

BIOLASE, INC  
Form 10-K  
March 10, 2017

UNITED STATES

SECURITIES AND EXCHANGE COMMISSION

WASHINGTON, DC 20549

FORM 10-K

(Mark One)

ANNUAL REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934  
For the fiscal year ended December 31, 2016

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  
(State or Other Jurisdiction  
of Incorporation or Organization)

87-0442441  
(I.R.S. Employer  
Identification No.)

4 Cromwell

Irvine, California 92618

(Address of Principal Executive Offices, including zip code)

(949) 361-1200

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(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

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

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

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

The aggregate market value of the Registrant's common stock held by non-affiliates was \$38,006,498 based on the last sale price of common stock on June 30, 2016.

As of March 6, 2017, there were 67,570,951 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 2017 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, 2016, are incorporated by reference into Part III of this Annual Report on Form 10-K.

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BIOLASE, INC.

ANNUAL REPORT ON FORM 10-K

FOR THE FISCAL YEAR ENDED DECEMBER 31, 2016

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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 2017, 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;
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- 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 regulatory requirements of the Food and Drug Administration (“FDA”) 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.

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## PART I

### Item 1. Business

#### Overview

BIOLASE, Inc. (“BIOLASE” and, together with its consolidated subsidiaries, the “Company,” “we,” “our” or “us”) is 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. 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 230 issued and 85 pending U.S. and international patents, the majority of which are related to Waterlase technology. From 1998 through December 31, 2016, we sold approximately 33,600 laser systems in over 90 countries around the world. Contained in this total are over 11,800 Waterlase systems, including approximately 7,800 Waterlase MD and 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 \$51.8 million, \$48.5 million, and \$47.7 million in 2016, 2015, and 2014, respectively, and we had net losses of \$15.4 million, \$20.3 million, and \$18.9 million for the same periods, respectively. We had assets of \$41.9 million and \$42.3 million as of December 31, 2016 and 2015, respectively.

#### Recent Developments

#### Leadership Changes

On March 1, 2017, we announced the appointment of a new Senior Vice President and Chief Financial Officer, with significant leadership and technical experience in finance and business management from both public and private companies, who will be joining our leadership team effective March 27, 2017.

Throughout 2016 and consistent with our goal to focus 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 have made strategic personnel additions to our senior management team, including a Vice President and Managing Director for Europe, the Middle East and Africa to lead our sales in that region, a Vice President of Clinical and Dental Affairs and Chief Dental Officer to lead our educational, dental and clinical matters, and a Vice President of Marketing to lead our marketing efforts. We have also added a new Vice President of Human Resources at our

headquarters in Irvine, California to support our key initiatives. With a solid senior management team, we believe we are better suited to achieve our goals of strengthening our worldwide market presence, sales, and competitiveness.

## Private Placement

On August 8, 2016, we completed a private placement with several institutional and individual investors, and certain of our directors and officers, under which we sold an aggregate of 88,494 shares of our preferred stock and warrants to purchase up to an aggregate of 2,035,398 unregistered shares of our common stock at an exercise price of \$2.00 per share. Each share of preferred stock was automatically upon receipt of stockholder approval convertible into 100 shares of our common stock, reflecting a conversion price equal to \$1.13 per share, which was the closing price of our common stock quoted on the NASDAQ Capital Market on July 29, 2016. On September 30, 2016, we held a meeting of our stockholders and received requisite stockholder approval with respect to the issuance of 8,849,400 shares of common stock upon automatic conversion of the preferred stock and the issuance of our common stock related to exercise of the warrants by certain holders whose warrants were subject to a beneficial ownership limitation. Gross proceeds from the sale were approximately \$10.0 million, and net proceeds, after offering expenses of approximately \$0.5 million, were approximately \$9.5 million. The warrants became exercisable on February 8, 2017, six months after the closing of the private placement, and have a term of five years from the date of issuance. We are using the proceeds of the sale for working capital and general corporate purposes. In connection with the registration rights granted to these investors, we filed a registration statement on Form S-3 with the SEC, which was declared effective on November 3, 2016.

