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

4 Cromwell

Irvine, California 92618

(Address of Principal Executive Offices) (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 expressi 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.
-

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	100.0	%

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

	Years Ended December 31,		
	2018	2017	2016
United States	$28,661	$29,296	$33,385
International	$17,494	17,630	18,425
	$46,155	$46,926	$51,810

International revenue accounts for a significant portion of our total revenue and accounted for approximately 38%, 38%, and 36% of our net revenue in 2018, 2017, and 2016, respectively. No individual country outside the United States represented more than 10% of our net revenue during the years ended December 31, 2018, 2017, and 2016.

For financial information about our long-lived assets, see Notes 3, 4, and 9 to the consolidated financial statements.

United States Sales. In the United States, 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, 2018, 2017, and 2016, sales to our largest distributor worldwide accounted for approximately 4%, 4%, and 4%, respectively, of our net revenue. We had one customer that represented approximately 12% of our total outstanding accounts receivable as of December 31, 2018, and zero that represented more than 10% of our total outstanding accounts receivable as of December 31, 2017.

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, 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 higher 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 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 15 individuals with medical device and or laser development experience, including one Ph.D. During the years ended December 31, 2018, 2017, and 2016, our engineering and product development expenses totaled approximately $5.2 million, $6.2 million, and $7.8 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 Medical. The development and distribution agreement between the Company and IPG Medical 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 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, 2018, we had approximately 255 issued patents and 73 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: 2 in 2019 and 2 in 2020, with the majority having expiration dates ranging from 2025 to 2036. With approximately 73 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. 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, it is possible 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 (“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.

Any devices we manufacture and distribute pursuant to clearance or approval by the FDA are subject to extensive 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 ("cGMP") requirements, as set forth in the FDA's Quality System Regulation ("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. In the EU, placing our medical devices on the market must comply with the requirements of Council Directive 93/42/EEC concerning medical devices ("MDD"). Applicable requirements include compliance with the essential requirements of the MDD (the "Essential Requirements") and the CE marking process. Our devices are classified as Class I, Class IIa, Class IIb or Class III devices.

Medical devices marketed in the EU must meet all proper regulatory requirements and have a CE marking affixed to them. For devices falling within Class I (low risk), the manufacturer is responsible for ensuring that the product complies with the Essential Requirements and must draw up a written statement to this effect (a "Declaration of Conformity"). Class I devices without a measuring function and supplied in non-sterile condition do not require the involvement of an organization designated by an EU-competent authority to assess the conformity of certain products before being placed on the EU market (a "Notified Body"). Manufacturers of sterile products and devices with a measuring function must apply to a Notified Body for certification of the aspects of manufacture relating to sterility or metrology.

For devices falling within Class IIa (low – medium risk), in order to affix the CE marking and place the product on the EU market, the manufacturer must follow one of several authorization procedures involving the engagement of a Notified Body. For Class I devices, the manufacturer is responsible for declaring conformity with the provisions of the MDD and ensuring that the products comply with the Essential Requirements. This declaration must be supported by a conformity assessment by a Notified Body. Once the manufacturer has received certification from the Notified Body and issued a Declaration of Conformity, it may affix the CE marking to the relevant products and place them on the EU market.

For devices falling within Class IIb (medium – high risk) and Class III (high risk), in order to affix the CE marking and place the product on the EU market, the manufacturer must follow one of several authorization procedures. For Class IIa devices, this requires the engagement of a Notified Body. The procedure for placing Class III devices on the market is similar to that applicable for Class IIb devices. However, the manufacturer must also submit a design dossier to the Notified Body for approval under Annex II of the MDD, and some of the authorization procedures permitted for Class IIb devices are not permitted.

Once medical devices correctly have a CE marking and comply with other applicable regulatory requirements, they may be placed on the market in any member state of the European Economic Area ("EEA"). However, a CE marking does not indicate that the manufacturer's quality system or that a product's safety profile has been approved or assessed by competent authority.

In addition, other EU regulatory requirements may apply to our medical devices, including other types of CE markings having different requirements, where applicable. For example, Directive 2014/35/EU relating to the making available on the market of electrical equipment designed for use within certain voltage limits, Directive 2014/30/EU on electromagnetic compatibility and Directive 2011/65/EU on the restriction of the use of certain hazardous substances in electrical and electronic equipment may apply to our electrical products. Moreover, we must ensure compliance with applicable EU chemical legislation such as Directive 2011/65/EU on the restriction of the use of certain hazardous substances in electrical and electronic equipment and Regulation 1907/2006 on the Registration, Evaluation, Authorization and Restriction of Chemicals. Additional EU requirements may also include safety, health, and environmental protection.

The European Association for the Co-ordination of Consumer Representation in Standardization has cautioned that, amongst other things, CE marking cannot be considered a “safety mark” for consumers.

In addition, CE marking is a self-certification program. Retailers sometimes refer to products as “CE approved,” but the CE marking does not actually signify approval. As mentioned above, certain categories of products (such as Class IIa, Class IIb and Class III medical devices) require involvement of a Notified Body to ensure conformity with relevant technical standards, but CE marking by the manufacturer in itself does not certify that this has been done.

