BIOLASE, INC
Form 10-K
March 08, 2019

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, 2018

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) (Zip code)

(949) 361-1200

(Registrant's Telephone Number, including Area Code)

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

Title of each class	Name of each exchange on which registered
Common Stock, par value $0.001 per share	The NASDAQ Stock Market LLC (NASDAQ Capital Market)

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

None.

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

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 every Interactive Data File required to be submitted 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 such files). Yes No

Indicate by check mark if disclosure of delinquent filers pursuant to Item 405 of Regulation S-K (§ 229.405) is not contained herein, and will not be contained, to the best of registrant's knowledge, in 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, smaller reporting company, or an emerging growth company. See the definitions of "large accelerated filer," "accelerated filer," "smaller reporting company," and "emerging growth company" in Rule 12b-2 of the Exchange Act.

Large accelerated filer	Accelerated filer
Non-accelerated filer	Smaller reporting company
	Emerging growth company

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 13(a) of the Exchange Act.

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 $9,577,160 based on the last sale price of common stock on June 30, 2018.

As of March 5, 2019, there were 21,126,162 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 2019 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, 2018, are incorporated by reference into Part III of this Annual Report on Form 10-K.

BIOLASE, INC.

ANNUAL REPORT ON FORM 10-K

FOR THE FISCAL YEAR ENDED DECEMBER 31, 2018

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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 plans to expand our product line and clinical applications, future demand for improved dental care, compliance with laws and regulatory requirements, expenses, the impact of cost-saving measures, excise tax expenses, anticipated cash needs, capital requirements and capital expenditures, needs for additional financing, anticipated use of proceeds from debt financing, use of working capital, plans for future products and services and for enhancements of existing products and services, plans to explore potential collaborations, potential acquisitions of products and technologies, effects of engineering and development efforts, plans to expand our field sales force, the development of distributor relationships, anticipated growth strategies, ability to attract customers, the adequacy of our facilities, products and solutions from competitors, ability to maintain product quality standards, protection of patents and other technology, the ability of third party payers to pay for costs of our products, 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," "expect," "believe," "anticipate," "estimate," "predict," "outlook," "potential," "plan," "seek" and similar expressio variations or the negatives of these terms or other comparable terminology.

These forward-looking statements are based on the expectations, estimates, projections, beliefs and assumptions of our management based on information 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;
- failure in our efforts to train dental practitioners or to overcome the hesitation of dentists and patients to adopt laser technologies;
- 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;

- issues with our suppliers, including the failure of our suppliers to supply us with a sufficient amount or adequate quality of materials;
- rapidly changing standards and competing technologies;
- our inability to effectively manage and implement our growth strategies;
- risks associated with operating in international markets, including potential liabilities under the Foreign Corrupt Practices Act ("FCPA");
- breaches of our information technology systems;
- seasonality;
- 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;
- 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;
- risks relating to the Credit Agreement (as further described below) with SWK Funding LLC and failure to comply with certain debt covenants therein, including interest rate risk, limited operational flexibility and foreclosure of the Company's assets;
- 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 and 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;
- recall or other regulatory action concerning our products after receiving FDA clearance or approval; and
- risks relating to ownership of our common stock, including low liquidity, low trading volume, high volatility and dilution.

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

PART I

Item 1. Business

Overview

BIOLASE, Inc. ("BIOLASE" and, together with its consolidated subsidiaries, the "Company," "we," "our" or "us") is a medic device company that develops, manufactures, markets, and sells laser systems in dentistry and medicine and also markets, sells, and distributes dental imaging equipment, including three-dimensional CAD/CAM intra-oral scanners and digital dentistry software. 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 United States. 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 255 issued and 73 pending U.S. and international patents, the majority of which are related to Waterlase technology. From 1998 through December 31, 2018, we sold over 38,900 laser systems in over 80 countries around the world. Contained in this total are approximately 13,000 Waterlase systems, including approximately 8,900 Waterlase MD, MDX, Express 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 $46.2 million, $46.9 million, and $51.8 million, in 2018, 2017, and 2016, respectively, and we had net losses of $21.5 million, $16.9 million, and $15.4 million for the same periods, respectively. We had total assets of $38.5 million and $43.0 million as of December 31, 2018 and 2017, respectively.

Recent Developments

New Leadership Additions

Consistent with our goal to focus our energies on worldwide competitiveness, strengthening our leadership, 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.

Effective October 8, 2018, the Company's board of directors (the "Board") elected Elaine C. Wagner to the Board. Dr. Wagner is a retired United States Navy Rear Admiral with 33 years of service. Dr. Wagner most recently the Director of Readiness and Health at the Navy Bureau of Medicine and Surgery. Additionally, Dr. Wagner is a renowned leader in the practice of pediatric dentistry.