## New Product Offerings

In February 2017, we launched the fifth-generation Waterlase Express all-tissue laser system. Waterlase Express represents the newest addition to our Waterlase portfolio of Er,Cr:YSGG all-tissue lasers. Waterlase Express was exhibited at the Chicago Dental Society's Mid-Winter meeting in February 2017. Designed for easy and intuitive operation, integrated learning, and portability, Waterlase Express is our next-generation Waterlase system. Waterlase Express has regulatory clearance for commercial distribution from the FDA, and is available for sale to dentists in the U.S. as well as select international markets in Europe, the Middle East and Asia.

In January 2017, we received FDA clearance and launched Epic Pro, a powerful and innovative dental diode laser system, making it available for sale in the U.S., as well as in select countries in Europe, the Middle East and Asia. The Epic Pro, which offers more power than most diode lasers in dentistry, is the first product to be introduced resulting from our strategic development agreement with IPG Photonics Corporation's medical laser division, IPG Medical ("IPG"). The newest addition to the Epic family of dental soft-tissue lasers, Epic Pro features several new innovations, such as a new super pulse technology for more precise, enhanced laser tissue cutting; real-time automatic power control to enhance speed and consistency when performing surgery; and pre-initiated, bendable, disposable tips with new smart tip technology to ensure tip performance and quality. In January 2017, the Epic Pro laser system received clearance from the U.S. FDA for dental and surgical operations, intended for use in contact and non-contact techniques for incision, excision, vaporization, ablation, hemostasis, or coagulation of intraoral and extra-oral soft tissue (including marginal and interdental gingiva and epithelial lining of free gingiva).

In 2015, we launched several key updates to the Waterlase iPlus all-tissue laser system, including enabling the system with integrated step-by-step laser protocols for addressing periodontal and peri-implant disease. The two protocols, known as REPAIR Perio and REPAIR Implant, enable general dentists and dental specialists to address the growing trend of periodontal disease (commonly referred to as "gum disease") and peri-implantitis. These destructive inflammatory processes affect soft and hard tissues surrounding permanent teeth or expensive dental implants and can lead to significant oral healthcare complications if not addressed. Waterlase iPlus offers general dentists and dental specialists a turnkey, step-by-step approach to managing these rising disease states. In addition, the Waterlase iPlus remains one of the most versatile clinical instruments available, with pre-programmed settings for more than 50 FDA-cleared procedures in the dental office.

In 2015, we also launched the redesigned SureFire YSGG Delivery System for use with Waterlase iPlus and Waterlase MD systems. The new SureFire design ensures greater uptime through enhanced precision, performance,

and reliability of the fiber optics, which were redesigned to more efficiently deliver precise laser energy. The system is further enhanced 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.

#### 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's ("ADA") last available Survey of Dental Services Rendered (the "ADA Study"), published in 2007, 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 periodontists, pediatric dentists, implantologists, oral surgeons, prosthodontists, and endodontists. According to "Prevalence of Periodontitis in Adults in the United States" by Ede, Dye, Wei et al., recent evidence indicates that 47% of dental patients aged 30 or older have moderate to severe periodontitis that would benefit from intervention and Waterlase therapy. The ADA Health Policy Institute reported that in 2014, several key indicators of demand for dental services showed positive growth, including per capita dental expenditures, overall dental visits, and dentist earnings. The ADA Health Policy Institute also reported promising trends in patient access to health insurance coverage and increased consumerism of oral healthcare. Overall, the demand for dental services has continued to evolve positively due to population growth, aging demographics, 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.

According to "The Oral Health Atlas, 2<sup>nd</sup> edition," untreated tooth decay was the most prevalent of 291 oral disease conditions studied by the FDI World Dental Federation in 2015, with periodontal disease and associated complications being the 6<sup>th</sup> most prevalent oral disease state.

We believe there is a growing awareness among consumers globally 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 utilize 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. Many of the instruments available today are based on decades-old practices. Examples are as follows:

**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. However, most alternatives have addressed either hard or soft tissue applications but not both, or have other limitations.