Our facilities manufacturing medical devices for the EEA market are EN ISO 13485 (Medical devices - Quality management systems - Requirements for regulatory purposes) Certified. Moreover, our Waterlase and Diode laser systems have a CE marking. In addition, we have attained the proper licensing for Waterlase and Diode laser systems for sale in Canada, meeting the Canadian Medical Device Regulation requirements 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 $74,792 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 $21,916 (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 (the "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 $24,253 per claim (as adjusted for annual inflation), up to $161,692 for circumvention schemes, and up to $11,052 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's anti-bribery provisions generally prohibit 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 by a corporation or business entity 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/or imprisonment, in addition to civil penalties of up to $16,000, per violation.

The FCPA's accounting provisions require that all issuers 1) make and keep books, records, and accounts that, in reasonable detail, accurately and fairly reflect an issuer's transactions and dispositions of an issuer's assets; and 2) devise and maintain a system of internal accounting controls sufficient to ensure management's control, authority, and responsibility over the firm's assets. Violations of the accounting provisions by a corporation or other business entity can result in criminal fines of up to $25 million per violation and civil penalties of up to $725,000. Individuals can be subject to a criminal fine of up to $5 million per violation and/or imprisonment and civil penalties of up to $150,000.

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 comply 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.

In 2013, the Office for Civil Rights ("OCR") of HHS released an omnibus final rule (the "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 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, 2018, the Company employed approximately 190 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, which follows the annual meeting of stockholders, and at other Board meetings, as appropriate.

At March 6, 2019, the executive officers of the Company were as follows:

Name	Age	Position
Todd A. Norbe	51	President and Chief Executive Officer
John R. Beaver	57	Executive Vice President and Chief Financial Officer
Ryan T. Meardon	39	Vice President of U.S. Sales
Richard R. Whipp	65	Vice President of Operations

Todd A. Norbe was named President and Chief Executive Officer in August 2018. Prior to joining the Company as a Director in June 2018, Mr. Norbe was the President, North America of KaVo Kerr, a subsidiary of the Danaher Corporation, where he held executive leadership positions from 2006 to 2018, including President of Kerr North America, and Vice President and General Manager, Metrex Medical – Sybron Dental Specialties. Mr. Norbe holds a Bachelor of Science degree in Marketing from Bloomsburg University and a Master of Business Administration in Management from Fairleigh Dickinson University.

John R. Beaver was named Senior Vice President and Chief Financial Officer in October 2017 and was promoted to Executive Vice President and Chief Financial Officer in August 2018. Prior to joining the Company, Mr. Beaver served as the Chief Financial Officer of Silicor Materials, Inc., a global leader in the production of solar silicon, from 2009 to 2013 and 2015 to 2017. Mr. Beaver also served on the Board of Directors of Silicor Materials, Inc. from 2013 to 2015. From 2013 to 2015, Mr. Beaver was Chief Financial Officer for Modumetal, Inc., a nano-laminated alloy coatings company focused on oil and gas applications. Prior to 2009, Mr. Beaver was Senior Vice President – Finance and Chief Financial Officer at Sterling Chemicals, a mid-sized public commodity chemical manufacturer. Mr. Beaver holds a Bachelor of Business Administration in Accounting from the University of Texas at Austin and is a Certified Public Accountant.

Ryan T. Meardon joined the Company in August 2011 as an Account Manager and advanced to the role of Sales Director in August 2013. In January 2018, Mr. Meardon was named Vice President of U.S. Sales. Prior to joining the Company, Mr. Meardon served as a Regional Product Specialist and Key Account Manager for Brasseler USA, a dental and surgical instrumentation company, from 2005 to 2011. Mr. Meardon holds Bachelor of Arts and Masters of Science degrees in Kinesiology from The University of Colorado.

Richard R. Whipp joined the Company in July 2011 as Director of Operations and was promoted to Vice President of Operations in October 2011. Prior to joining the Company, 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.

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®, ComfortPulse®, Waterlase®, Waterlase Dentistry®, Waterlase Express®, iLase®, iPlus®, Epic®, Epic Pro®, WCLI®, World Clinical Laser Institute®, Waterlase MD®, Waterlase Dentistry®, and EZLase® are registered trademarks of BIOLASE, and Pedolase™ is a trademark of BIOLASE. All other product and company names are registered trademarks or trademarks of their respective owners.

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, 2018, 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, 2018.

Our audited financial statements for the fiscal year ended December 31, 2018 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 we are 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, raise 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 operations 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 $216.7 million at December 31, 2018. We recorded net losses of approximately $21.5 million, $16.9 million, and $15.4 million for the years ended December 31, 2018, 2017, and 2016, respectively. In order to achieve profitability, we must increase net revenue through new sales and control our costs. 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. We believe these disruptions are likely to have an ongoing adverse effect on the world economy. A continuing economic downturn and financial market disruptions could have a material adverse effect on our business, financial condition, and results of operations, including by:

