, 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 2016, future demand for improved dental care, regulatory requirements, earnings, revenue, sales and operations, operating expenses, sales and marketing expenses, legal expenses and professional fees, general and administrative expenses, the impact of cost-saving measures, 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 explore potential collaborations, effects of engineering and development efforts, plans to expand our field sales force, intentions to implement new software, anticipated growth strategies, ability to attract customers, 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, intellectual property license fees and royalty revenues, pending patent applications and expiring patents, Affordable Care Act compliance, regulators related to health care information, regulatory approvals or enforcement actions, the perceived benefits of any technology acquisitions, critical accounting policies and the impact of recent accounting pronouncements, recording tax benefits or other financial items in the future, plans, strategies, expectations, or objectives of management for future operations, our financial condition or prospects, and any other statement that is not historical fact. Forward-looking statements are often identified by the use of words such as "may," "might," "will," "intend," "should," "could," "can," "would," "continue," "believe," "anticipate," "estimate," "predict," "potential," "plan," "seek" and similar expressions.

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;
- problems in manufacturing our products;
- warranty obligations if our products are defective;
- adverse publicity regarding our technology or products;
- adverse events to our patients during the use of our products, regardless of whether caused by our products;
- litigation, including the failure of our insurance policies to cover certain expenses relating to litigation and our inability to reach a final settlement related to certain litigations;

- failure of our suppliers to supply us with a sufficient amount or adequate quality of materials;
- a change in suppliers, including our inability to purchase certain key components of our products from suppliers other than our current suppliers;
- rapidly changing standards and competing technologies;

- our inability to effectively manage and implement our growth strategies;
- failure of our efforts to emphasize the importance of our imaging products to translate into increased sales of the same;
- 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;
- failure to comply with the reporting obligations of the Securities Exchange Act of 1934, as amended (the "Exchange Act") and Section 404 of the Sarbanes-Oxley Act of 2002, as amended (the "Sarbanes-Oxley Act") or maintain adequate internal control over financial reporting;
- climate change initiatives;
- failure of our intellectual property rights to adequately protect our technologies;
- potential third-party claims that our products infringe their intellectual property rights;
- changes in government regulation or the inability to obtain or maintain necessary governmental approvals;
- our failure to comply with existing or new laws and regulations, including fraud and abuse and health information privacy and securities laws;
- changes in the Food and Drug Administration's ("FDA's") regulatory requirements applicable to laser products, dental devices, or both; and
- recall or other regulatory action concerning our products after receiving FDA clearance or approval.

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 a medica
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, in most cases without the need for local or general anesthesia. We have clearance from 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 340 issued and 90 pending U.S. and international patents, the majority of which are related to WaterLase technology. From 1998 through December 31, 2015, we sold approximately 30,500 laser systems in over 90 countries around the world. Contained in this total are over 11,200 WaterLase systems, including more than 7,200 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 $48.5 million, $47.7 million, and $56.4 million in 2015, 2014, and 2013, respectively, and we had net losses of $20.3 million, $18.9 million, and $11.5 million for the same periods, respectively. We had assets of $42.3 million, $59.4 million, and $31.0 million as of December 31, 2015, 2014, and 2013, respectively.

Recent Developments

Leadership Changes

Consistent with our goal to refocus our energies on strengthening our leadership, and worldwide competitiveness and increasing the amount of attention we pay to our professional customers and their patients, we announced the appointment of a new Chief Financial Officer in March 2015 and a new Director, President, and Chief Executive Officer in July 2015. In September 2015, we completed a series of internal corporate organizational restructuring activities where we streamlined operations and reduced payroll, payroll-related expenses, and consulting-related expenses by approximately $2.6 million, net, on an annualized basis. Expenses related to this restructuring during the year ended December 31, 2015 totaled approximately $269,000. We experienced cost savings related to these measures in the fourth quarter of 2015 and expect to continue to realize the cost savings throughout 2016.

New Product Offerings

In February 2015, we launched the WaterLase iPlus 2.0, our next generation minimally invasive all-tissue flagship laser, along with our exclusive Practice Growth Guarantee™ Program (our "PGG Program"). The latter assists our clients' dental practices by providing focused training on a select number of clinical procedures and support for billing and marketing. In November 2015, we announced an upgrade to the WaterLase iPlus 2.0 to provide dental practitioners a clinical protocol and application to assist in the effective management of peri-implantitis. A growing problem in dentistry, peri-implantitis is a destructive inflammatory process affecting the soft and hard tissues surrounding dental implants. With the addition of the new clinical protocol, the WaterLase iPlus 2.0 provides pre-programmed settings and step-by-step applications for more than 50 FDA-cleared procedures and clinical indications.

The WaterLase iPlus 2.0 includes innovations and improvements designed to enhance patients' and dentists' experiences and generate practice growth for dental practitioners through routine use. During the second quarter of 2015, we fully implemented the PGG Program in the United States. By partnering with our WaterLase iPlus 2.0 customers via the PGG Program, we are actively and routinely soliciting feedback, which provides them and us with highly valuable information.

The WaterLase iPlus 2.0 also marks the debut of the SureFire YSGG Delivery System, which ensures greater uptime through enhanced precision, performance, and reliability. SureFire has redesigned optics that efficiently deliver precise laser energy with a replaceable, disposable shield for better dependability. SureFire offers improved clinical access and comfort with its minimally invasive flagship dental laser system and exclusive contra-angle hand-piece.

In December 2014, we introduced the EPIC X diode laser, an enhanced soft tissue laser system featuring upgrades and improvements from our EPIC 10 line of lasers, which were first cleared by the FDA and 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. EPIC X was cleared by the FDA in 2014.

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.

The American Dental Association ("ADA") 2007 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 device market dynamics, estimated that approximately 400 million hard tissue procedures are performed annually outside the United States.

The ADA also estimates that 46.5 million periodontal, implant, or soft tissue surgical procedures are performed annually in the United States. Periodontal procedures are performed on the supporting structures to remove periodontal and gum disease, which leads to tooth loss. Implant procedures include dental implant placement and restoration, and the treatment of peri-mucositis and peri-implantitis to mitigate implant failure, which is estimated to affect as many as 48% of all implants placed since 2000.

Furthermore, according to the ADA Study, over 90% of hard tissue procedures and 60% of periodontal, implants, and soft tissue, procedures in the United States are performed by general dentists. The remainder are performed by dental specialists, such as oral surgeons, endodontists, periodontists, and prosthodontists.

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. Periodontitis and peri-implantitis are two rapidly growing disease states requiring therapy in a dental practice.

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 were 177,625 active private practitioners in the U.S. According to the World Health Organization, there were 1.8 million dentists worldwide in 2012. 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, less anesthesia, 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 microfractures, 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 2.0, 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, both of which could lead to improved patient-reported outcomes.

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 for dental as well as dermatological, aesthetic, and other general surgery uses.

Diode systems. Our Diode (soft tissue) laser systems currently consist of the EPIC X, EPIC 10 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 X, EPIC 10, 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 10, 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. In December 2014 we introduced the EPIC X diode laser, an enhanced soft tissue laser system featuring upgrades and improvements from our EPIC 10. 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 for dental as well as dermatological, aesthetic, and other general surgery uses.

Imaging systems. Our dental imaging systems include state-of-the-art extra-oral and intra-oral dental digital imaging devices. Our imaging systems include the CEFLA NewTom VGi and VG3, three-dimensional (“3-D”) Cone Beam Computed Tomography devices. We also offer the 3Shape Trios CAD/CAM digital impression systems for offering high-speed digital 3-D picture taking, and the Galaxy BioMill CAD/CAM system which enables dental practitioners to design, scan, mill and finish crowns, inlays and veneers inside the dental office during a single appointment. We distribute all of these products under the manufacturer’s FDA 510(k) clearance. We believe that by combining high-end digital imaging, laser systems, intra-oral scanning, digital x-rays, CAD/CAM design, chair-side milling, and 3-D printing, dental offices can accurately and rapidly address a variety of unmet patient needs conveniently.

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 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, reduce the need to use anesthesia, 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.

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 and patient satisfaction levels, patient retention rates, new patient attraction rates, 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 indications for use that comprise our REPAIR Perio™ and REPAIR Implant™, our proprietary periodontal protocols for subgingival calculus removal and debridement of root surfaces and implant surfaces using the WaterLase system and patented Radial Firing Perio Tips. This is a minimally invasive treatment for moderate to advanced gum and peri-implant diseases, which are among the leading causes of dental health conditions for adults over age 35 and conditions that impact more than half of Americans over the age of 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 3Shape Trios and Galaxy BioMill System 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 rates, attract new patients, and increase revenue per patient, demand for elective procedures, acceptance of treatment plans, and word-of-mouth referrals.
- Improved clinical outcomes. Our laser systems can be used for dozens of clinical indications with reduced trauma, swelling, and general discomfort of the patient, resulting in improved clinical outcomes and less follow-up treatment. In parallel, our digital imaging systems provide greater clarity and information, making it possible for the doctor to determine the optimal diagnosis and treatment plan. The Galaxy BioMill System further expands treatment options available to patients and allows for same-day crowns. Our products collectively improve clinical outcomes, making it possible for practitioners to devote time to new cases, rather than managing or 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 and efficiency. Procedures utilizing 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 procedures utilizing our WaterLase system, patients may be more likely to consider cosmetic and other elective procedures resulting in better smiles and oral health. Our WaterLase system received expanded clearance from the FDA for dermatological, aesthetic, and general surgery uses, as well as dental procedures. 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 convenience 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.

- 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 plan to continue to explore potential collaborations to bring our proprietary laser technologies with expanded FDA-cleared indications for other medical applications in the future. 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, maintain high quality standards, and address and timely resolve customer complaints. 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 our field sales force. During 2012, we augmented our field sales force by establishing an in-house sales organization. The in-house sales organization is located at our corporate headquarters and is comprised of sales representatives and lead generators who work in partnership with the field sales team to maximize sales by leveraging the existing installed customer base. In 2013, we also added regional imaging specialists to the in-house sales organization to provide technical and clinical expertise in coordination with our field sales representatives. In addition to our field 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 one to two years from the date of sale to the end-user by us or a distributor. WaterLase systems and Diode systems sold internationally are covered by a warranty against defects in material and workmanship for a period of up to 28 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 unauthorized 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.

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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 provide assurance 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 (power suppliers, 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.

As discussed below, we are subject to periodic inspections by the FDA as a manufacturer of medical devices. Such inspections can cover manufacturing, design, production, reporting, recordkeeping, and other processes and can lead to FDA observations requiring corrective action, which can disrupt normal processes.

Marketing and Sales

Marketing

We 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 educational events, seminars, industry tradeshows, trade publications, the internet, field sales forces (in North America and Canada), and agents and distributors. We also use brochures, direct mail, public relations, and other promotional tools and materials.

Our primary marketing message to dental practitioners focuses on the improved cash flow and return on investment ("ROI") generated by delivering improved patient-reported outcomes. In 2015, we revamped our clinical and practical educational events for prospective laser dentists to include practice management and ROI information. In 2014, we introduced the Journal of Laser-Assisted Dentistry as a platform to provide education and research to users. 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 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 LinkedIn at www.linkedin.com/company/biolase, 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 field 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.