**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.

#### BIOLASE Products

Combining our laser systems with 3D CAD/CAM intraoral scanning and imaging solutions can provide dental professionals with enhanced capabilities for early diagnosis and minimally invasive treatment. Our product offering consists of the following:

**Waterlase all-tissue laser systems.** Our all-tissue Waterlase dental laser systems currently consist of the Waterlase Express, our flagship Waterlase iPlus, and the Waterlase MD Turbo. Each of these systems features proprietary laser crystal technology that produces energy with specific absorption and tissue interaction characteristics specifically designed for dental procedures. 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 laser light and water, our Waterlase systems may eliminate the need for anesthesia in most cases 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 operator to operator 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, CE mark-approved in Europe, and approved for sale in more than 90 other countries for dental uses. In the United States, we also have regulatory clearance for dermatological, aesthetic, and other general surgery uses.

Diode soft-tissue laser systems. Our Diode soft tissue laser systems currently consist of the Epic Pro, Epic X, Epic 10 and iLase semiconductor diode lasers that perform soft tissue, hygiene, cosmetic procedures and teeth whitening and provide temporary pain relief. Epic X, Epic 10, and iLase systems feature our proprietary 940nm wavelength and patented pulse technology called ComfortPulse, which is designed for added patient comfort. iLase was the first “personal” laser with no wires, footswitch, or cumbersome cables to manage. Epic 10 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. Epic Pro, released in 2016, is a soft-tissue diode laser with Super Thermal Pulse and Automatic Power Control features for enhanced patient comfort and clinical outcomes. The iLase, Epic X, Epic10, and Epic Pro are FDA-cleared in the United States, CE mark-approved in Europe, and approved for sale in more than 90 other countries for dental uses. In the United States, we also have regulatory clearance for 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 product line features 3Shape Trios intraoral scanner and 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 also sell the award-winning line of CEFLA NewTom VGi and VG3 3-D Cone Beam Computed Tomography devices in North America. We distribute all of these products under the manufacturer's FDA 510(k) clearances.

#### 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.

#### BIOLASE Laser Solutions

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.

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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 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.

**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 offers 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® (“WCLP”) (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.

**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.

**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 2016, we augmented our field sales force efforts with outbound, phone-based sales support initiatives. These initiatives are driven from our corporate headquarters and are comprised of sales representatives and lead generators working in partnership with the field sales team to maximize effectiveness in engaging and servicing customers. 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 regions. 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.

**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.

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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.

Expanding our product portfolio to dental practitioners. By combining our Waterlase and Epic laser systems with select, in-line digital imaging, intra-oral scanners, CAD/CAM design, and chairside milling products, dental offices can accurately and timely address unmet patient needs with convenience. We plan to continue to evaluate how to optimize the manner in which we market and sell additional products to supplement our core Waterlase and Epic franchises.

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, 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.

#### Warranties

Our Waterlase laser systems and Diode systems sold domestically are covered by a warranty against defects in material and workmanship for a period of up to two years from the date of sale to the end-user by us or a distributor. 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.

#### 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 for BIOLASE laser solutions 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, social media, and other promotional tools and materials.

Our primary marketing message to dental practitioners focuses on the ability of BIOLASE lasers to resolve dental challenges and deliver improved cash flow and return on investment ("ROI"), which can be realized with 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. We believe that, as the community of BIOLASE dental practitioners expands, the WCLI will continue to deliver fresh, exciting laser educational opportunities utilizing the latest in learning methodologies and platforms. 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 dental 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.