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

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

To remain competitive, we must continue to make significant investments in the development of our products, the expansion of our sales and marketing activities, and the expansion of our operating and management infrastructure as we increase sales domestically and internationally. If cash generated from our operations is insufficient to fund such growth, we could be required to raise additional funds through the issuance of equity or debt securities in the public or private markets, or through a collaborative arrangement or sale of assets. Additional financing opportunities may not be available to us, or if available, may not be on favorable terms. The availability of financing opportunities will depend, in part, on market conditions, and the outlook for our business. Any future issuance of equity securities or securities convertible into equity securities could result in substantial dilution to our stockholders, and the securities issued in such a financing could have rights, preferences or privileges senior to those of our common stock. In addition, if we raise additional funds through debt financing, we could be subject to debt covenants that place limitations on our operations. We could not be able to raise additional capital on reasonable terms, or at all, or we could use capital more rapidly than anticipated. If we cannot raise the required capital when needed, we may not be able to satisfy the demands of existing and prospective customers, we could lose revenue and market share and we may have to curtail our capital expenditures. The following factors, among others, could affect our ability to obtain additional financing on favorable terms, or at all:

- our results of operations;
- general economic conditions and conditions in the dental or medical device industries;
- the perception of our business in the capital markets;
- our ratio of debt to equity;
- our financial condition;
- our business prospects; and
- interest rates.

If we are unable to obtain sufficient capital in the future, we could have to curtail our capital expenditures. Any curtailment of our capital expenditures could result in a reduction in net revenue, reduced quality of our products, increased manufacturing costs for our products, harm to our reputation, or reduced manufacturing efficiencies and could have a material adverse effect on our business, financial condition, and results of operations.

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

We rely on exclusive and non-exclusive third-party distributors for a portion of our sales in North America and a majority of our sales in countries outside of the U.S. For the fiscal years ended December 31, 2018, 2017, and 2016, revenue from distributors accounted for approximately 34%, 32%, and 30% of our total net revenue, respectively. Our distributors have significant discretion in determining the efforts and resources they apply to the sale of our products, and we face significant challenges and risks in expanding, training, and managing our third-party distributors, particularly given their geographically dispersed operations. Our distributors may not commit the necessary resources to market and sell our products to the level of our expectations, and, regardless of the resources they commit, they may not be successful. From time to time, we may face competition or pricing pressure from one or more of our non-exclusive distributors in certain geographic areas where those distributors are selling inventory to the same customer base as us. Additionally, most of our distributor agreements can be terminated with limited notice, and we may not be able to replace any terminating distributor in a timely manner or on terms agreeable to us, if at all. If we are not able to maintain our distribution network, if our distribution network is not successful in marketing and selling our products, or if we experience a significant reduction in, cancellation, or change in the size and timing of orders from our distributors, our revenues could decline significantly and lead to an inability to meet operating cash flow requirements, which would have a material adverse effect on our business, financial condition, and results of operations.

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

Our dental laser systems represent relatively new technologies in the dental market. Only a small percentage of dentists use lasers to perform dental procedures. Our future success will depend on our ability to increase demand for our products by demonstrating to a broad spectrum of dentists and patients the potential performance advantages of our laser systems over traditional methods of treatment and over competitive laser systems, and our inability to do so could have a material adverse effect on our business, financial condition, and results of operations. Historically, we have experienced long sales cycles because dentists have been, and could continue to be, slow to adopt new technologies on a widespread basis. As a result, we generally are required to invest a significant amount of time and resources to educate dentists about the benefits of our products in comparison to competing products and technologies before completing a sale, if any.

Factors that could inhibit adoption of laser technologies by dentists include cost and concerns about the safety, efficacy, and reliability of lasers. In order to invest in a Waterlase system, a dentist generally needs to invest time to understand the technology, consider how patients may respond to the new technology, assess the financial impact the investment could have on the dentist’s practice and become comfortable performing procedures with our products. Absent an immediate competitive motivation, a dentist may not feel compelled to invest the time required to learn about the potential benefits of using a laser system. Dentists may not accept or adopt our products until they see additional clinical evidence supporting the safety and efficiency of our products or recommendations supporting our laser systems by influential dental practitioners. In addition, economic pressure, caused, for example, by an economic slowdown, changes in health care reimbursement or by competitive factors in a specific market, could make dentists reluctant to purchase substantial capital equipment or invest in new technologies. Patient acceptance will depend on the recommendations of dentists and specialists, as well as other factors, including the relative effectiveness, safety, reliability, and comfort of our systems as compared to other instruments and methods for performing dental procedures.

Any failure in our efforts to train dental practitioners could result in the misuse of our products, reduce the market acceptance of our products and have a material adverse effect on our business, financial condition, and results of operations.

There is a learning process involved for dental practitioners to become proficient users of our laser systems. It is critical to the success of our sales efforts to adequately train a sufficient number of dental practitioners. Following completion of training, we rely on the trained dental practitioners to advocate the benefits of our products in the broader marketplace. Convincing dental practitioners to dedicate the time and energy necessary for adequate training is challenging, and we cannot provide assurance that we will be successful in these efforts. If dental practitioners are not properly trained, they could misuse or ineffectively use our products, or could be less likely to appreciate our laser systems. This could also result in unsatisfactory patient outcomes, patient injury, negative publicity, FDA regulatory action, or lawsuits against us, any of which could negatively affect our reputation and sales of our laser systems.