The following table summarizes our net revenues by category for the years ended December 31, 2015, 2014, and 2013 (dollars in thousands):

	Years Ended December 31,								
	2015			2014			2013		
Laser systems	$32,691	67.5	%	$29,490	61.9	%	$38,736	68.6	%
Imaging systems	2,237	4.6	%	4,286	9.0	%	4,632	8.2	%
Consumables and other	6,877	14.2	%	6,524	13.7	%	6,458	11.5	%
Services revenue	6,465	13.3	%	7,211	15.1	%	6,360	11.3	%
Products and services revenue	48,270	99.6	%	47,511	99.7	%	56,186	99.6	%
License fees and royalties	205	0.4	%	145	0.3	%	244	0.4	%
Net revenue	$48,475	100.0	%	$47,656	100.0	%	$56,430	100.0	%

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

	Years Ended December 31,		
	2015	2014	2013
United States	$29,433	$29,848	$35,653
International	19,042	17,808	20,777
	$48,475	$47,656	$56,430

International revenue accounts for a significant portion of our total revenue and accounted for approximately 39%, 37%, and 37% of our net revenue in 2015, 2014, and 2013, respectively. No individual country outside the United States represented more than 10% of our net revenue during the years ended December 31, 2015, 2014, and 2013.

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 field sales force consisting of laser sales representatives, imaging specialists, and regional managers. During 2012, we augmented our field sales force by establishing an in-house sales organization. The in-house sales force is located at our corporate headquarters and is comprised of sales representatives and lead generators who work in partnership with the field 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 field sales force, agents, and distributors. For the years ended December 31, 2015, 2014, and 2013, sales to our largest distributor worldwide accounted for approximately 3%, 6%, and 5%, 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 several third-party financial institutions with which we have established good relationships. In the United States and Canada, third-party customers enter into a financing agreement with one of the financial institutions that purchases the product from us or one of our distributors. We are not party to these financing agreements. Thus 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 20 individuals with medical device and laser development experience, including two Ph.Ds. During the years ended December 31, 2015, 2014, and 2013, our engineering and product development expenses totaled approximately $7.3 million, $4.6 million, and $4.0 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 new and improved protocols or procedures that are less painful and have clinically superior results. Some examples of the improvements we are pursuing for our laser systems include faster cutting speed, improved ease of use, less need for anesthesia, 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.

To further our development efforts, we have entered into a development and distribution agreement with IPG Photonics Corporation's medical laser division, IPG Medical. The development and distribution agreement between the Company and IPG covers several projects in various stages of development, with the expectation that these projects will culminate in commercialized joint dental laser products, accessories, or integral system components. The parties will collaborate in the design and development of these new products and applications, with each party contributing its technological expertise, know-how, and development resources. We will be responsible for U.S. and international registrations of all dental products resulting from the agreement, and we will have exclusive worldwide commercial distribution rights for certain products over a multi-year initial term after completion of development.

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, 2015, we had approximately 340 issued patents and 90 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: 23 in 2016, 4 in 2017, and 21 in 2018, with the majority having expiration dates ranging from 2025 to 2038. With approximately 90 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 and our WaterLase systems have been FDA-cleared for a wide range of uses beyond dentistry, including dermatological, aesthetics, and other general surgery uses. 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) premarket 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 12 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 premarket notification requesting 510(k) clearance, unless an exemption applies. After the FDA clears a device, the FDA requires that a 510(k) be submitted for certain, though not all, changes to the device.

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 devices are 510(k)-cleared Class II devices or 510(k)-exempt devices.

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, 510(k) premarket notification submissions are subject to user fees unless a specific exemption applies. 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, many of which we believe, based on the FDA's regulation and existing guidance, will not require new 510(k) clearances. We cannot provide assurance 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 provide assurance 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.

Additional FDA requirements apply to radiation emitting products, such as medical lasers, under the Radiation Control Health Safety Act of 1968 (“RCHSA”). These include:

- conformance to the FDA’s laser performance standard, which establishes certain requirements for emssions, testing, safety features, labeling, and other aspects of laser products;
- certification of compliance with the laser performance standard;
- reporting and recordkeeping requirements;
- notification to the FDA and dealers, distributors, and purchasers of certain product defects; and
- complying with a recall or an order to repair, replace, or refund an electronic product if ordered by the FDA.

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.

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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;
- product recall or seizure;
- interruption of production;
- operating restrictions;
- injunctions; and
- criminal prosecution.

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

Advertising and promotion of medical devices, in addition to being regulated by the FDA, are also regulated by the Federal Trade Commission ("FTC") and by state regulatory and enforcement authorities. 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.

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 provide assurance 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. Furthermore, we are 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. In the U.S., there are federal and state anti-kickback Statute 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 Statute 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 Statute 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 federal Anti-Kickback Statute. 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 federal Anti-Kickback Statute. However, arrangements that do not fit squarely within an exception or safe harbor do not necessarily violate the federal Anti-Kickback Statute. 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 federal Anti-Kickback Statute 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 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 (or at such other intervals, as indicated by medical necessity) are generally covered by Medicaid. Although not required to cover dental services for adults, most state Medicaid programs still provide a degree of coverage for at least emergency 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 if the dental procedure itself made hospitalization necessary. 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 2% cut. The Bipartisan Budget Act of 2015 extended the 2% sequestration cut for Medicare through fiscal year 2025 and realigned the fiscal year 2025 Medicare sequestration amounts so that there will be a 4% sequester for the first six months and a 0% sequester for the second six months, instead of a 2% 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 50 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, 2015, the Company employed approximately 200 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 our board of directors (our "Board"), which follows the annual meeting of stockholders, and at other Board meetings, as appropriate.

At March 11, 2016, the executive officers of the Company were as follows:

Name	Age	Position
Harold C. Flynn Jr.	50	President and Chief Executive Officer
David C. Dreyer	59	Chief Financial Officer
Clark Barousse	50	Senior Vice President of Worldwide Sales and Account Management
William E. Brown, Jr.	68	Vice President of Business Development
Richard R. Whipp	63	Vice President of Operations
Joseph Rotino	63	Vice President of Quality and Regulatory Affairs

Dmitri Boutoussov	52	Vice President of Research and Development
Brendan O'Connell	39	Vice President of Finance and Corporate Controller

Harold C. Flynn was named President and Chief Executive Officer of BIOLASE in July 2015. Prior to joining BIOLASE, Mr. Flynn was the President of Zimmer Dental, a division of Zimmer Holdings Inc. and a leading manufacturer and provider of medical devices for the dental market, including implants, prosthetics, and a range of other oral rehabilitation products from 2007 to 2015. From 2004 to 2007, Mr. Flynn was Divisional Vice President and General Manager at Abbott Hematology, a division of Abbott Laboratories. Prior to joining Abbott Hematology, Mr. Flynn spent 14 years in a variety of positions of increasing responsibility at IDEXX Laboratories, a global leader in veterinary, food, and environmental diagnostics. Mr. Flynn has a Bachelor of Science degree in Electrical Engineering from the University of Maine at Orono. He holds patents in laser-based hematology and implantable devices for dentistry.

David C. Dreyer was named Chief Financial Officer of BIOLASE in March 2015. Prior to joining BIOLASE, he was Chief Financial Officer of Patient Safety Technologies, Inc. (OTCQB: PSTX), a start-up public company that created the technology for preventing surgical retained sponge errors, from 2010 to 2014. From 2004 to 2009, Mr. Dreyer served as Chief Financial Officer of AMN Health Services, Inc. (NYSE:AHS), a healthcare staffing company. From 2002 to 2004, Mr. Dryer served as Chief Financial Officer of Sicor, Inc. (NASDAQ:SCRI), a specialty pharmaceutical company. Mr. Dreyer has a Bachelor of Science degree in Accounting from Golden Gate University graduating Magna Cum Laude. He is a Certified Public Accountant and a member of the AICPA.

Clark Barousse joined BIOLASE in August 2014 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 focused on implant procedures, from August 2012 to August 2014. From 2008 to 2012, Mr. Barousse was Senior Vice President of Global Sales & Marketing for Biohorizons Implant Systems, a dental implant and biologics company. Mr. Barousse earned his Master of Business Administration degree from Georgia State University and holds a Bachelor of Arts degree in Economics and Spanish from Hampden-Sydney College in Hampden-Sydney, Virginia.

William E. Brown, Jr. joined BIOLASE in 2002 as Director of Marketing and advanced to Vice President in 2006, Vice President of Sales and Marketing in 2008, and his current role as Vice President of Business Development in July 2013. Prior to joining BIOLASE, Mr. Brown was a co-founder of Kreativ, Inc., an international advanced dental equipment company, from 1995 until it was acquired by Welch-Allyn, Inc.in 1999. From 1999 to 2002 he served as Director of New Product Development and as a board director for Welch-Allyn Kreativ, Inc. From 1990 to 1995, he was Vice President of Sales and Marketing at HGM Medical Laser Systems, Inc., an international medical laser manufacturer. Mr. Brown holds a Bachelor of Science degree in Electrical Engineering from the University of Alabama.

Richard R. Whipp joined BIOLASE in July 2011 as Director of Operations and was promoted to Vice President of Operations in October 2011. Prior to joining BIOLASE, Mr. Whipp served as Senior Director of Operations at Discus Dental, which became a division of Philips Electronics, from 1998 to 2011. From 1992 to 1998, Mr. Whipp was Director of Operations at Leica Geosystems, Inc. Mr. Whipp previously held operations management positions at Gulton Industries, Inc., Conrac Industries, Inc., and Hydril. Mr. Whipp holds a Bachelor of Science degree in Industrial Engineering from the Newark College of Engineering.

Joseph Rotino joined BIOLASE in January 2015 as Vice President of Quality and Regulatory Affairs. Prior to joining BIOLASE, Mr. Rotino was Director of Quality Assurance for Johnson & Johnson's Advanced Sterilization Products division, leading quality efforts in both new product development and life-cycle management, as well as playing a lead role in the Terminal Sterilization Strategic Business Unit. Prior to Johnson & Johnson, Mr. Rotino served as Vice President of Quality and Regulatory for Pro-Dex, Inc. which developed and manufactured powered surgical devices, and Vice President of Quality Assurance for Sybron Dental Specialties (a Danaher Company), a leader in orthodontic, endodontic, dental composites, and implants. Mr. Rotino holds a Masters of Science degree in Quality Assurance from California State University – Dominguez Hills and a Bachelor of Science degree in Mathematics from William Paterson University of New Jersey.

Dmitri Boutoussov, Ph.D. joined BIOLASE in 2000 as the Director of Engineering and advanced to Vice President of Engineering in 2005, Chief Technology Officer in 2010, and his current role as Vice President of Research and Development in July 2013. Mr. Boutoussov holds a Doctorate degree in Philosophy and a Master of Science degree in Physics from Polytechnic University in St. Petersburg, Russia.

Brendan O'Connell was promoted from Corporate Controller to 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 degree in Accounting and a Masters of Business Administration degree from the University of California, Riverside.

Available Information

Our Annual Report on Form 10-K, Quarterly Reports on Form 10-Q, Current Reports on Form 8-K and amendments to reports filed or furnished pursuant to Sections 13(a) and 15(d) of the 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

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

Item 1A. Risk Factors

The following risk factors should be carefully considered when reviewing the other information included in this Form 10-K. 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 could 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

Although our financial statements have been prepared on a going concern basis, our management and independent auditors in their report accompanying our consolidated financial statements for the year ended December 31, 2015, believe that our recurring losses from operations and other factors have raised substantial doubt about our ability to continue as a going concern as of December 31, 2015.

Our audited financial statements for the fiscal year ended December 31, 2015 were prepared on a going concern basis in accordance with U.S. GAAP. The going concern basis assumes that we will continue in operation for the next 12 months and will be able to realize our assets and discharge our liabilities and commitments in the normal course of business, thus our financial statements do not include any adjustments that might be necessary if the Company is unable to continue as a going concern. Our recurring losses, negative cash flow, potential need for additional capital and the uncertainties surrounding our ability to raise such funding, raises substantial doubt about our ability to continue as a going concern. In order for us to continue operations beyond the next 12 months and be able to discharge our liabilities and commitments in the normal course of business, we must sell our products directly to end-users and through distributors, establish profitable operations through increased sales, decrease expenses, generate cash from operation or raise additional funds when needed. We intend to improve our financial condition and ultimately improve our financial results by increasing revenues through expansion of our product offerings, continuing to expand and develop our field sales force and distributor relationships both domestically and internationally, forming strategic arrangements within the dental and medical industries, educating dental and medical patients as to the benefits of our advanced medical technologies, and reducing expenses. If we are unable to increase sales, reduce expenses or raise sufficient additional capital we may be unable to continue to fund our operations, develop our products, realize value from our assets, or discharge our liabilities in the normal course of business. If we become unable to continue as a going concern, we could have to liquidate our assets, and potentially realize significantly less than the values at which they are carried on our financial statements, and stockholders could lose all or part of their investment in our common stock.