Effective August 7, 2018, the Board appointed Todd A. Norbe as our President and Chief Executive Officer and John R. Beaver, who was serving as our Interim Chief Executive Officer, was promoted to Executive Vice President and Chief Financial Officer.

Effective June 15, 2018, the Board elected Mr. Norbe and Jess Roper to the Board. Mr. Norbe has more than 25 years of experience as a senior executive with companies within the dental industry. Mr. Roper has more than 25 years of experience as a senior executive with companies in the medical industry and has held financial management positions with publicly traded and venture-funded companies.

Effective April 10, 2018, and with the resignation of Harold C. Flynn, Jr. as our President and Chief Executive Officer and as a director, the Board appointed John Beaver as our Interim Chief Executive Officer to focus on business performance improvement and continuing operational efficiencies.

Effective April 4, 2018, the Board elected Garrett Sato to the Board. Mr. Sato has more than 30 years of experience as a successful consultant and senior executive with companies in the dental industry and has served as a senior advisor and executive partner with private equity and investment banking firms.

Also consistent with our goal to focus our energies on worldwide competitiveness, strengthening our leadership, 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.

Southern California Model Market

In 2018, we bolstered efforts in southern California to significantly enhance the region's oral health and dental care by increasing awareness and education in laser dentistry. We added local specialists to our staff to offer dentists more support in maximizing the use of their lasers. In addition, we began to offer more educational courses, informational events and community activities to help ensure that dentists and their patients are provided with the latest information in laser dentistry. In April 2018, we formed a Southern California Dental Advisory Board, which is comprised of local dentistry veterans whose collective expertise serves as excellent resources to help propel the local market forward. Based on the success of this initiative, in October 2018, we began a similar initiative in the Dallas/Fort Worth, Texas area.

Reverse Stock Split

Effective May 10, 2018, we effectuated a one-for-five reverse stock split. In connection with the reverse stock split, the number of authorized shares of our common stock was reduced from 200,000,000 shares to 40,000,000 shares. All share and per share data referenced throughout this Form 10-K have been retroactively restated to reflect the one-for-five reverse stock split. See Note 1 to the consolidated financial statements.

Debt Financing

On November 9, 2018, we entered into a five-year secured Credit Agreement with SWK Funding LLC ("SWK"), pursuant to which we have borrowed $12.5 million (the "SWK Loan"). Our obligations are secured by substantially all of our assets. The SWK Loan matures on November 9, 2023, and the interest rate on the SWK Loan is London Interbank Offered Rate ("LIBOR") plus 10% (or another index that approximates LIBOR if LIBOR is discontinued). Approximately $0.9 million of the proceeds from the SWK Loan were used to pay off all amounts owed to Western Alliance Bank under the Business Financing Agreement (as amended and defined and described further in Item 7, "Management Discussion and Analysis of Financial Condition and Results of Operations"), and we plan to use the remaining proceeds to provide additional working capital to fund our growth initiatives, such as broadening our customer base and increasing the utilization of our products to drive recurring higher margin consumables revenue. See Note 6 to the consolidated financial statements for additional information.

Intellectual Property Litigation

On January 25, 2019 (the "Effective Date"), the Company entered into a settlement agreement ("Settlement Agreement") with CAO Group, Inc. ("CAO"). Under the terms of the Settlement Agreement, CAO agreed to dismiss with prejudice the previously-disclosed lawsuits filed by CAO against the Company in April 2012 and January 2018 alleging, among other things, that the Company's ezlase dental laser and diode laser infringe on certain of the patents owned by CAO. In addition, CAO granted to the Company and its affiliates a non-exclusive, non-transferable (except as provided in the Settlement Agreement,), royalty free, fully-paid, worldwide license to the licensed patents for use in the licensed products and agreed not to sue the Company (the "Stock Consideration"), its affiliates or any of its manufacturers, distributors, suppliers or customers for use of the licensed patents in the licensed products, and the parties agreed to a mutual release of claims. The Company agreed (i) to pay to CAO, within five days of the Effective Date, $500,000 in cash, (ii) to issue to CAO, within 30 days of the Effective Date, 500,000 restricted shares of

common stock of the Company, and (iii) to pay to CAO, within 30 days of December 31, 2021, an amount in cash equal to the difference (if positive) between $1,000,000 and the value of the Stock Consideration on December 31, 2021. The Stock Consideration vests and becomes transferrable on December 31, 2021, subject to the terms of a restricted stock agreement to be entered into between the parties. The Company has recorded a contingent loss relating to the settlement of $1.5 million in its consolidated financial statements as of December 31, 2018. See Notes 7 and 11 to the consolidated financial statements for additional information.