If future data proves to be inconsistent with our clinical results or if competitors' products present more favorable results our revenues could decline and our business, financial condition, and results of operations could be materially and adversely affected.

If new studies or comparative studies generate results that are not as favorable as our clinical results, our revenues could decline. Additionally, if future studies indicate that our competitors' products are more effective or safer than ours, our revenues could decline. Furthermore, dental practitioners could choose not to purchase our laser systems until they receive additional published long-term clinical evidence and recommendations from prominent dental practitioners that indicate our laser systems are effective for dental applications.

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

A number of competitors have substantially greater capital resources, larger customer bases, larger technical, sales and marketing forces and stronger reputations with target customers than ours. We compete with a number of domestic and foreign companies that market traditional dental products, such as dental drills, as well as companies that market laser technologies in the dental and medical markets. The marketplace is highly fragmented and very competitive. We expect that the rapid technological changes occurring in the health care industry could lead to the entry of new competitors, particularly if dental and medical lasers gain increasing market acceptance. If we do not compete successfully, our revenue and market share could decline, which would impact our ability to meet our operating cash flow requirements and our business, financial condition, and results of operations could be adversely affected.

Our long-term success depends upon our ability to (i) distinguish our products through improving our product performance and pricing, protecting our intellectual property, improving our customer support, accurately timing the introduction of new products, and developing sustainable distribution channels worldwide; and (ii) develop and successfully commercialize new products, new or improved technologies, and additional applications for our laser systems. We may not be able to distinguish our products and commercialize any new products, new or improved technologies, or additional applications for our laser systems.

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

Our products are generally purchased by dental or medical professionals who have various billing practices and patient mixes. Such practices range from primarily private pay to those who rely heavily on third-party payers, such as private insurance or government programs. In the United States, third-party payers review and frequently challenge the prices charged for medical products and/or services. In many foreign countries, the prices for dental services are predetermined through government regulation. Payers could deny coverage and reimbursement on various grounds, including if they determine that the procedure was not medically necessary or that the device used in the procedure was investigational. Accordingly, both coverage and reimbursement can vary significantly from payer to payer. For the portion of dentists who rely heavily on third-party reimbursement, the inability to obtain reimbursement for services using our products could deter them from purchasing or using our products. We cannot predict the effect that future health care reforms or changes in financing for health and dental plans could have on our business. Any such changes could have an adverse effect on the ability of a dental or medical professional to generate a profit using our current or future products. In addition, such changes could act as disincentives for capital investments by dental and medical professionals.

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

Section 382 of the Internal Revenue Code of 1986 ("IRC") generally imposes an annual limitation on the amount of net operating loss carryforwards that may be used to offset taxable income when a corporation has undergone material changes in its stock ownership. In 2006, we completed an analysis to determine the applicability of the annual limitations imposed by IRC Section 382 caused by previous changes in our stock ownership and determined that such limitations should not be significant. Given our continued generation of losses since the completion of 2006 study, we have not updated the study. However, we plan to update the study if we expect to utilize net operating loss carryforwards in any future year. If we experience an ownership change as defined in IRC Section 382, utilization of the net operating loss carryforwards, research and development credit carryforwards, and other tax attributes, would be subject to an annual limitation under Section 382 of the IRC. In addition, our ability to utilize net operating loss carryforwards, research and development credit carryforwards, and other tax attributes may be limited by other changes outside our control, such as changes to applicable tax law. Any limitation may result in the expiration of a portion of the net operating loss or research and development credit carryforwards before utilization. If we lose our ability to use net operating loss carryforwards, any income we generate will be subject to tax earlier than it would be if we were able to use net operating loss carryforwards, resulting in lower profits which could have a material adverse effect on our business, financial condition, and results of operations.

We could incur problems in manufacturing our products.

In order to grow our business, we must expand our manufacturing capabilities to produce the systems and accessories necessary to meet any demand we may experience. We could encounter difficulties in increasing the production of our products, including problems involving production capacity and yields, quality control and assurance, component supply, and shortages of qualified personnel. In addition, before we can begin commercial manufacture of our products, we must ensure our manufacturing facilities, processes, and quality systems, and the manufacture of our laser systems, comply with FDA regulations governing facility compliance, quality control, and documentation policies and procedures. In addition, our manufacturing facilities are subject to periodic inspections by the FDA, as well as various state agencies and foreign regulatory agencies. From time to time, we could expend significant resources in obtaining, maintaining, and addressing our compliance with these requirements. Our success will depend in part upon our ability to manufacture our products in compliance with the FDA's QSR and other regulatory requirements. We have experienced quality issues with components of our products supplied by third parties, and we could continue to do so. Our future success depends on our ability to manufacture our products on a timely basis with acceptable manufacturing costs, while at the same time maintaining good quality control and complying with applicable regulatory requirements, and an inability to do so could have a material adverse effect on our product sales, cash collections from customers, and our ability to meet operating cash flow requirements, which could have a material adverse effect on our business, financial condition, and results of operations.