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

We had an accumulated deficit of approximately $163 million at December 31, 2015. We recorded net losses of approximately $20.3 million, $18.9 million, and $11.5 million for the years ended December 31, 2015, 2014, and 2013, 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 and could have a material adverse effect on our business, financial condition, and results of 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 could have a material adverse effect on our business, financial condition, and results of operations, including by:

- reducing demand for our products and services, increasing order cancellations and resulting in longer sales cycles and slower adoption of new technologies;
- increasing the difficulty of collecting accounts receivable and the risk of excess and obsolete inventories;
- increasing price competition in our served markets; and
- resulting in supply interruptions, which could disrupt our ability to produce our products.

We could need to raise additional capital in the future, and if we are unable to secure adequate funds on terms acceptable to us, we could 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 could 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 could have rights, preferences or privileges senior to those of our common stock. In addition, if we raise additional funds through debt financing, we could be subject to debt covenants that place limitations on our operations. We could not be able to raise additional capital on reasonable terms, or at all, or we could 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 could 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 could 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, or reduced manufacturing efficiencies and could have a material adverse effect on our business, financial condition, and results of operations.

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, 2015, 2014, and 2013, revenue from distributors accounted for approximately 34%, 30%, and 30% 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 and could have a material adverse effect on our business, financial condition, and results of operations.

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, and our inability to do so could have a material adverse effect on our business, financial condition, and results of operations. Historically, we have experienced long sales cycles because dentists have been, and could 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 could 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 could 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, could 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, reduce the market acceptance of our products and have a material adverse effect on our business, financial condition, and results of operations.

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 provide assurance that we will be successful in these efforts. If dental practitioners are not properly trained, they could misuse or ineffectively use our products, or could be less likely to appreciate our laser systems. This could also result in unsatisfactory patient outcomes, patient injury, negative publicity, FDA regulatory action, 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 could decline and our business, financial condition, and results of operations could be materially and adversely affected.

If new studies or comparative studies generate results that are not as favorable as our clinical results, our revenues could decline. Additionally, if future studies indicate that our competitors' products are more effective or safer than ours, our revenues could decline. Furthermore, dental practitioners could 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 could 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 could decline and our business, financial condition, and results of operations could be adversely affected.

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. There is no assurance that we will be able to distinguish our products and commercialize any new products, new or improved technologies, or additional applications for our laser systems.

If our customers cannot obtain third-party reimbursement for their use of our products, they could be less inclined to purchase our products and our business, financial condition, and results of operations could be adversely affected.

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 could 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 could 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 could 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, 2015, approximately $109.5 million of net operating loss carryforwards were available to us for federal income tax purposes. A detailed analysis will be required at the time we begin utilization of any net operating losses to determine if there is 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, could 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 which could have a material adverse effect on our business, financial condition, and results of operations.

We could 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 could 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 could 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, and we could continue to do so. 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, and an inability to do so could have a material adverse effect on our business, financial condition, and results of operations

We could be subject to significant warranty obligations if our products are defective, which could have a material adverse effect on our business, financial condition, and results of operations.

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 could continue to experience such non-compliance in the future, which could lead to higher costs and reduced margins.

Our products could contain defects that cannot be repaired easily and inexpensively, and we have experienced in the past and could 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, which could have a material adverse effect on our business, financial condition, and results of operations.

Our products are used in minimally invasive surgical procedures, usually, though not always, without anesthesia. All surgical procedures carry some risk. Patients could experience adverse events or outcomes following a surgical procedure due to a multitude of different factors alone or in combination, including deficits in the skill, experience, and preparedness of the surgeon, the existence of underlying conditions or overall poor health of the patient, and defects, age, and misuse of medical products used in the procedure. Should an adverse patient event occur during the use of a BIOLASE product, there could be adverse publicity, increased scrutiny from regulatory agencies, and a loss

of good will, even if it is ultimately shown to be caused by factors other than a BIOLASE product.

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 provide assurance that we will be able to obtain such insurance in the future on terms acceptable to us, or at all. Regardless of merit or eventual outcome, any product liability claim brought against us could result in harm to our reputation, decreased demand for our products, costs related to litigation, product recalls, loss of revenue, an increase in our product liability insurance rates, or the inability to secure coverage in the future, and could have a material adverse effect on our business, financial condition, and results of operations.

Our suppliers may not supply us with a sufficient amount or adequate quality of materials, which could have a material adverse effect on our business, financial condition, and results of operations.

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 could affect their ability to deliver components for us in a timely manner. Moreover, our suppliers could 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 could need to reengineer our components, which could 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, result in significant additional costs, and have a material adverse effect on our business, financial condition, and results of operations.

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 could emerge that 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 could incur higher manufacturing costs if manufacturing processes or standards change, and we could need to replace, modify, design, or build and install equipment, all of which would require additional capital expenditures.

We could be unable to effectively manage and implement our growth strategies, which could have a material adverse effect on our business, financial condition, and results of operations

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, could require longer implementation times or greater start-up expenditures than anticipated, and could otherwise fail to achieve the desired results in a timely fashion, if at all. These efforts could 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 could be unable to increase our sales and earnings by expanding our product offerings in a cost-effective manner, and we could fail to accurately predict future customer needs and preferences or to produce viable technologies. In addition, we could 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 could incur substantial costs in doing so. In addition, promising new products could 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, 2015, 2014, and 2013, international sales accounted for approximately 39%, 37%, and 37% 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 which could have a material adverse effect on our business, financial condition, and results of operations, 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 could do so in the future.

We could 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, or employee error, malfeasance or other disruptions that cause an IS security breach could lead to a material disruption of our IS and/or the loss of business information. Such an attack could result in, among other things:

- the theft, destruction, loss, misappropriation or release of confidential data and intellectual property;
- operational or business delays;
- liability for a breach of personal financial and health information belonging to our customers and their patients or to our employees; and
- Damage to our reputation

any of which could have a material adverse effect on our business, financial condition, and results of operations. In the event of an attack, we would be exposed to a risk of loss or litigation and possible liability, including under laws that protect the privacy of personal information.

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 could 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 could 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 carryforwards under the provisions of IRC Section 382 and similar state laws;
- developments concerning the protection of our intellectual property rights;

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- 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 could 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 and could materially and adversely affect our business, financial condition, and results of operations.

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 could divert our management's attention, and we could incur significant expenses in defending these lawsuits. In addition, we could be required to pay damage awards or settlements or become subject to unfavorable equitable remedies. Moreover, any insurance or indemnification rights that we could 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 and have a material adverse effect on our business, financial condition, and results of operations.

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. Although we have taken precautions to safeguard our facilities including disaster recovery planning and off-site backup of computer data, 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 could 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 and our business, financial condition, and results of operations could be materially and adversely affected. In general, our officers could 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 could 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 could 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 could 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 results of operations.

If we fail to comply with the reporting obligations of the Exchange Act and Section 404 of the Sarbanes-Oxley Act, or if we fail to maintain adequate internal control over financial reporting, our business, financial condition, and results of operations, 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 ("NASDAQ"), 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 could have complex supply chains that could 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, 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 could identify areas requiring improvement and could 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 the Company and our ability to access capital markets for financing.

Climate change initiatives could materially and adversely affect our business, financial condition, and results of operations.

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 could 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 could 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 ensure 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 could 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 (the "USPTO"), and there could be future proposed changes that, if enacted, 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 could be adversely affected, and there could be a material adverse effect on our business, financial condition, and results of operations.

If third parties claim that we infringe their intellectual property rights, we could incur liabilities and costs and have to redesign or discontinue selling certain products, which could have a material adverse effect on our business, financial condition, and results of operations.

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 could 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, could 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 have a material adverse effect on our business, financial condition, and results of operations.

Our products are subject to extensive government regulation, both in the United States and in other countries. Too 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 could 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 and 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. For example, in 2010, President Obama signed the Affordable Care Act into law, which included various reforms impacting Medicare coverage and reimbursement, including revision to prospective payment systems, any of which could adversely impact any Medicare reimbursements received by our end-user customers. . In addition, as a result of the focus on health care reform, there is risk that Congress could implement changes in laws and regulations governing health care service providers, including measures to control costs, and reductions in reimbursement levels. 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. If providers cannot obtain adequate coverage and reimbursement for our products, or the procedures in which they are used, our business, results of operations, and financial condition could suffer.

We could 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 and which includes the RCHSA, under which the FDA has established reporting, recordkeeping, and performance requirements for laser products;
- state food and drug laws;
- the federal Anti-Kickback Statute, 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 could be made under FHCPs such as Medicare, Medicaid, and TRICARE;
- state law equivalents to the federal Anti-Kickback Statute, 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 could be subject to the applicable penalty associated with the violation, which could 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 could 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, damage our reputation, and cause a material adverse effect on our business, financial condition, and results of operations.

We could be exposed to liabilities under the FCPA, and any determination that we violated the FCPA could have a material adverse effect on our business, financial condition, and results 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 could 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 results of operations.

Product sales or introductions could be delayed or canceled as a result of the FDA regulatory requirements applicable to laser products, dental devices, or both, which could cause our sales or profitability to decline and have a material adverse effect on our business, financial condition, and results of operations.

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 provide assurance 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 PMA. 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 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 provide assurance 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 could occur. We cannot provide assurance that the FDA will not require a new product or product enhancement to go through the lengthy and

expensive PMA process. Delays in obtaining regulatory clearances and approvals could:

- 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 provide assurance 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 recalls and other regulatory actions 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. However, any recall could have a material adverse effect on our business, financial condition, and results of operations.

Risks Related to Our Stock

The liquidity and trading volume of our common stock could 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 could 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.

Three of our stockholders beneficially own approximately 50% of our outstanding common stock, in the aggregate, as of February 3, 2016, 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.

We have received a delisting notice from NASDAQ. Our common stock could be involuntarily delisted from trading on the NASDAQ Capital Market if we fail to regain compliance with the minimum closing bid price requirement of $1.00 per share. A delisting of our common stock is likely to reduce the liquidity of our common stock and could inhibit or preclude our ability to raise additional financing.

The quantitative listing standards of NASDAQ require, among other things, that listed companies maintain a minimum closing bid price of $1.00 per share. We failed to satisfy this threshold for 30 consecutive trading days, and on November 10, 2015, we received a letter from NASDAQ indicating that we have been provided an initial period of 180 calendar days, or until May 9, 2016, in which to regain compliance. To regain compliance, the Company's common stock must have a closing bid price of at least $1.00 per share for a minimum of ten consecutive business days. In the event the Company does not regain compliance by May 9, 2016, the Company could be eligible for an additional 180-day grace period to regain compliance. The Company is considering available options to resolve the noncompliance with the minimum bid price requirement, which could include a reverse stock split. If we do not regain compliance, or receive an additional 180-day grace period to regain compliance by May 9, 2016, the NASDAQ staff

will provide written notice that our common stock is subject to delisting. Given recent market volatility and the concentration of ownership of our common stock, we could be unable to regain compliance with the closing bid price requirement by May 9, 2016 or, if we receive an additional 180-day grace period, by November 5, 2016. A delisting of our common stock is likely to reduce the liquidity of our common stock and could inhibit or preclude our ability to raise additional financing.