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, 2nd 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 6th 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. As of 2017, according to the ADA, there were 198,517 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.

Our Products

Our laser systems and three-dimensional CAD/CAM intraoral scanning and imaging solutions can provide dental professionals with enhanced capabilities for 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 new Waterlase Express, our flagship Waterlase iPlus, and the Waterlase MD, and MDX. 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 can eliminate the need for anesthesia in most cases and result in faster healing times compared to traditional methods of treatment, both of which could lead to improved patient-reported outcomes.

The Waterlase systems incorporate an ergonomic hand-piece and a user-friendly digital interface with clinical applications to control the mix of laser energy, air, and water, as well as the pulse rate. Each system also has been designed to be easily moved from operatory to operatory within a practice. We developed the Waterlase systems using internally developed intellectual property, as well as intellectual property obtained through various acquisitions. The Waterlase systems are FDA-cleared in the United States, CE mark-approved in Europe, and approved for sale in more than 80 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 diode lasers that perform soft tissue, hygiene, cosmetic procedures, teeth whitening, and provide temporary pain relief. Epic X, Epic 10, and iLase systems feature our proprietary 940nm wavelength and Epic Pro features our proprietary 940nm plus 980nm wavelength with 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 80 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 imaging product line includes a full line of 3Shape TRIOS intraoral scanners, digital impression systems and software for taking highly accurate three-dimensional scans, which can be used to design crowns, study models, surgical guides for implant placement, and event orthodontic and athletic appliances. We distribute the 3Shape 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.

Our 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.

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 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 and Side 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. 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.
- 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.
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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. 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. We believe that these factors will lead to greater patient case acceptance.

Business Strategy

Our business strategy includes the following key elements:

- Increasing awareness of and demand for our products among dental practitioners. We intend to increase demand for our products by educating dental practitioners and patients about the clinical benefits of our product suite. We plan to continue participation in key industry trade shows, the World Clinical Laser Institute ("WCLI") (which we founded in 2002), dental schools, and other educational forums. Our products are also used for clinical research, which often leads to published articles that can garner attention from dental practitioners.
- Increasing awareness and education in laser dentistry. We added local specialists to our staff in southern California and northern Texas to offer dentists more support in maximizing the use of their lasers. In addition, we plan to offer more educational courses, informational events and community activities to help ensure that dentists and their patients are provided with the latest information in laser dentistry. We have developed a local advisory board of dentistry veterans whose collective expertise should serve as an excellent resource that will help propel these local markets forward.
- 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 have primarily distributed 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.
- 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. 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 sold domestically are covered by a warranty against defects in material and workmanship for a period of up to one year from the date of sale to the end-user by us or a distributor. Our 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 extended warranty 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 distribute extended warranties on certain imaging products, including our digital radiography products. However, all imaging products that we distribute are initially covered by manufacturer's warranties.

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, an unexpected interruption from a single-source supplier could cause manufacturing delays, re-engineering, significant costs, and sales disruptions, any of which could have a material adverse effect on our operations. We are continually seeking to identify and qualify 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 driving brand awareness and demand for our laser solutions with 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, digital/social media, field sales forces, and agents and distributors. We also use brochures, direct communications, public relations, and other promotional tools and materials.

Our primary marketing message to dental practitioners focuses on the ability of our lasers to resolve dental challenges and deliver improved cash flow and return on investment ("ROI"), which can be realized with improved patient-reported outcomes. Our WCLI is a leader in educating and training dental practitioners in laser dentistry. We believe that, as the community of dental practitioners that use our products expands, the WCLI will continue to deliver fresh and 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 continue to 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 www.biolase.com, and on Facebook, Twitter, LinkedIn, YouTube, and Instagram. 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, 2018, 2017, and 2016 (dollars in thousands):

	Years Ended December 31,								
	2018			2017			2016		
Laser systems	$29,733	64.4	%	$29,121	62.0	%	$35,150	67.9	%
Imaging systems	1,694	3.7	%	3,685	7.9	%	3,066	5.9	%
Consumables and other	8,287	18.0	%	7,332	15.6	%	6,906	13.3	%

Services	6,429	13.9	%	6,660	14.2	%	6,539	12.6	%
Total products and services	46,143	100.0	%	46,798	99.7	%	51,661	99.7	%
License fees and royalty	12	—	%	128	0.3	%	149	0.3	%
Net revenue	$46,155	100.0	%	$46,926	100.0	%	$51,810		