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

In manufacturing our products, we depend upon third parties for the supply of various components. Many of these components require a significant degree of technical expertise to design and produce. If we fail to adequately design, or if our suppliers fail to produce components to specification, or if the suppliers, or we, use defective materials or workmanship in the manufacturing process, the reliability and performance of our products will be compromised. We have experienced such non-compliance with manufacturing specifications in the past and could continue to experience such non-compliance in the future, which could lead to higher costs and reduced margins.

Our products could contain defects that cannot be repaired easily and inexpensively, and we have experienced in the past and could experience in the future some or all of the following:

- loss of customer orders and delay in order fulfillment;
- damage to our brand reputation;
- increased cost of our warranty program due to product repair or replacement;
- inability to attract new customers;
- diversion of resources from our manufacturing and engineering and development departments into our service department; and
- legal action.

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

Adverse publicity regarding any of our products or similar products marketed or sold by others could negatively affect us. If any studies raise or substantiate concerns regarding the efficacy or safety of our products or other concerns, our reputation could be harmed and demand for our products could diminish, which could have a material adverse effect on growth in new customers and sales of our product, leading to a decline in revenues, cash collections, and ultimately our ability to meet operating cash flow requirements.

Our products are used in minimally invasive surgical procedures, usually, though not always, without anesthesia. All surgical procedures carry some risk. Patients could experience adverse events or outcomes following a surgical procedure due to a multitude of different factors alone or in combination, including deficits in the skill, experience, and preparedness of the surgeon, the existence of underlying conditions or overall poor health of the patient, and

defects, age, and misuse of medical products used in the procedure. Should an adverse patient event occur during the use of our products, there could be adverse publicity, increased scrutiny from regulatory agencies, and a loss of good will, even if it is ultimately shown to be caused by factors other than our product.

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

The sale of dental and medical devices involves the risk of product liability claims against us. Claims could exceed our product liability insurance coverage limits. Our insurance policies are subject to various standard coverage exclusions, including damage to the product itself, losses from recall of our product, and losses covered by other forms of insurance such as workers compensation. We cannot be certain that we will be able to successfully defend any claims against us, nor can we be certain that our insurance will cover all liabilities resulting from such claims. In addition, we cannot provide assurance that we will be able to obtain such insurance in the future on terms acceptable to us, or at all. Regardless of merit or eventual outcome, any product liability claim brought against us could result in harm to our reputation, decreased demand for our products, costs related to litigation, product recalls, loss of revenue, an increase in our product liability insurance rates, or the inability to secure coverage in the future, and could have a material adverse effect on our business by reducing cash collections from customers and limiting our ability to meet our operating cash flow requirements.

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

Our business depends on our ability to obtain timely deliveries of materials, components, and subassemblies of acceptable quality and in acceptable quantities from third-party suppliers. We generally purchase components and subassemblies from a limited group of suppliers through purchase orders, rather than written supply contracts. Consequently, many of our suppliers have no obligation to continue to supply us on a long-term basis. In addition, our suppliers manufacture products for a range of customers, and fluctuations in demand for the products those suppliers manufacture for others could affect their ability to deliver components for us in a timely manner. Moreover, our suppliers could encounter financial hardships, be acquired, or experience other business events unrelated to our demand for components, which could inhibit or prevent their ability to fulfill our orders and satisfy our requirements.

Certain components of our products, particularly specialized components used in our laser systems, are currently available only from a single source or limited sources. For example, the crystal, fiber, and hand pieces used in our Waterlase systems are each supplied by a separate single supplier. Our dependence on single-source suppliers involves several risks, including limited control over pricing, availability, quality, and delivery schedules.

If any of our suppliers cease to provide us with sufficient quantities of our components in a timely manner or on terms acceptable to us, or ceases to manufacture components of acceptable quality, we could incur manufacturing delays and sales disruptions while we locate and engage alternative qualified suppliers, and we might be unable to engage acceptable alternative suppliers on favorable terms. In addition, we could need to reengineer our components, which could require product redesign and submission to the FDA of a 510(k) application, which could significantly delay production. Any interruption or delay in the supply of components or materials, or our inability to obtain components or materials from alternate sources at acceptable prices in a timely manner, could impair our ability to meet the demand of our customers and cause them to cancel orders or switch to competitive procedures. We are continually in the process of identifying and qualifying alternate source suppliers for our key components. There can be no assurance, however, that we will successfully identify and qualify an alternate source supplier for any of our key components or that we could enter into an agreement with any such alternate source supplier on terms acceptable to us, or at all.

Rapidly changing standards and competing technologies could harm demand for our products, result in significant additional costs, and have a material adverse effect on our business, financial condition, and results of operations.

The markets in which our products compete are subject to rapid technological change, evolving industry standards, changes in the regulatory environment, and frequent introductions of new devices and evolving dental and surgical techniques. Competing products could emerge that render our products uncompetitive or obsolete. The process of developing new medical devices is inherently complex and requires regulatory approvals or clearances that can be

expensive, time-consuming, and uncertain. We cannot guarantee that we will successfully identify new product opportunities, identify new and innovative applications of our technology, or be financially or otherwise capable of completing the research and development required to bring new products to market in a timely manner. An inability to expand our product offerings or the application of our technology could limit our growth. In addition, we could incur higher manufacturing costs if manufacturing processes or standards change, and we could need to replace, modify, design, or build and install equipment, all of which would require additional capital expenditures.