Our stock price has been, and could 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 could negatively affect the market price of our stock. The market price and volume of our common stock could 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 could 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, our significant stockholders, 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, 2015, an aggregate of 11,550,000 shares of common stock were reserved for future issuance under our equity incentive plan, 4,493,000 of which were subject to options outstanding as of that date at a weighted-average exercise price of $2.72 per share. In addition, as of December 31, 2015, 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 4,493,000 stock options outstanding at December 31, 2015, 2,739,000 stock options were vested and exercisable. To the extent that outstanding warrants or options are exercised, our existing stockholders could 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 could 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 for gross proceeds 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 193,032 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 the Company.

Provisions in our restated certificate of incorporation and amended and restated bylaws could 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.

On November 10, 2015, we entered into Standstill Agreements with certain stockholders restricting them from (i) purchasing or acquiring any shares of BIOLASE common stock if such a purchase would result in aggregate beneficial ownership in excess of 25% of the issued and outstanding shares of BIOLASE common stock and (ii) selling, transferring or otherwise conveying shares of BIOLASE common stock (or warrants or other rights to acquire shares of BIOLASE common stock) to anyone who would immediately thereafter beneficially own shares in excess of 20% of the issued and outstanding shares of BIOLASE common stock, as a result of such transfer and other transfers from third parties. These Standstill Agreements may discourage, delay, or prevent a change in control of the Company.

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.

Item 1B. Unresolved Staff Comments

None.

Item 2. Properties

As of December 31, 2015, 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 30, 2020. 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 — Supplementary Balance Sheet Information — 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 June 5, 2015, the United States District Court for the Central District of California approved, on a preliminary basis, the settlement of the consolidated securities class action lawsuit. The hearing on the final approval of the settlement was held on October 9, 2015, and the court entered final judgment and ordered the case dismissed on October 30, 2015.

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 (the "Patent 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 the Patent Board. On July 1, 2014, the Patent Board noted that request and docketed the case for consideration. A hearing on reconsideration was held in November 2014. On July 1, 2015, the Patent Board issued a Decision that was generally favorable to the Company. On July 31, 2015, CAO requested a rehearing of the decision. On November 27, 2015, the Patent Board issued its decision on Request for Rehearing, partially granting CAO's request. On January 27, 2016, CAO filed its Notice of Appeal to the United States Court of Appeals for the Federal Circuit for review of the Patent Board's decision dated July 1, 2015 and the Patent Board's decision regarding CAO's request for rehearing.

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. 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. 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.

Subsequent to the foregoing responses, on March 24, 2015 the parties reached an agreement to settle the foregoing litigation and to dismiss the litigation with prejudice. As part of the settlement, Fotona agreed to pay the Company a total of $1.4 million, with $550,000 payable within 10 days of March 24, 2015 and the remaining, $825,000 payable in three increments of $275,000 each to be paid no later than the first, second, and third anniversary of the effective date of the agreement. Pursuant to the settlement agreement, the Company (i) granted Fotona a three-year, non-exclusive, paid-up license in the United States market and a five-year, non-exclusive, paid-up license in markets outside of the United States and (ii) agreed to grant Fotona a non-exclusive, royalty-based license following the expiration of the paid-up licenses. The Company calculated the present value of the settlement amount to be $1.2 million and allocated such amount to each significant element of the settlement on a relative fair value basis. $731,000 and $68,000 were allocated towards the recovery of the Company's legal expenses and as settlement for the dismissal of the patent infringement lawsuit and are reflected as legal settlement and license fees and royalty revenue, respectively, on the Consolidated Statements of Operations and Comprehensive Loss. The remaining amount of $379,000 was allocated towards the three-year, non-exclusive, paid-up license in the United States market and the five-year, non-exclusive, paid-up license in markets outside of the United States which was reflected within other assets and long-term deferred revenue on the Consolidated Balance Sheets. The deferred revenue is being recognized as license revenue over the terms of the paid-up licenses.

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:

	2015		2014	
	High	Low	High	Low
First Quarter	$2.73	$1.90	$3.36	$2.29
Second Quarter	$2.61	$1.39	$2.39	$1.76
Third Quarter	$1.76	$0.89	$2.72	$1.92
Fourth Quarter	$1.08	$0.62	$2.97	$2.28

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

As of February 29, 2016, the closing price of our common stock on the NASDAQ Capital Market was $0.89 per share, and the number of stockholders of record was 180. 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. Additionally, we do not anticipate paying any stock dividends in 2016. Our dividend policy may be changed at any time, and from time to time, by our Board.

There were no dividends paid or declared in 2015. The following table sets forth certain information relating to our stock dividends declared during 2014:

	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	193,032

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 2016 Annual Meeting of Stockholders, is incorporated by reference herein.

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 on $100 invested, assuming the reinvestment of all dividends, on December 31, 2010, the last trading day before our 2011 fiscal year, through the end of fiscal 2015 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,					
	2010	2011	2012	2013	2014	2015
BIOLASE, Inc.	$100.00	$152.82	$112.22	$175.13	$163.57	$52.31
NASDAQ Composite Index	100.00	100.53	116.92	166.19	188.78	199.95
NASDAQ Medical Equipment	100.00	115.55	128.17	151.89	175.17	190.80

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,				
	2015	2014	2013	2012	2011
	(in thousands, except per share data)				
Consolidated Statements of Operations Data:					
Net revenue	$48,475	$47,656	$56,430	$57,356	$48,858
Net cost of revenue(1)	32,525	29,484	34,900	30,878	27,540
Gross profit	15,950	18,172	21,530	26,478	21,318
Operating expenses:					
Sales and marketing(1)	18,696	16,375	18,682	16,250	13,075
General and administrative(1)	10,256	14,854	9,377	8,075	7,936
Engineering and development(1)	7,283	4,577	4,029	4,684	4,311
Excise tax	361	307	438	—	—
Patent infringement legal settlement	(731)	—	—	—	—
Total operating expenses	35,865	36,113	32,526	29,009	25,322
Loss from operations	(19,915)	(17,941)	(10,996)	(2,531)	(4,004)
Non-operating loss	(185)	(873)	(650)	(414)	(393)
Loss before income taxes	(20,100)	(18,814)	(11,646)	(2,945)	(4,397)
Income tax provision (benefit)	178	112	(164)	111	89
Net loss as reported	$(20,278)	$(18,926)	$(11,482)	$(3,056)	$(4,486)
Net loss from operations per share:					
Basic	$(0.34)	$(0.42)	$(0.34)	$(0.08)	$(0.13)
Diluted	$(0.34)	$(0.42)	$(0.34)	$(0.08)	$(0.13)
Net loss per share:					
Basic	$(0.35)	$(0.45)	$(0.35)	$(0.10)	$(0.15)
Diluted	$(0.35)	$(0.45)	$(0.35)	$(0.10)	$(0.15)
Shares used in computing net loss from operations per share and net loss per share(2):					
Basic	58,189	42,232	32,768	32,162	30,762
Diluted	58,189	42,232	32,768	32,162	30,762
Consolidated Balance Sheet Data:					
Working capital	$19,694	$38,647	$3,915	$7,542	$9,044
Total assets	$42,251	$59,403	$31,038	$31,973	$29,807
Long-term liabilities	$2,220	$1,196	$618	$804	$956
Stockholders' equity	$24,925	$42,056	$8,481	$11,794	$12,569

(1) 2015, 2014, 2013, 2012, and 2011 include $3.4 million, $1.2 million, $1.6 million, $1.6 million, and $1.5 million, respectively, in total compensation cost related to stock options classified in cost of revenue, sales and marketing, general and administrative, and engineering and development expenses.

(2)

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. 2015, 2014, 2013, 2012, and 2011 include $0, $193 thousand, $667 thousand, $634 thousand, and $1.2 million, respectively, in 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 340 issued and 90 pending U.S. and international patents, the majority of which are related to WaterLase technology. From 1998 through December 31, 2015, we sold approximately 30,500 laser systems in over 90 countries around the world. Contained in this total are over 11,200 WaterLase systems, including more than 7,200 WaterLase MD and iPlus systems.

2015 was a year of major change and transformation at BIOLASE. After a tough year of leadership transition in 2014 with our Board of Directors, Chairman and appointed CEO all in place, the Company's initial focus in 2015 was on addressing product quality issues, rebuilding our U.S. sales force, and re-launching our two main laser products, the EPIC X and the WaterLase iPlus 2.0. In March 2015, we also launched the PGG Program, the first of its kind offering to all customers of our new U.S. WaterLase iPlus product. The PGG Program offers training to our customers on seven to ten key laser procedures and helps assure them that their investments in our WaterLase iPlus products will enhance and grow their practices by greatly improving their patients' dental experiences and reducing their treatment times on common procedures. The PGG Program also provides our customers with professional marketing and billing support. The PGG Program helps our customers grow their practices in terms of number of patients, patient satisfaction levels, and billings. With the implementation of the PGG Program, we significantly increased our focus on customer service and training.

In 2015, Harold C. Flynn Jr. was named our President and Chief Executive Officer and David C. Dreyer was named our Chief Financial Officer. Messrs. Flynn and Dreyer bring decades of experience to BIOLASE with respect to turning distressed businesses into successful growth companies that evolve to become market leaders of their respective industry segments. Some of the management team's accomplishments in 2015 under the guidance of Messrs. Flynn and Dreyer include:

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Reprioritized the Company's focus on conserving cash, supported by the implementation of key controls over spending and improvements to the sales cycle to facilitate larger and more reliable cash receipts. This included resolving a number of disagreements and threatened lawsuits and addressing a significant amount of past due liabilities with positive results.

- Established a new strategic plan for the Company, incorporating valuable solicited input and support from our key stakeholders, including customers, vendors, employees, industry leaders, our Board, and shareholders.
- Completed in-depth assessments of the Company's new product developments, resulting in the focusing of our efforts on developing a more limited number of new dentistry products and utilizing industry experts to help design products to meet the market's needs. In addition, implemented new project management techniques using appropriate risk assessment tools and solution management techniques.

- Entered into a product development arrangement with IPG to jointly develop new dental laser products to increase our access to resources and expertise, and potentially add more new products to the Company's bench of future products launches.
- Increased our focus and emphasis on supporting customers and patients by significantly improving training and customer service support functions. Launched our new BIOLASE Learning Center at our Irvine facility that is now providing world class training and education.

In summary, 2015 was a year of transformation for BIOLASE, positioning the Company to begin executing on our strategic goals of returning BIOLASE to a successful growing company that offers multiple new products each year and re-establishes itself as the clear worldwide industry leader in the dental laser segment. Although we have made improvements throughout the year, it will take time for the financial statements to reflect the changes and as such, for the three years ended December 31, 2015 we have reported recurring losses from operations and have not generated cash from operations. Our level of cash used in operations, the potential need for additional capital, and the uncertainties surrounding our ability to raise additional capital, raises substantial doubt about our ability to continue as a going concern. As a result, the opinion we have received from our independent registered public accounting firm, on our consolidated financial statements, contains an explanatory paragraph stating that there is a substantial doubt regarding our ability to continue as a going concern.

The accompanying financial statements have been prepared on a going concern basis, which assumes that we will continue in operation for the next 12 months and will be able to realize our assets and discharge our liabilities and commitments in the normal course of business. The financial statements do not include any adjustments that might be necessary if the Company is unable to continue as a going concern.

Critical Accounting Policies

The preparation of consolidated financial statements and related disclosures in conformity with generally accepted accounting principles in the United States ("GAAP") requires us to make estimates and assumptions that affect the amounts reported in the consolidated financial statements and the accompanying notes. 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 field 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. For sale of deliverables that are part of a multiple-element arrangement, we apply a method which approximates the relative selling price method, which requires that arrangement consideration be allocated at the inception of an 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 appropriate expiration of time offered under the agreement.