**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 [biolase.com](http://biolase.com), and on Facebook, Twitter, LinkedIn, Instagram, and YouTube. 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, 2016, 2015, and 2014 (dollars in thousands):

	Years Ended December 31,					
	2016		2015		2014	
Laser systems	\$35,150	67.9 %	\$32,691	67.5 %	\$29,490	61.9 %

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Imaging systems	3,066	5.9 %	2,237	4.6 %	4,286	9.0 %
Consumables and other	6,906	13.3 %	6,877	14.2 %	6,524	13.7 %
Services revenue	6,539	12.6 %	6,465	13.3 %	7,211	15.1 %
Products and services revenue	51,661	99.7 %	48,270	99.6 %	47,511	99.7 %
License fees and royalties	149	0.3 %	205	0.4 %	145	0.3 %
Net revenue	\$51,810	100.0%	\$48,475	100.0%	\$47,656	100.0%

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

	Years Ended December 31,		
	2016	2015	2014
United States	\$33,385	\$29,433	\$29,848
International	18,425	19,042	17,808
	\$51,810	\$48,475	\$47,656

International revenue accounts for a significant portion of our total revenue and accounted for approximately 36%, 39%, and 37% of our net revenue in 2016, 2015, and 2014, respectively. No individual country outside the United States represented more than 10% of our net revenue during the years ended December 31, 2016, 2015, and 2014.

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 and regional managers. We also have an in-house sales force, which 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. We have sold our products directly to end users in Germany since 2011 and directly to end users in India and neighboring countries since 2012.

**Customer Concentration.** We sell our products through our field sales force, agents, and distributors. For the years ended December 31, 2016, 2015, and 2014, sales to our largest distributor worldwide accounted for approximately 4%, 3%, and 6%, 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, 2016, 2015, and 2014, our engineering and product development expenses totaled approximately \$7.8 million, \$7.3 million, and \$4.6 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. 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, 2016, we had approximately 230 issued patents and 85 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: 4 in 2017, 21 in 2018, and 3 in 2019, with the majority having expiration dates ranging from 2025 to 2038. With approximately 85 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 Regulations

### FDA and Related Regulatory Requirements

Our products are subject to extensive regulation particularly as to safety, efficacy and adherence to FDA Quality System Regulation, and related manufacturing standards. Medical device products are subject to rigorous FDA and other governmental agency regulations in the United States and similar regulations of foreign agencies abroad. The FDA regulates the design, development, research, preclinical and clinical testing, introduction, manufacture, advertising, labeling, packaging, marketing, distribution, import and export, and record keeping for such products, in order to ensure that medical products distributed in the United States are safe and effective for their intended use. In addition, the FDA is authorized to establish special controls to provide reasonable assurance of the safety and effectiveness of most devices. Non-compliance with applicable requirements can result in import detentions, fines, civil and administrative penalties, injunctions, suspensions or losses of regulatory approvals, recall or seizure of products, operating restrictions, refusal of the government to approve product export applications or allow us to enter into supply contracts, and criminal prosecution.

Unless an exemption applies, the FDA requires that a manufacturer introducing a new medical device or a new indication for use of an existing medical device obtain either a Section 510(k) premarket notification clearance or a premarket approval, or PMA, before introducing it into the U.S. market. The type of marketing authorization is generally linked to the classification of the device. The FDA classifies medical devices into one of three classes (Class I, II, or III) based on the degree of risk the FDA determines to be associated with a device and the level of regulatory control deemed necessary to ensure the device's safety and effectiveness.

Our products currently marketed in the United States are marketed pursuant to 510(k) pre-marketing clearances and are either Class I, Class II, or Class III devices. The process of obtaining a Section 510(k) clearance generally requires the submission of performance data and often clinical data, which in some cases can be extensive, to demonstrate that the device is “substantially equivalent” to a device that was on the market before 1976 or to a device that has been found by the FDA to be “substantially equivalent” to such a pre-1976 device (referred to as “predicate device”). As a result, FDA clearance requirements may extend the development process for a considerable length of time. In addition, in some cases, the FDA may require additional review by an advisory panel, which can further lengthen the process. The PMA process, which is reserved for new devices that are not substantially equivalent to any predicate device and for high-risk devices or those that are used to support or sustain human life, may take several years and requires the submission of extensive performance and clinical information.