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

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

We have significant international sales and are subject to risks associated with operating in international markets.

International sales comprise a significant portion of our net revenue, and we intend to continue to pursue and expand our international business activities. For the fiscal years ended December 31, 2018, 2017, and 2016, international sales accounted for approximately 38%, 38%, and 36% of our net revenue, respectively. Political and economic conditions outside the United States could make it difficult for us to increase our international revenue or to operate abroad. International operations are subject to many inherent risks, which could have a material adverse effect on our revenues and operating cash flow, including among others:

- adverse changes in tariffs and trade restrictions;
- political, social, and economic instability and increased security concerns;
- fluctuations in foreign currency exchange rates;
- longer collection periods and difficulties in collecting receivables from foreign entities;
- exposure to different legal standards;
- transportation delays and difficulties of managing international distribution channels;
- reduced protection for our intellectual property in some countries;
- difficulties in obtaining domestic and foreign export, import, and other governmental approvals, permits, and licenses, and compliance with foreign laws;
- the imposition of governmental controls;
- unexpected changes in regulatory or certification requirements;
- difficulties in staffing and managing foreign operations; and
- potentially adverse tax consequences and the complexities of foreign value-added tax systems.

We believe that international sales will continue to represent a significant portion of our net revenue, and we intend to expand our international operations further. In international markets where our sales are denominated in U.S. dollars, an increase in the relative value of the dollar against the currency in such markets could indirectly increase the price of our products in those markets and result in a decrease in sales. We do not currently engage in any transactions as a hedge against risks of loss due to foreign currency fluctuations. However, we could do so in the future.

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

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

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

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

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

Any of these results could have a material adverse effect on our business due to the time and expense to respond to such an attack, recover data, and remediate IS weaknesses, which would disrupt our daily business operations. Further, in the event of an attack, we would be exposed to a risk of loss or litigation and possible liability, including under laws that protect the privacy of personal information.

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

Our revenue typically fluctuates from quarter to quarter due to a number of factors, many of which are beyond our control. Revenue in the first quarter typically is lower than average, and revenue in the fourth quarter typically is stronger than average due to the buying patterns of dental practitioners. We believe that this trend exists because a significant number of dentists purchase their capital equipment towards the end of the calendar year in order to maximize their practice earnings while seeking to minimize their taxes. They often use certain tax incentives, such as accelerated depreciation methods for purchasing capital equipment, as part of their year-end tax planning. In addition, revenue in the third quarter could be affected by vacation patterns, which can cause revenue to be flat or lower than in the second quarter of the year. Our historical seasonal fluctuations could also be impacted by sales promotions used by large dental distributors that encourage end-of-quarter and end-of-year buying in our industry. Other factors that might cause quarterly fluctuations in our revenue and operating results include the following:

- variation in demand for our products;
- our ability to research, develop, market, and sell new products and product enhancements in a timely manner;
- our ability to control costs;
- our ability to control quality issues with our products;
- regulatory actions that impact our manufacturing processes;
- the size, timing, rescheduling, or cancellation of orders from distributors;

- the introduction of new products by competitors;
- the length of and fluctuations in sales cycles;
- the availability and reliability of components used to manufacture our products;
- changes in our pricing policies or those of our suppliers and competitors, as well as increased price competition in general;
- legal expenses, particularly related to litigation matters;
- general economic conditions including the availability of credit for our existing and potential customer base to finance purchases;
- the mix of our domestic and international sales and the risks and uncertainties associated with international business;
- costs associated with any future acquisitions of technologies and businesses;
- limitations on our ability to use net operating loss carryforwards under the provisions of IRC Section 382 and similar state laws;
- developments concerning the protection of our intellectual property rights;
- catastrophic events such as hurricanes, floods, and earthquakes, which can affect our ability to advertise, sell, and distribute our products, including through national conferences held in regions in which these disasters strike; and
- global economic, political, and social events, including international conflicts and acts of terrorism.

The expenses we incur are based, in large part, on our expectations regarding future net revenue. Since many of our costs are fixed in the short term, we could be unable to reduce expenses quickly enough to avoid losses if we experience a decrease in expected net revenue. Accordingly, you should not rely on quarter-to-quarter comparisons of our operating results as an indication of our future performance.

Litigation against us could be costly and time-consuming to defend and could materially and adversely affect our business, financial condition, and results of operations.

We are from time to time involved in various claims, litigation matters and regulatory proceedings incidental to our business, including claims for damages arising out of the use of our products or services and claims relating to intellectual property matters, employment matters, commercial disputes, competition, sales and trading practices, environmental matters, personal injury, and insurance coverage. Some of these lawsuits include claims for punitive as well as compensatory damages. The defense of these lawsuits could divert our management's attention, and we could incur significant expenses in defending these lawsuits. In addition, we could be required to pay damage awards or settlements or become subject to unfavorable equitable remedies. Moreover, any insurance or indemnification rights that we could have may be insufficient or unavailable to protect us against potential loss exposures.

Our operations are consolidated primarily in one facility. A disruption at this facility could result in a prolonged interruption of our business and have a material adverse effect on our business, financial condition, and results of operations.