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 contracts, 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. Trade-in rights are not established or 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 trade-ins of 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. 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 record 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 goods sold, 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 more than 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 or market, with cost determined using the first-in, first-out method. 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 subject to amortization 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, 2015 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 years ended December 31, 2015, 2014, and 2013 laser systems sold domestically were covered by our warranty for a period of up to two years from the date of sale by us or the distributor to the end-user. Laser systems sold internationally were covered by our warranty for a period of up to 28 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 significant 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 2015, 2014, and 2013 and the available evidence, management has determined that it is more likely than not that the deferred tax assets as of December 31, 2015 will not be realized in the near term. Consequently, we have established a valuation allowance against our net deferred tax asset totaling approximately $49.5 million and $42.1 million as of December 31, 2015 and 2014, 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, capital lease obligation and accrued liabilities, approximate fair value because of the short-term 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 is based on assumptions that market participants would use, including a consideration of non-performance risk. Under the accounting guidance for value hierarchy, there are three levels of measurement inputs. Level 1 inputs are quoted prices in active markets for identical assets or liabilities. Level 2 inputs are observable, either directly or indirectly. Level 3 inputs are unobservable due to little or no corroborating market data.

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Results of Operations

The following table sets forth certain data from our operating results for each of the years ended December 31, 2015, 2014, and 2013, expressed as percentages of revenue:

	Years Ended December 31,		
	2015	2014	2013
Products and services	99.6 %	99.7 %	99.6 %
License fees and royalty	0.4	0.3	0.4
Net revenue	100.0	100.0	100.0
Cost of revenue	67.1	61.9	61.8
Gross profit	32.9	38.1	38.2
Operating expenses:			
Sales and marketing	38.6	34.4	33.1
General and administrative	21.2	31.2	16.6
Engineering and development	15.0	9.6	7.2
Excise tax	0.7	0.6	0.8
Patent infringement legal settlement	(1.5)	—	—
Total operating expenses	74.0	75.8	57.7
Loss from operations	(41.1)	(37.7)	(19.5)
Non-operating loss, net	(0.4)	(1.8)	(1.1)
Loss before income taxes	(41.5)	(39.5)	(20.6)
Income tax provision (benefit)	0.4	0.2	(0.3)
Net loss	(41.9)%	(39.7)%	(20.3)%

The following table summarizes our net revenues by category for the years ended December 31, 2015, 2014, and 2013 (dollars in thousands):

	Years Ended December 31,					
	2015		2014		2013	
Laser systems	$32,691	67.5 %	$29,490	61.9 %	$38,736	68.6 %
Imaging systems	2,237	4.6 %	4,286	9.0 %	4,632	8.2 %
Consumables and other	6,877	14.2 %	6,524	13.7 %	6,458	11.5 %
Services	6,465	13.3 %	7,211	15.1 %	6,360	11.3 %
Total products and services	48,270	99.6 %	47,511	99.7 %	56,186	99.6 %
License fees and royalty	205	0.4 %	145	0.3 %	244	0.4 %
Net revenue	$48,475	100.0 %	$47,656	100.0 %	$56,430	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 ongoing 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 compensation, 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,		
	2015	2014	2013
GAAP net loss, as reported	$(20,278)	$(18,926)	$(11,482)
Adjustments:			
Interest expense (income), net	(74)	458	600
Income tax (benefit) provision	178	112	(164)
Depreciation and amortization	880	696	601
Stock-based, other equity instruments, and other non-cash compensation	3,350	1,356	1,965
Non-GAAP net loss	$(15,944)	$(16,304)	$(8,480)

Comparison of Results of Operations

Year Ended December 31, 2015 Compared with Year Ended December 31, 2014

Net Revenue. Net revenue for the year ended December 31, 2015 ("Fiscal 2015") was $48.5 million, an increase of $819,000, or 2%, as compared with net revenue of $47.7 million for the year ended December 31, 2014 ("Fiscal 2014"). Domestic revenues were $29.5 million, or 61% of net revenue, for Fiscal 2015 compared to $29.8 million, or 63% of net revenue, for Fiscal 2014. International revenues for Fiscal 2015 were $19.0 million, or 39% of net revenue, compared to $17.8 million, or 37% of net revenue for Fiscal 2014. The increase in period-over-period net revenue resulted from increases in domestic and international laser system revenue, and license fees and royalty revenue, partially offset by decreases in imaging systems, consumables and other, and services revenue. Our goal has been to refocus on strengthening our leadership position in dental markets worldwide through increased focus on our professional customers and their patients. We have strengthened our management team with new key personnel and invested in our sales resources both domestically and internationally.

Laser system net revenues increased by approximately $3.2 million, or 11%, in Fiscal 2015 compared to Fiscal 2014. As expected, we experienced an improvement in the sales of our core laser products during Fiscal 2015 as compared with the prior year. We began to realize some of the changes to our sales cycle that were implemented late in 2015.

Imaging system net revenue decreased by approximately $2 million, or 48%, in Fiscal 2015 compared to Fiscal 2014. This decrease was due to an increased focus by our sales group on our core laser system product line.

Consumables and other net revenue, which includes products such as disposable tips and shipping revenue, increased approximately $353,000, or 5%, in Fiscal 2015, as compared to Fiscal 2014. The 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 primarily of extended warranty service contracts and advanced training programs, decreased by approximately $746,000, or 10%, in Fiscal 2015, as compared to Fiscal 2014. The decrease in revenue was mainly attributed to the impact from recognizing $708,000 in deferred training service revenues during the third quarter of 2014, which resulted from making a change in estimate in the period over which deferred training service revenue are being recognized.

License fees and royalty revenues increased by approximately $60,000, or 41%, to approximately $205,000 in Fiscal 2015 compared to $145,000 in Fiscal 2014. These license fees and royalty revenues were attributable to intellectual property related to our laser technologies. The increase was primarily due to the settlement of the Fotona Proizvodnja Optoelektronskih Naprav D.D. and Fotona LLC intellectual property litigation (the "Fotona Litigation"). We anticipate license fees and royalty revenue to return to more normalized levels in the year ending December 31, 2016 ("Fiscal 2016").

Cost of Revenue. Cost of revenue in Fiscal 2015 increased by $3.0 million, or 10%, to $32.5 million, or 67% of net revenue, compared with cost of revenue of $29.5 million, or 62% of net revenue, in Fiscal 2014. The increase in cost of revenue was mainly attributable to increased bundling and other promotional arrangements related to the launch of the EPIC X and WaterLase iPlus 2.0 and an increased concentration of international sales. International sales typically have lower margins than our domestic sales.

Gross Profit. Gross profit for Fiscal 2015 was $16.0 million, or 33% of net revenue, a decrease of approximately $2.2 million, or 12%, as compared with gross profit of $18.2 million, or 38% of net revenue, for Fiscal 2014. The decrease was primarily due to increased bundling and other promotional arrangements related to the launch of the EPIC X and WaterLase iPlus 2.0 and an increased concentration of international sales.

Operating Expenses. Operating expenses for Fiscal 2015 were $35.9 million, or 74% of net revenue, a decrease of approximately $248,000, or 1%, as compared with $36.1 million, or 76% of net revenue, for Fiscal 2014. We expect that operating expenses as a percentage of net revenue will continue to decrease for Fiscal 2016, due to the cost reductions that were implemented in the second half of 2015, along with the implementation of tighter controls. The year-over-year decrease in expense is primarily due to the $5.7 million decrease in legal expenses, partially offset by a $5.4 million increase in payroll-related expenses. See the following expense categories for further explanations.

Sales and Marketing Expense. Sales and marketing expenses for Fiscal 2015 increased by $2.3 million, or 14%, to $18.7 million, or 39% of net revenue, as compared with $16.4 million, or 34% of net revenue, during Fiscal 2014. The increase was primarily a result of increased payroll and consulting-related expenses of $1.8 million, increased media and advertising expenses of $442,000, increased supplies of $273,000, and increased commissions of $244,000, partially offset by decreased convention-related expenses of $267,000 and decreased travel and entertainment expenses of $247,000. The increase in payroll and consulting-related expenses resulted primarily from increased salary expenses of $745,000, an increase of $278,000 in stock-based compensation attributable to grants to existing and new employees, and an increase of $121,000 in severance-related expenses associated with our internal corporate organizational restructuring changes in the second half of 2015. As we continue to transform and return to revenue growth, we expect sales and marketing expenses to decrease as a percentage of revenue in Fiscal 2016.

General and Administrative Expense. General and administrative expenses for Fiscal 2015 decreased by $4.6 million, or 31%, to $10.3 million, or 21% of net revenue, as compared with $14.9 million, or 31% of net revenue, for Fiscal 2014. The decrease to general and administrative expenses was primarily due to decreased legal expenses of $5.7 million, and a decrease to our provision for doubtful accounts of $1.1 million, partially offset by increased payroll and consulting-related expenses of $1.9 million, increased licensing fees of $205,000, and increased depreciation expenses of $195,000. The decrease in legal expenses resulted from the atypical defense of the director dispute and resulting shareholder litigation incurred during the first half of 2014, as well as a reduction of $1.7 million in legal fees in December 2015 which related to settling legal fees owed in connection with the 2014 shareholder litigation. The increase in payroll-related and consulting-related expenses resulted primarily from an increase of $1.4 million in stock-based compensation expenses attributable to grants to existing and new employees. We expect general and administrative expenses to decrease as a percentage of revenue in Fiscal 2016.

Engineering and Development Expense. Engineering and development expenses for Fiscal 2015 increased by $2.7 million, or 59%, to $7.3 million, or 15% of net revenue, as compared with $4.6 million, or 10% of net revenue, in Fiscal 2014. The increase was primarily related to increased payroll, consulting and temporary labor expenses of $1.4 million and increased supplies of $795,000 resulting from our development efforts relating to our new and existing products and technologies. We expect to increase our investment in engineering and development activity as we continue our efforts on new product development during 2016.

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 2015 were $361,000, or 1% of net revenue, as compared with $307,000, or 1% of net revenue, for Fiscal 2014. The increase of $54,000, or 18%, was

directly associated with our increased sales in the U.S. Under the recently signed Protecting Americans from Tax Hikes Act of 2015 (the "PATH Act"), the medical device excise tax has been suspended for calendar years 2016 and 2017. Because of the PATH Act, we do not anticipate any excise tax expenses on our products during Fiscal 2016.

Non-Operating Income (Loss)

(Loss) Gain on Foreign Currency Transactions. We recognized a $259,000 loss on foreign currency transactions for Fiscal 2015 compared to a $415,000 loss for Fiscal 2014 due to exchange rate fluctuations primarily between the U.S. dollar and the Euro. During Fiscal 2015, the Euro fell approximately 10% in translation value against the U.S. dollar.

Interest Income (Expense), Net. Interest income during Fiscal 2015 represented interest recognized from the discounted present value of the settlement in connection with the Fotona Litigation. Interest expense in Fiscal 2015 consisted of interest incurred on our capital lease obligations in connection with the lease of information technology equipment. Interest expense for Fiscal 2014 consisted primarily of interest on our revolving credit facilities and amortization of debt issuance costs and debt discount. Interest income (expense), net totaled approximately $74,000 of interest income, or 0.1% of net revenue for Fiscal 2015, as compared to an interest expense of $458,000, or 1% of net revenue for Fiscal 2014. The decrease in interest expense was primarily a result of the Company paying in full all amounts due under the revolving lines of credit with Comerica Bank in July 2014.

Provision (benefit) for Income Taxes. Our provision for income taxes was $178,000 for Fiscal 2015, an increase of $66,000, or 59%, as compared with our provision of income taxes of $112,000 in Fiscal 2014. The increase is due to additional income earned in foreign jurisdictions in Fiscal 2015.

Net Loss. For the reasons stated above, our net loss was $20.3 million for Fiscal 2015 compared to a net loss of $18.9 million for Fiscal 2014. The increase in net loss of approximately $1.4 million, or 7%, was primarily due to decreased gross profit of $2.2 million, offset by decreased operating expenses of $248,000 and a decrease in non-operating loss of $688,000.