Medical devices can be marketed only for the indications for which they are cleared or approved. After a device has received 510(k) clearance for a specific intended use, any change or modification that significantly affects its safety or effectiveness, such as a significant change in the design, materials, method of manufacture, or intended use, may require a new 510(k) clearance or PMA approval and payment of an FDA user fee. The determination as to whether or not a modification could significantly affect the device's safety or effectiveness is initially left to the manufacturer using available FDA guidance; however, the FDA may review this determination to evaluate the regulatory status of the modified product at any time and may require the manufacturer to cease marketing and recall the modified device until 510(k) clearance or PMA approval is obtained. The manufacturer may also be subject to significant regulatory fines or penalties. The FDA is currently reviewing its guidance describing when it believes a manufacturer is obligated to submit a new 510(k) submission for modifications or changes to a previously cleared device. The FDA is expected to issue revised guidance to assist device manufacturers in making this determination. It is unclear whether the FDA's approach in this new guidance will result in substantive changes to existing policy and practice regarding the assessment of whether a new 510(k) clearance is required for changes or modifications to existing devices.

Any devices we manufacture and distribute pursuant to clearance or approval by the FDA are subject to pervasive and continuing regulation by the FDA and certain state agencies. These include product listing and establishment registration requirements, which help facilitate FDA inspections and other regulatory actions. As a medical device manufacturer, all of our manufacturing facilities are subject to inspection on a routine basis by the FDA. We are required to adhere to applicable regulations setting forth detailed current good manufacturing practice (or cGMP) requirements, as set forth in the QSR, which require, manufacturers, including third-party manufacturers, to follow stringent design, testing, control, documentation and other quality assurance procedures during all phases of the design and manufacturing process. Noncompliance with these standards can result in, among other things, fines, injunctions, civil penalties, recalls or seizures of products, total or partial suspension of production, refusal of the government to grant 510(k) clearance or PMA approval of devices, withdrawal of marketing approvals, and criminal prosecutions. We believe that our design, manufacturing, and quality control procedures are in compliance with the FDA's regulatory requirements.

We must also comply with post-market surveillance regulations, including medical device reporting requirements which require that we review and report to the FDA any incident in which our products may have caused or contributed to a death or serious injury. We must also report any incident in which any of our products has malfunctioned if that malfunction would likely cause or contribute to a death or serious injury if it were to recur.

Labeling and promotional activities are subject to scrutiny by the FDA and, in certain circumstances, by the Federal Trade Commission ("FTC") and by state regulatory and enforcement authorities. Medical devices approved or cleared by the FDA may not be promoted for unapproved or uncleared uses, otherwise known as "off-label" promotion. The FDA and other agencies actively enforce the laws and regulations prohibiting the promotion of off-label uses, and a company that is found to have improperly promoted off-label uses may be subject to significant liability, including substantial monetary penalties and criminal prosecution.

Promotional activities for FDA-regulated products of other companies have also been the subject of enforcement actions brought under health care reimbursement laws and consumer protection statutes. In addition, under the federal Lanham Act and similar state laws, competitors and others can initiate litigation relating to advertising claims. If the FDA determines that our promotional materials or training constitutes promotion of an uncleared or unapproved use,

the FDA could request that we modify our training or promotional materials or subject us to regulatory or enforcement actions, including the issuance of an untitled letter, a notice of violation, a warning letter, an injunction, a seizure, a civil fine, or criminal penalties. In that event, our reputation could be damaged and adoption of the products could be impaired.

We 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.

#### Foreign Regulation

Sales of medical devices outside the United States are subject to regulatory requirements that vary widely from country to country. Approval for sale of our medical devices in Europe is through the CE mark process. Where appropriate, our products are CE marked to the European Union's Medical Device Directive. Under the CE marketing scheme, our products are classified as either Class I, Class II or Class III.

Medical devices marketed in the EU must meet all proper regulatory requirements and bear the “CE Mark” (“CE”). Existing in its present form since 1985, the CE marking indicates that the manufacturer or importer claims compliance with the relevant EU legislation applicable to a product, regardless of where manufactured. By affixing the CE marking on a product, a manufacturer is declaring, at its sole responsibility, conformity with all of the legal requirements to achieve CE marking which allows free movement and sale of the product throughout the European Economic Area (the “EEA”).