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

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

Our success is dependent, in part, upon our ability to hire and retain management, engineers, marketing and sales personnel, and technical, research and other personnel who are in high demand and are often subject to competing employment opportunities. Our success will depend on our ability to retain our current personnel and to attract and retain qualified like personnel in the future. Competition for senior management, engineers, marketing and sales personnel, and other specialized technicians is intense and we may not be able to retain our personnel. If we lose the services of any executive officers or key employees, our ability to achieve our business objectives could be harmed or delayed, which could have a material adverse effect on our daily operations, operating cash flows, results of operations, and ultimately share price. In general, our officers could terminate their employment at any time without notice for any reason.

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

Successful acquisitions depend upon our ability to identify, negotiate, complete, and integrate suitable acquisitions and to obtain any necessary financing. We expect to continue to consider opportunities to acquire or make investments in other technologies, products and businesses that could enhance our capabilities, complement our current products, or expand the breadth of our markets or customer base. We have limited experience in acquiring other businesses and technologies. Even if we complete acquisitions, we could experience:

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

In addition, an acquisition could cause us to incur debt or issue shares, resulting in dilution to existing stockholders. We could also discover deficiencies in internal controls, data adequacy and integrity, product quality, regulatory compliance, and product liabilities that we did not uncover prior to our acquisition of such businesses, which could result in us becoming subject to penalties or other liabilities. Any difficulties in the integration of acquired businesses or unexpected penalties or liabilities in connection with such businesses could have a material adverse effect on our business, financial condition, and results of operations.

Failure to meet covenants in the Credit Agreement, dated as of November 9, 2018 (the “Credit Agreement”), between BIOLASE, Inc. and SWK Funding LLC, as agent (“SWK”), could result in acceleration of our payment obligations thereunder, and we may not be able to find alternative financing.

Under the Credit Agreement, we are required to maintain a specified amount of consolidated unencumbered liquid assets as of the end of fiscal quarter, generate minimum levels of revenue as of the end of each period specified in the Credit Agreement and maintain specified levels of consolidated EBITDA as of the end of each period specified in the Credit Agreement. Our ability to comply with these covenants may be affected by factors beyond our control. If we fail to comply with the covenants contained in the Credit Agreement, or if the Required Lenders (as defined in the Credit Agreement) contend that we have failed to comply with these covenants or any other restrictions, it could result in an event of default under the Credit Agreement, which would permit or, in certain events, require SWK to declare all amounts outstanding thereunder to be immediately due and payable. There can be no assurances that we will be able to repay all such amounts or able to find alternative financing in an event of a default. Even if alternative financing is available in an event of a default under the Credit Agreement, it may be on unfavorable terms, and the interest rate charged on any new borrowings could be substantially higher than the interest rate under the Credit Agreement, thus adversely affecting cash flows, results of operations, and ultimately, our ability to meet operating

cash flow requirements.

Our variable rate indebtedness under the Credit Agreement subjects us to interest rate risk, which could result in higher expense in the event of increases in interest rates and adversely affect our business, financial condition, and results of operations.

Borrowings under the Credit Agreement bear interest at a rate that varies depending on the London Interbank Offered Rate ("LIBOR") or a replacement index that approximates LIBOR should LIBOR no longer be available. As a result, we are exposed to interest rate risk. If LIBOR rises, the interest rate on outstanding borrowings under the Credit Agreement will increase. Therefore, an increase in LIBOR will increase our interest payment obligations under the Credit Agreement and have a negative effect on our cash flow and possibly our ability to meet operating cash flow requirements.

The restrictive covenants in the Credit Agreement and the Company's obligation to make debt payments under the Credit Agreement may limit our operating and financial flexibility and may adversely affect the Company's business, financial condition, and results of operations.

The Credit Agreement imposes operating and financial restrictions and covenants, which may limit or prohibit our ability to, among other things:

- incur additional indebtedness;
- make investments, including acquisitions;
- create liens;
- make dividends, distributions or other restricted payments;
- effect affiliate transactions;
- enter into mergers, divisions, consolidations or sales of substantially all of our or our subsidiaries' assets;
- change business activities and issue equity interests; or
- sell material assets (without using the proceeds thereof to repay the obligations under the Credit Agreement).

In addition, we are required to comply with certain financial covenants under the Credit Agreement as described above.

Such restrictive covenants in the Credit Agreement and the Company's repayment obligations under the Credit Agreement could have adverse consequences to the Company, including:

- limiting our flexibility in operating our business and planning for, or reacting to, changes in our business and our industry;
- requiring the dedication of a substantial portion of any cash flow from operations to the payment of principal of, and interests on, the indebtedness, thereby reducing the availability of such cash flow to fund our operations, working capital, capital expenditures, future business opportunities and other general corporate purposes;
- restricting us from making strategic acquisitions or causing us to make non-strategic divestitures;
- limiting our ability to obtain additional financing;
- limiting our ability to adjust to changing market conditions; and
- placing us at a competitive disadvantage relative to our competitors who are less highly leveraged.

If we fail to comply with the terms of the Credit Agreement and there is an event of default, the creditor(s) may foreclose upon the assets securing our obligations thereunder.