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

Net Revenue. Net revenue for 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. See Note 7 to the Notes to the Consolidated Financial Statements — Litigation — Shareholder Litigation.

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, which we instituted 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 due to higher pricing. 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 demand 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. 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.

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 Chief Executive Officer in the shareholder litigation brought by Oracle Partners L.P. 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 Chief Executive Officer in July 2014, which litigation was subsequently dismissed.

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 and improvements of our products and technologies beginning in the third quarter of Fiscal 2014.

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 were $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.

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.

	(in thousands, except per share data)			
	March 31,	June 30,	September 30,	December 31,
2015				
Net revenue	$10,855	$11,869	$ 11,234	$ 14,517
Gross profit	$3,210	$3,701	$ 3,381	$ 5,658
Loss from operations(1)	$(5,259)	$(7,029)	$ (5,352)	$ (2,275)
Net loss(1)	$(5,436)	$(7,041)	$ (5,343)	$ (2,458)
Net loss per share(3):				
Basic	$(0.09)	$(0.12)	$ (0.09)	$ (0.04)
Diluted	$(0.09)	$(0.12)	$ (0.09)	$ (0.04)
2014				
Net revenue	$11,518	$10,186	$ 12,714	$ 13,238
Gross profit	$3,941	$3,729	$ 5,393	$ 5,109
Loss from operations(2)	$(4,635)	$(6,192)	$ (3,295)	$ (3,819)
Net loss(2)	$(4,887)	$(6,439)	$ (3,495)	$ (4,104)
Net loss per share(3):				
Basic	$(0.13)	$(0.17)	$ (0.08)	$ (0.08)
Diluted	$(0.13)	$(0.17)	$ (0.08)	$ (0.08)

(1) Loss from operations and net loss includes $700,000, $935,000, $621,000, and $1,094,000 in compensation cost related to stock options for the quarters ended March 31, June 30, September 30, and December 31, 2015, respectively.

(2) Loss from operations and net loss includes $310,000, $276,000, $301,000, and $346,000 in compensation cost related to stock options for the quarters ended March 31, June 30, September 30, and December 31, 2014, respectively.

(3) Net loss per share calculations for each of the quarters were based upon the weighted-average number of shares outstanding for each period, adjusted to reflect the effects of stock dividends, and the sum of the quarters may not necessarily be equal to the full year net loss per common share amount.

Liquidity and Capital Resources

At December 31, 2015, we had approximately $11.7 million in cash and cash equivalents. Management defines cash and cash equivalents as highly liquid deposits with original maturities of 90 days or less when purchased. The decrease in our cash and cash equivalents by $19.9 million from December 31, 2014 was primarily due to cash used in operating, investing, and financing activities of $17.8 million, $1.8 million, and $105,000 respectively, and the effect of exchange rates on cash of $206,000. The $17.8 million of net cash used in operating activities was primarily driven by the Company’s net loss of $20.3 million during the year.

At December 31, 2015, we had approximately $19.7 million in working capital. Our principal sources of liquidity at December 31, 2015, consisted of approximately $11.9 million in cash, cash equivalents and restricted cash and

$8.9 million of net accounts receivable.

We have reported recurring losses from operations and have not generated cash from operations for the three years ended December 31, 2015. Our level of cash used in operations, the potential need for additional capital, and the uncertainties surrounding our ability to raise additional capital, raises substantial doubt about our ability to continue as a going concern. The accompanying financial statements have been prepared on a going concern basis, which assumes that we will continue in operation for the next 12 months and will be able to realize our assets and discharge our liabilities and commitments in the normal course of business. The financial statements do not include any adjustments that might be necessary if the Company is unable to continue as a going concern.

In order for us to continue operations beyond the next 12 months and be able to discharge our liabilities and commitments in the normal course of business, we must sell our products directly to end users and through distributors, establish profitable operations through increased sales, decrease expenses, generate cash from operations or obtain additional funds when needed. We intend to improve our financial condition and ultimately improve our financial results by increasing revenues through expansion of our product offerings, continuing to expand and develop our field sales force and distributor relationships both domestically and internationally, forming strategic arrangements within the dental and medical industries, educating dental and medical patients as to the benefits of our advanced medical technologies, and reducing expenses.

Additional capital requirements may depend on many factors, including, among other things, the rate at which our business grows, demands for working capital, manufacturing capacity, and any acquisitions that we may pursue. From time to time, we could be required, or may otherwise attempt, to raise capital through either equity or debt offerings. We cannot provide assurance that we will enter into any such equity or debt financings in the future or that the required capital will be available on acceptable terms, if at all, or that any such financing activity will not be dilutive to our stockholders.

Concentration of Credit Risk

Financial instruments which potentially expose us to a concentration of credit risk consist principally of cash and cash equivalents, restricted cash, and trade accounts receivable. We maintain our cash and cash equivalents and restricted cash with established commercial banks. At times, balances may exceed federally insured limits. To minimize the risk associated with trade accounts receivable, we perform ongoing credit evaluations of customers' financial condition and maintain relationships with our customers that allow us to monitor changes in business operations so we can respond as needed. We do not, generally, require customers to provide collateral before we sell them our products. However we have required certain distributors to make prepayments for significant purchases of our products. For the years ended December 31, 2015, 2014, and 2013, sales to Henry Schein, Inc. worldwide accounted for approximately 3%, 6%, and 5%, respectively, of our net sales.

Receivables and Allowance for Doubtful Accounts

Trade accounts receivable are recorded at the invoiced amount and do not bear interest. The allowance for doubtful accounts is our best estimate of the amount of probable credit losses in the existing accounts receivable. We determine the allowance based on a quarterly specific account review of past due balances over 90 days. All other balances are reviewed on a pooled basis by age of receivable. Account balances are charged off against the allowance when it is probable the receivable will not be recovered. We do not have any off-balance-sheet credit exposure related to our customers.

See "Item 7A. Quantitative and Qualitative Disclosures About Market Risk" for discussion on the impact of interest rate risk and foreign currency exchange rate risk.

Consolidated Cash Flows

The following table summarizes our statements of cash flows for Fiscal 2015, Fiscal 2014, and Fiscal 2013 (in thousands):

	Years Ended December 31,		
	2015	2014	2013
Net cash provided by (used in):			
Operating activities	$(17,772)	$(16,201)	$(9,296)

Investing activities	(1,778)	(197)	(685)
Financing activities	(105)	46,752	8,847
Effect of exchange rates on cash	(206)	(234)	31
Net change in cash and cash equivalents	$(19,861)	$30,120	$(1,103)

Fiscal 2015 Compared to Fiscal 2014

The $1.6 million increase in net cash used in operating activities for Fiscal 2015 compared to Fiscal 2014 was primarily due to our increased net loss of $1.4 million. The increased net loss was primarily driven by a decrease in gross profit of $2.2 million. Cash used in operating activities for Fiscal 2015 totaled $17.8 million and was primarily comprised of non-cash adjusted net loss, excluding changes in operating assets and liabilities, of $15.2 million plus a decrease in accrued legal settlement of $1.7 million and an increase in inventory of $705,000.

The $1.6 million increase in net cash used in investing activities for Fiscal 2015 compared with Fiscal 2014 was primarily due to capital expenditures of $1.8 million driven by the initial implementation of a new enterprise resource planning software and a buildout for a world class training center in our Irvine office. We plan to complete the implementation of a new enterprise resource planning software in Fiscal 2016. As a result, we expect capital expenditures to total approximately $1.6 million in Fiscal 2016, and we expect depreciation and amortization to total approximately $840,000 for Fiscal 2016.

The $46.9 million decrease in net cash provided by financing activities for Fiscal 2015 compared to Fiscal 2014 was primarily due to net proceeds from equity offerings in February, July, and November 2014 totaling $51.1 million, in the aggregate.

The effect of exchange rates on cash for Fiscal 2015 compared to Fiscal 2014 remained relatively unchanged.

Fiscal 2014 Compared to Fiscal 2013

The $6.9 million increase in net cash used in operating activities for Fiscal 2014 compared to Fiscal 2013 was primarily due to our increased net loss of $7.4 million. The increased net loss was primarily driven by increased legal expenses and professional fees of $4.3 million associated with the shareholder litigation and decreased sales transactions stemming from distractions and disruptions within both management and the marketplace in connection with such litigation, as well as a lack of sales management. Net cash used in operating activities consists of our net loss, adjusted for our non-cash charges, plus or minus working capital changes. Cash used in operating activities for Fiscal 2014 totaled $16.2 million and was primarily comprised of non-cash adjusted net loss, excluding changes in operating assets and liabilities, of $14.6 million plus increases in inventory of $1.7 million.

The $488,000 decrease in net cash used in investing activities for Fiscal 2014 compared with Fiscal 2013 was primarily due to decreased capital expenditures resulting from the diversion of working capital to pay for legal expenditures and professional fees in connection with the shareholder litigation.

The $37.9 million increase in net cash provided by financing activities for Fiscal 2014 compared to Fiscal 2013 was primarily due to net proceeds from equity offerings in February, July and November 2014 totaling $51.1 million, in the aggregate.

The $265,000 decrease in effect of exchange rate on cash for Fiscal 2014 compared to Fiscal 2013 was primarily due to a recognized $415,000 loss on foreign currency transactions during Fiscal 2014.

Contractual Obligations

We lease our facility under a non-cancellable operating lease that expires in April 2020.

In February 2015, the Company entered into a 30-month capital lease agreement for information technology equipment.

The following table presents our expected cash requirements for contractual obligations outstanding as of December 31, 2015, for the years ending as indicated below (in thousands):

	Less Than 1 Year	1 to 3 Years	3 to 5 Years	More Than 5 years	Total

Operating lease obligations	$717	$1,275	$865	—	$2,857
Capital lease obligations	147	160	—	—	307
Purchase obligations	13,371	9	—	—	13,380
Other liabilities	10	—	—	—	10
Total	$14,245	$1,444	$865	$ —	$16,554

Purchase obligations relate to purchase orders with suppliers that we expect to complete primarily during the year ending December 31, 2016. In conformity with GAAP, purchase obligations and operating lease obligations are not reported in the consolidated balance sheet as of December 31, 2015.

Recent Accounting Pronouncements

See Note 2 to the Notes to the Consolidated Financial Statements — Summary of Significant Accounting Policies — Recent Accounting Pronouncements to the Consolidated Financial Statements in Part IV, Item 15 of this Annual Report on Form 10-K, which is incorporated herein by reference.

Off-Balance Sheet Arrangements

We do not have any off-balance sheet arrangements as defined in Regulation S-K Item 303(A)(4)(ii).

Item 7A. Quantitative and Qualitative Disclosures About Market Risk

Substantially all of our revenue is denominated in U.S. dollars, including sales to our international distributors. Only a small portion of our revenue and expenses is denominated in foreign currencies, principally the Euro and Indian Rupee. Our foreign currency expenditures primarily consist of the cost of maintaining our offices, including the facilities, consulting services, and employee-related costs. We have not entered into any foreign currency hedging contracts through December 31, 2015. Future fluctuations in the value of the U.S. dollar may affect the price competitiveness of our products outside the United States.

Inflation has not had a significant effect on our results of operations during the three years ending December 31, 2015 as we do not have significant operations in countries that have experienced high rates of inflation.

Item 8. Financial Statements and Supplementary Data

All financial statements and supplementary data required by this Item 8, including the report of the independent registered public accounting firm, are listed in Part IV, Item 15 of this Form 10-K, are set forth beginning on Page F-1 of this Form 10-K, and are hereby incorporated herein by reference. The Selected Quarterly Financial Data required by this Item 8 is set forth in Item 7 (Management’s Discussion and Analysis of Financial Condition and Results of Operations) of this Form 10-K and is hereby incorporated herein by reference.