For example, most electrical products must comply with the Low Voltage Directive and the EMC Directive. The marking does not indicate EEA manufacture or that a product has been approved as safe by the EU or by another authority. The EU requirements may include safety, health, and environmental protection, and, if stipulated in any EU product legislation, assessment by a Notified Body or manufacture according to a certified production quality system. The CE marking also indicates that the product complies with directives in relation to Electro Magnetic Compatibility, meaning the device will work as intended, without interfering with the use or function of any other device.

Not all products need CE marking to be traded in the EEA; only product categories subject to relevant directives or regulations are required (and allowed) to bear CE marking. Most CE-marked products can be placed on the market subject to an internal production control by the manufacturer with no independent check of the conformity of the product with EU legislation; ANEC has cautioned that, amongst other things, CE marking cannot be considered a “safety mark” for consumers.

In addition, CE marking is a self-certification scheme. Retailers sometimes refer to products as “CE approved”, but the mark does not actually signify approval. Certain categories of products require type-testing by an independent body to ensure conformity with relevant technical standards, but CE marking in itself does not certify that this has been done.

We are ISO 13485 (Medical devices - Quality management systems - Requirements for regulatory purposes) Certified. We have received and are authorized for CE Marking for our Waterlase and Diode laser systems. In addition, we have attained the proper licensing for Waterlase and Diode laser systems for sale in Canada, meeting the CMDR (Canadian Medical Device Regulation) as part of the ISO certification process

#### 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 statutes 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 \$73,588 per violation (as adjusted for annual inflation) 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 of up to \$21,653 (as adjusted for annual 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 \$23,863 per claim (as adjusted for annual inflation), up to \$159,089 for circumvention schemes, and up to \$10,874 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 \$110 to more than \$55,000 per violation, with a maximum penalty of \$1,650,300 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, 2016, the Company employed approximately 225 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 10, 2017, the executive officers of the Company were as follows:

Name	Age	Position
Harold C. Flynn, Jr.	51	President and Chief Executive Officer
Brendan H. O'Connell	40	Vice President of Finance and Corporate Controller
Dmitri Boutousssov, Ph.D.	53	Vice President of Research and Development
Michael Roux	49	Vice President of Marketing
Richard R. Whipp	64	Vice President of Operations
Joseph Rotino	64	Vice President of Quality and Regulatory Affairs

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.

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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.

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.

Michael Roux joined BIOLASE in April 2016 as the Vice President of Marketing. Before joining BIOLASE, Mr. Roux served as Vice President of Product Management with Patient Safety Technologies (acquired by Stryker Corporation in 2014), a manufacturer of the SurgiCount Safety-Sponge system, where Mr. Roux oversaw Stryker's SurgiCount product offerings for retained surgical sponge prevention, as well as expansion into additional patient safety product and software solutions, from March 2013 to April 2016. From 2009 to 2013, Mr. Roux was Global Product Director for the respiratory care division for Hill-Rom Holdings, Inc., a global medical technology company. Prior to Hill-Rom Holdings, Inc., Mr. Roux was with 3M Company for 19 years, holding positions of increasing responsibility within product engineering, six-sigma, global product marketing leadership and business development. Mr. Roux earned his Master of Business Administration degree from the University of St. Thomas in Saint Paul, Minnesota and holds a Bachelor of Science degree in Industrial Engineering from the University of Minnesota.

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.

### 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

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## Item 1A. Risk Factors

Investing in our securities involves a high degree of risk. You should carefully consider the following risk factors together with all of 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 could 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, 2016, 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, 2016.

Our audited financial statements for the fiscal year ended December 31, 2016 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 \$178.3 million at December 31, 2016. We recorded net losses of approximately \$15.4 million, \$20.3 million, and \$18.9 million for the years ended December 31, 2016, 2015, and 2014, 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