Item 9. Changes in and Disagreements with Accountants on Accounting and Financial Disclosure

None.

Item 9A. Controls and Procedures

Disclosure Controls and Procedures

Our management has evaluated, with the participation of our President and Chief Executive Officer and Chief Financial Officer, the effectiveness of the Company’s disclosure controls and procedures (as defined in Rules 13a-15(e) and 15d-15(e) under the Exchange Act) as of the end of the period covered by this report. Based on that evaluation, our President and Chief Executive Officer and Chief Financial Officer have concluded that the Company’s disclosure controls and procedures were effective as of December 31, 2015.

Management’s Report on Internal Control over Financial Reporting

Our management is responsible for establishing and maintaining adequate internal control over financial reporting, as such term is defined in Rules 13a-15(f) and 15d-15(f) under the Exchange Act. Under the supervision and with the participation of our management, including our principal executive officer and principal financial officer, we conducted an evaluation of the effectiveness of our internal control over financial reporting based on the framework established by the Committee of Sponsoring Organizations of the Treadway Commission entitled "Internal Control — Integrated Framework (2013)" (the "COSO Framework"). Based on our evaluation under the COSO Framework, our management concluded that our internal control over financial reporting was effective as of December 31, 2015.

BDO USA, LLP, our independent registered public accounting firm that audited the consolidated financial statements included in this Form 10-K, issued an attestation report on our internal control over financial reporting as of December 31, 2015. Their report is included herein.

Changes in Internal Control over Financial Reporting

There have been no changes in our internal control over financial reporting that occurred during the Company's fiscal quarter ended December 31, 2015 that have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

Report of Independent Registered Public Accounting Firm

Board of Directors and Stockholders

BIOLASE, Inc.

Irvine, California

We have audited BIOLASE, Inc.'s (the "Company's") internal control over financial reporting as of December 31, 2015, based on criteria established in Internal Control — Integrated Framework (2013) issued by the Committee of Sponsoring Organizations of the Treadway Commission (the COSO criteria). The Company's management is responsible for maintaining effective internal control over financial reporting and for its assessment of the effectiveness of internal control over financial reporting, included in the accompanying Item 9A, Management's Report on Internal Control Over Financial Reporting. Our responsibility is to express an opinion on the Company's internal control over financial reporting based on our audit.

We conducted our audit in accordance with the standards of the Public Company Accounting Oversight Board (United States). Those standards require that we plan and perform the audit to obtain reasonable assurance about whether effective internal control over financial reporting was maintained in all material respects. Our audit included obtaining an understanding of internal control over financial reporting, assessing the risk that a material weakness exists, and testing and evaluating the design and operating effectiveness of internal control based on the assessed risk. Our audit also included performing such other procedures as we considered necessary in the circumstances. We believe that our audit provides a reasonable basis for our opinion.

A company's internal control over financial reporting is a process designed to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles. A company's internal control over financial reporting includes those policies and procedures that (1) pertain to the maintenance of records that, in reasonable detail, accurately and fairly reflect the transactions and dispositions of the assets of the company; (2) provide reasonable assurance that transactions are recorded as necessary to permit preparation of financial statements in accordance with generally accepted accounting principles, and that receipts and expenditures of the company are being made only in accordance with authorizations of management and directors of the company; and (3) provide reasonable assurance regarding prevention or timely detection of unauthorized acquisition, use, or disposition of the company's assets that could have a material effect on the financial statements.

Because of its inherent limitations, internal control over financial reporting may not prevent or detect misstatements. Also, projections of any evaluation of effectiveness to future periods are subject to the risk that controls may become inadequate because of changes in conditions, or that the degree of compliance with the policies or procedures may deteriorate.

In our opinion, BIOLASE, Inc. maintained, in all material respects, effective internal control over financial reporting as of December 31, 2015, based on the COSO criteria.

We also have audited, in accordance with the standards of the Public Company Accounting Oversight Board (United States), the consolidated balance sheets of BIOLASE, Inc. as of December 31, 2015 and 2014, and the related consolidated statements of operations and comprehensive loss, stockholders' equity, and cash flows for each of the three years in the period ended December 31, 2015 and our report dated March 11, 2016 expressed an unqualified opinion thereon and included an explanatory paragraph regarding the Company's ability to continue as a going concern.

/s/ BDO USA, LLP

Costa Mesa, California

March 11, 2016

Item 9B. Other Information

None.

PART III

Item 10. Directors, Executive Officers and Corporate Governance

Information regarding our executive officers is included in Part I of this Form 10-K under “Item 1. Business — Executive Officers of the Registrant.” In addition, the information set forth under the caption “Election of Directors” and “Security Ownership of Certain Beneficial Owners and Management — Section 16(a) Beneficial Ownership Reporting Compliance” in the Proxy Statement is incorporated by reference herein.

The Biolase, Inc. Code of Business Conduct and Ethics applies to all of our employees, officers, and directors, including our President and Chief Executive Officer. The Code of Business Conduct can be found on our website at the following address: http://www.biolase.com/Pages/code-of-conduct.html.

Item 11. Executive Compensation

The information set forth under the captions “Executive Compensation” and “Election of Directors — Director Compensation” in the Proxy Statement is incorporated by reference herein.

Item 12. Security Ownership of Certain Beneficial Owners and Management and Related Stockholder Matters

The information set forth under the captions “Security Ownership of Certain Beneficial Owners and Management” and “Executive Compensation — Equity Compensation Plan Information” in the Proxy Statement is incorporated by reference herein.

Item 13. Certain Relationships and Related Transactions, and Director Independence

The information set forth under the captions “Election of Directors” and “Certain Relationships and Related Transactions” in the Proxy Statement is incorporated by reference herein.

Item 14. Principal Accountant Fees and Services

The information set forth under the caption “Principal Accountant Fees and Services” in the Proxy Statement is incorporated by reference herein.

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PART IV

Item 15. Exhibits and Financial Statement Schedules

(a) The following documents are filed as part of this Annual Report on Form 10-K beginning on the pages referenced below:

(1) Financial Statements:

(2) Financial Statement Schedule:

All other schedules have been omitted as they are not applicable, not required or the information is included in the consolidated financial statements or the notes thereto.

(3) Exhibits:

The exhibits filed as a part of this Annual Report on Form 10-K are listed in the accompanying Exhibit Index on page 59.

SIGNATURES

Pursuant to the requirements of Section 13 or 15(d) of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned, thereunto duly authorized.

BIOLASE, INC.,

a Delaware Corporation
(registrant)

Dated: March 11, 2016 By: /s/ HAROLD C. FLYNN, JR.
Harold C. Flynn, Jr.
President and Chief Executive Officer

Dated: March 11, 2016 By: /s/ DAVID C. DREYER
David C. Dreyer
Chief Financial Officer

Pursuant to the requirements of the Securities Exchange Act of 1934, this report has been signed below by the following persons on behalf of the registrant and in the capacities and on the dates indicated:

Signature	Title	Date
/s/ HAROLD C. FLYNN, JR Harold C. Flynn, Jr.	President and Chief Executive Officer (Principal Executive Officer) and Director	March 11, 2016
/s/ DAVID C. DREYER David C. Dreyer	Chief Financial Officer (Principal Financial Officer and Accounting Officer)	March 11, 2016
/s/ PAUL N. CLARK Paul N. Clark	Director	March 11, 2016
/s/ DR. JONATHAN T. LORD Dr. Jonathan T. Lord	Director	March 11, 2016
/s/ DR. FREDERIC H. MOLL Dr. Frederic H. Moll	Director	March 11, 2016

/s/ JAMES R. TALEVICH James R. Talevich	Director	March 11, 2016

BIOLASE, INC.

Index to Exhibits

Exhibit	Description	Filed Herewith	Incorporated by Reference Form	Period Ending/Date of Report	Exhibit	Filing Date
3.1.1	Restated Certificate of Incorporation, including, (i) Certificate of Designations, Preferences and Rights of 6% Redeemable Cumulative Convertible Preferred Stock of the Registrant; (ii) Certificate of Designations, Preferences and Rights of Series A 6% Redeemable Cumulative Convertible Preferred Stock of the Registrant; (iii) Certificate of Correction Filed to Correct a Certain Error in the Certificate of Designation of the Registrant; and (iv) Certificate of Designations of Series B Junior Participating Cumulative Preferred Stock of the Registrant		S-1, Amendment No. 1	12/23/2005	3.1	12/23/2005
3.1.2	Amendment to Restated Certificate of Incorporation		8-K	05/10/2012	3.1	05/16/2012
3.1.3	Second Amendment to Restated Certificate of Incorporation		8-A/A	11/04/2014	3.1.3	11/04/2014
3.1.4	Certificate of Elimination of Series B Junior Participating Cumulative Preferred Stock		8-K	11/10/2015	3.1	11/12/2015
3.2	Sixth Amended and Restated Bylaws of the Registrant, adopted on June 26, 2014		8-K	06/26/2014	3.1	06/30/2014
4.1	Rights Agreement, dated as of December 31, 1998, by and between the Registrant and U.S. Stock Transfer Corporation		8-A	12/31/1998	1	12/29/1998
4.2	Amendment to Rights Agreement, dated December 19, 2008, by and between the Registrant and Computershare Trust Company, N.A.		8-K	12/17/2008	4.1	12/22/2008
4.3	Amended and Restated Second Amendment to Rights Agreement, dated March 17, 2014, by and between the Registrant and Computershare Trust Company, N.A.		10-K	12/31/2013	4.4	03/17/2014
4.4	Third Amendment to Rights Agreement, dated November 3, 2014, by and between the Registrant		8-A/A	11/04/2014	4.4	11/04/2014

	and Computershare Trust Company, N.A.				
4.5	Fourth Amendment to Rights Agreement, dated November 10, 2015, by and between the Registrant and Computershare Trust Company, N.A.	8-K	11/10/2015	4.1	11/12/2015
4.6	Specimen of common stock certificate	S-3	06/03/2002	4.1	06/03/2002
4.7	Form of Warrant	8-K	11/03/2014	4.1	11/07/2014
4.8	Standstill Agreement, dated November 10, 2015, by and among the Registrant and Jack W. Schuler, Renate Schuler, and the Schuler Family Foundation	8-K	11/10/2015	99.1	11/12/2015

Exhibit	Description	Filed Herewith	Incorporated by Reference Form	Period Ending/Date of Report	Exhibit	Filing Date
4.9	Standstill Agreement, dated November 10, 2015, by and among the Registrant and Larry N. Feinberg, Oracle Partners, L.P., Oracle Institutional Partners, L.P., Oracle Ten Fund Master, L.P., Oracle Associates, LLC, and Oracle Investment Management, Inc.		8-K	11/10/2015	99.2	11/12/2015
10.1*	2002 Stock Incentive Plan, as amended		DEF 14A	05/16/2007	A	04/10/2007
10.2*	Form of Stock Option Agreement under the 2002 Stock Incentive Plan		10-K	12/31/2004	10.26	07/19/2005
10.3*	Form of Option Award Notice for California Employees under the 2002 Stock Incentive Plan		10-Q	09/30/2015	10.2	11/06/2015
10.4*	Form of Option Award Notice for Non-California Employees under the 2002 Stock Incentive Plan		10-Q	09/30/2015	10.3	11/06/2015
10.5*	Form of Option Award Notice for Non-Employee Directors under the 2002 Stock Incentive Plan		10-Q	09/30/2015	10.4	11/06/2015
10.6*	Form of Restricted Stock Unit Award Notice for Non-Employee Directors under the 2002 Stock Incentive Plan		10-Q	09/30/2015	10.5	11/06/2015
10.8*	Form of Indemnification Agreement between the Registrant and its officers and directors		10-Q	09/30/2005	10.1	11/09/2005
10.9	Lease, dated January 10, 2006, by and between the Registrant and The Irvine Company LLC		8-K	01/10/2006	10.1	01/17/2006
10.10	Third Amendment to Lease, dated March 16, 2015, by and between the Registrant and The Irvine Company LLC		10-Q	03/31/2015	10.1	05/01/2015
10.11†	Letter Agreement, dated June 28, 2006, by and between the Registrant and The Procter & Gamble Company		10-Q	06/30/2006	10.1	08/09/2006
10.12†	License Agreement, dated January 24, 2007, by and between The Procter & Gamble Company and the Registrant		10-Q	03/31/2007	10.1	05/10/2007
10.13	Letter Agreement, dated June 28, 2011, by and between the Registrant and The Proctor & Gamble Company		10-Q	06/30/2011	10.2	08/11/2011

10.14	Subscription Agreement, dated February 10, 2014, by and between the Registrant and the investor signatories thereto	8-K	02/10/2014	10.1	02/13/2014
10.15	Securities Purchase Agreement, dated July 18, 2014, by and among the Registrant and each person listed on Schedule I thereto	8-K	07/18/2014	10.1	07/22/2014
10.16	Securities Purchase Agreement, dated November 3, 2014, by and among the Registrant and each person listed on Schedule I thereto	8-K	11/03/2014	99.1	11/03/2014
10.17	Loan and Security Agreement, dated May 24, 2012, by and between the Registrant and Comerica Bank	10-Q	06/30/2012	10.1	08/09/2012

Exhibit	Description	Filed Herewith	Incorporated by Reference Form	Period Ending/Date of Report	Exhibit	Filing Date
10.18	Amendment No. 3 to Loan and Security Agreement, dated September 6, 2013, by and between the Registrant and Comerica Bank		10-Q	09/30/2013	10.1	11/12/2013
10.19	Amendment No. 4 to Loan and Security Agreement, dated November 8, 2013, by and between the Registrant and Comerica Bank		10-Q	09/30/2013	10.4	11/12/2013
10.20	Forbearance Agreement, dated April 10, 2014, by and between the Registrant and Comerica Bank		8-K	04/10/2014	10.1	04/22/2014
10.21	Amendment No. 1 to Forbearance Agreement, dated May 5, 2014, by and between the Registrant and Comerica Bank		10-Q	03/31/2014	10.1	05/12/2014
10.22	Amendment No. 2 to Forbearance Agreement, dated June 3, 2014, by and between the Registrant and Comerica Bank		8-K	06/06/2014	10.1	06/12/2014
10.23	Borrower Agreement, dated May 24, 2012, by the Registrant, in favor of the Export-Import Bank of the United States and Comerica Bank		10-Q	06/30/2012	10.2	08/09/2012
10.24	Master Revolving Note, dated May 24, 2012, by the Registrant in favor of Comerica Bank		10-Q	06/30/2012	10.3	08/09/2012
10.25	Amendment No. 1 to Master Revolving Note, dated May 5, 2014, by and between the Registrant and Comerica Bank		10-Q	03/31/2014	10.2	05/12/2014
10.26	Amendment No. 2 to Master Revolving Note, dated June 3, 2014, by and between the Registrant and Comerica Bank		8-K	06/06/2014	10.2	06/12/2014
10.27*	Offer of Employment, dated July 1, 2014, by and between the Registrant and Orlando Rodrigues		10-K/A	12/31/2014	10.26	04/29/2014
10.28*	Separation Agreement with General Release of All Claims, dated January 31, 2015, by and between the Registrant and Frederick D. Furry		10-Q	03/31/2015	10.1	05/01/2015
10.29*	Employment Agreement, dated February 22, 2015 and entered into on February 24, 2015, by and between the Registrant and David Dreyer		10-K	12/31/2015	10.25	03/06/2015

10.30*	Transition Letter Agreement, dated May 14, 2015, by and between the Registrant and Jeffrey M. Nugent		10-Q	06/30/2015	10.3	08/07/2015
10.31*	Employment Agreement, dated May 14, 2015, by and between the Registrant and Harold C. Flynn, Jr.		10-Q	06/30/2015	10.2	08/07/2015
10.32*	Inducement Restricted Stock Unit Award Agreement, dated July 14, 2015, by and between the Registrant and Harold C. Flynn, Jr.		8-K	07/12/2015	10.2	07/15/2015
21.1	Subsidiaries of the Registrant	X				
23.1	Consent of Independent Registered Public Accounting Firm, BDO USA, LLP	X				

Exhibit	Description	Filed Herewith	Incorporated by Reference Form	Period Ending/Date of Report	Exhibit	Filing Date
31.1	Certification of Chief Executive Officer pursuant to Rule 13a-14 and Rule 15d-14(a) of the Securities Exchange Act of 1934, as amended	X				
31.2	Certification of Chief Financial Officer pursuant to Rule 13a-14 and Rule 15d-14(a) of the Securities Exchange Act of 1934, as amended	X				
32.1	Certification of Chief Executive Officer pursuant to 18 U.S.C. 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002	**				
32.2	Certification of Chief Financial Officer pursuant to 18 U.S.C. 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002	**				
101	The following financial information from the Company's Annual Report on Form 10-K, for the year ended December 31, 2015, formatted in eXtensible Business Reporting Language: (i) Consolidated Balance Sheets, (ii) Consolidated Statements of Operations and Comprehensive Loss, (iii) Consolidated Statements of Stockholders' Equity (Deficit), (iv) Consolidated Statements of Cash Flows, (v) Notes to Consolidated Financial Statements	X				

† Confidential treatment was granted for certain confidential portions of this exhibit pursuant to Rule 24b-2 under the Securities Exchange Act of 1934. In accordance with Rule 24b-2, these confidential portions were omitted from this exhibit and filed separately with the Securities and Exchange Commission.
□ Confidential treatment was requested for certain confidential portions of this exhibit pursuant to Rule 24b-2 under the Securities Exchange Act of 1934. In accordance with Rule 24b-2, these confidential portions were omitted from this exhibit and filed separately with the Securities and Exchange Commission.
* Management contract or compensatory plan or arrangement.
** Furnished herewith.

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BIOLASE, INC.

Index to Consolidated Financial Statements and Schedule

All Schedules, except Schedule II, have been omitted as the required information is shown in the consolidated financial statements, or notes thereto, or the amounts involved are not significant or the schedules are not applicable.

Report of Independent Registered Public Accounting Firm

Board of Directors and Stockholders

BIOLASE, Inc.

Irvine, California

We have audited the accompanying consolidated balance sheets of BIOLASE, Inc. (the "Company") as of December 31, 2015 and 2014 and the related consolidated statements of operations and comprehensive loss, stockholders' equity, and cash flows for each of the three years in the period ended December 31, 2015. In connection with our audits of the consolidated financial statements, we have also audited the consolidated financial statement schedule listed in the accompanying index as of and for the years ended December 31, 2015, 2014, and 2013. These consolidated financial statements and schedule are the responsibility of the Company's management. Our responsibility is to express an opinion on these consolidated financial statements and schedule based on our audits.

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

In our opinion, the consolidated financial statements referred to above present fairly, in all material respects, the financial position of BIOLASE, Inc. at December 31, 2015 and 2014, and the results of its operations and its cash flows for each of the three years in the period ended December 31, 2015, in conformity with accounting principles generally accepted in the United States of America.

Also, in our opinion, the consolidated financial statement schedule, when considered in relation to the basic consolidated financial statements taken as a whole, presents fairly, in all material respects, the information set forth therein.

The accompanying consolidated financial statements have been prepared assuming that the Company will continue as a going concern. As discussed in Note 1 to the consolidated financial statements, the Company has suffered recurring losses from operations and has negative cash flows from operations for each of the three years in the period ended December 31, 2015. These factors, among others, raise substantial doubt about its ability to continue as a going concern. Management's plans in regard to these matters are also described in Note 1. The consolidated financial statements do not include any adjustments that might result from the outcome of this uncertainty.

We have also audited, in accordance with the standards of the Public Company Accounting Oversight Board (United Sates), the Company's internal control over financial reporting as of December 31, 2015, based on criteria established in Internal Control — Integrated Framework (2013) issued by the Committee of Sponsoring Organizations of the Treadway Commission (COSO) and our report dated March 11, 2016 expressed an unqualified opinion thereon.

/s/ BDO USA, LLP

Costa Mesa, California

March 11, 2016

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BIOLASE, INC.

CONSOLIDATED BALANCE SHEETS

(in thousands, except per share data)

	December 31,	
	2015	2014
ASSETS		
Current assets:		
Cash and cash equivalents	$11,699	$31,560
Restricted cash	200	—
Accounts receivable, less allowance of $1,765 and $1,711 in 2015 and 2014, respectively	8,948	9,004
Inventory, net	12,566	12,508
Prepaid expenses and other current assets	1,387	1,726
Total current assets	34,800	54,798
Property, plant, and equipment, net	3,727	1,295
Intangible assets, net	51	114
Goodwill	2,926	2,926
Other assets	747	270
Total assets	$42,251	$59,403
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities:		
Accounts payable	$5,960	$8,357
Accrued liabilities	5,906	5,188
Customer deposits	85	112
Deferred revenue, current portion	3,155	2,494
Total current liabilities	15,106	16,151
Deferred income taxes, net	738	677
Deferred revenue, long-term	142	—
Capital lease obligation, long-term	159	—
Warranty accrual, long-term	843	519
Other liabilities, long-term	338	—
Total liabilities	17,326	17,347
Commitments and contingencies (Note 7)		
Stockholders' equity:		
Preferred stock, par value $0.001; 1,000 shares authorized, no shares issued and outstanding	—	—
Common stock, par value $0.001; 100,000 shares authorized,58,228 and 58,115 shares issued and outstanding in 2015 and 2014, respectively	58	58
Additional paid-in capital	188,622	185,231

Accumulated other comprehensive loss	(801)	(557)
Accumulated deficit	(162,954)	(142,676)
Total stockholders' equity	24,925	42,056
Total liabilities and stockholders' equity	$42,251	$59,403

See accompanying notes to consolidated financial statements.

BIOLASE, INC.

CONSOLIDATED STATEMENTS OF OPERATIONS AND COMPREHENSIVE LOSS

(in thousands, except per share data)

	Years Ended December 31,		
	2015	2014	2013
Products and services revenue	$48,269	$47,511	$56,186
License fees and royalty revenue	206	145	244
Net revenue	48,475	47,656	56,430
Cost of revenue	32,525	29,484	34,900
Gross profit	15,950	18,172	21,530
Operating expenses:			
Sales and marketing	18,696	16,375	18,682
General and administrative	10,256	14,854	9,377
Engineering and development	7,283	4,577	4,029
Excise tax	361	307	438
Patent infringement legal settlement	(731)	—	—
Total operating expenses	35,865	36,113	32,526
Loss from operations	(19,915)	(17,941)	(10,996)
Loss on foreign currency transactions	(259)	(415)	(50)
Interest income (expense), net	74	(458)	(600)
Non-operating loss, net	(185)	(873)	(650)
Loss before income tax provision (benefit)	(20,100)	(18,814)	(11,646)
Income tax provision (benefit)	178	112	(164)
Net loss	(20,278)	(18,926)	(11,482)
Other comprehensive income (loss) items:			
Foreign currency translation adjustments	(244)	(283)	46
Comprehensive loss	$(20,522)	$(19,209)	$(11,436)
Net loss per share:			
Basic	$(0.35)	$(0.45)	$(0.35)
Diluted	$(0.35)	$(0.45)	$(0.35)
Shares used in the calculation of net loss per share:			
Basic	58,189	42,232	32,768
Diluted	58,189	42,232	32,768

See accompanying notes to consolidated financial statements.

BIOLASE, INC.

CONSOLIDATED STATEMENTS OF STOCKHOLDERS' EQUITY

(in thousands)

	Common Stock and Additional	Accumulated Other	Total