To secure the performance of our obligations under the Credit Agreement, we granted SWK security interests in substantially all of the assets of BIOLASE. and certain of our foreign and domestic subsidiaries. Our failure to comply with the terms of the Credit Agreement could result in an event of default thereunder. In that event, SWK will have the option to (and, in certain circumstances, will have the obligation to) foreclose on the assets of BIOLASE. and certain of our subsidiaries pledged as collateral under the Credit Agreement or the other documents executed in connection with the Credit Agreement. The foreclosure on the Company's assets could severely and negatively impact our business, financial condition, and results of operations.

If certain individuals (or permitted replacements thereof) no longer serve as our Chairman, Chief Executive Officer or Chief Financial Officer, we may be obligated to pay all outstanding obligations and certain fees under the Credit Agreement.

The Credit Agreement provides that, unless such actions are consented to in advance in writing by SWK, if two or more of the three of Jonathan Lord, Todd Norbe and John Beaver (or, in each case, his approved successor) at any one time no longer serves in their current positions with the Company and we do not find individuals to replace such individuals within 150 days (or in certain circumstances 210 days), with individuals of appropriate qualification and experience approved in writing by SWK (which approval may not be unreasonably withheld or delayed), there is a "Key Person Event" and all outstanding obligations and certain fees under the Credit Agreement become immediately due and payable. Whether Mr. Lord, Mr. Norbe and Mr. Beaver remain our Chairman, Chief Executive Officer and Chief Financial Officer, respectively, is not entirely under our control. Although we intend to find an appropriate replacement satisfactory to SWK if any of Mr. Lord, Mr. Norbe or Mr. Beaver leaves his current position, there is no assurance that we will be able find such a replacement within the time period permitted under the Credit Agreement, if at all. If there is a Key Person Event, there can be no assurance that we will be able to repay all outstanding obligations and fees payable or able to find alternative financing. Even if alternative financing is available, it may be on unfavorable terms, and the interest rate charged on any new borrowings could be substantially higher than the interest rate under the Credit Agreement, thus adversely affecting our business, financial condition, and results of operations.

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

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

In addition, pursuant to Section 404 of the Sarbanes-Oxley Act, we are required to evaluate and provide a management report of our systems of internal control over financial reporting. During the course of the evaluation of our internal control over financial reporting, we could identify areas requiring improvement and could be required to design enhanced processes and controls to address issues identified through this review. This could result in significant delays and costs to us and require us to divert substantial resources, including management time, from other activities. In addition, if we fail to maintain the adequacy of our internal control over financial reporting, we may not be able to ensure that we can conclude on an ongoing basis that we have effective internal control over financial reporting in accordance with the Sarbanes-Oxley Act. Moreover, effective internal controls are necessary for us to produce reliable financial reports and are important to help prevent fraud. Any failure to maintain compliance with the requirements of Section 404 on a timely basis could result in the loss of investor confidence in the reliability

of our financial statements, which in turn could, negatively impact the trading price of our stock, and adversely affect investors' confidence in the Company and our ability to access capital markets for financing.

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

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

Risks Related to Our Intellectual Property

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

Our future success depends, in part, on our ability to obtain and maintain patent protection for our products and technology, to preserve our trade secrets and to operate without infringing the intellectual property of others. We rely on patents to establish and maintain proprietary rights in our technology and products. We currently possess a number of issued patents and patent applications with respect to our products and technology. However, we cannot ensure that any additional patents will be issued, that the scope of any patent protection will be effective in helping us address our competition, or that any of our patents will be held valid if subsequently challenged. It is also possible that our competitors could independently develop similar or more desirable products, duplicate our products, or design products that circumvent our patents. The laws of foreign countries may not protect our products or intellectual property rights to the same extent as the laws of the United States. In addition, there have been recent changes in the patent laws and rules of the U.S. Patent and Trademark Office (the "USPTO"), and there could be future proposed changes that, if enacted, have a significant impact on our ability to protect our technology and enforce our intellectual property rights. If we fail to protect our intellectual property rights adequately, our competitive position could be adversely affected, and there could be a material adverse effect on sales, cash collections, and our ability to meet operating cash flow requirements.

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

We face substantial uncertainty regarding the impact that other parties' intellectual property positions will have on dental and other medical laser applications. The medical technology industry has in the past been characterized by a substantial amount of litigation and related administrative proceedings regarding patents and intellectual property rights. From time to time, we have received, and we expect to continue to receive, notices of claims of infringement, misappropriation, or misuse of other parties' proprietary rights. Some of these claims could lead to litigation. We may not prevail in any future intellectual property infringement litigation given the complex technical issues and inherent uncertainties in litigation. Any claims, with or without merit, could be time-consuming and distracting to management, result in costly litigation, or cause product shipment delays. Adverse determinations in litigation could subject us to significant liability and could result in the loss of proprietary rights. A successful lawsuit against us could also force us to cease selling or redesign products that incorporate the infringed intellectual property. Additionally, we could be required to seek a license from the holder of the intellectual property to use the infringed technology, and we may not be able to obtain a license on acceptable terms, or at all.

Risks Related to Our Regulatory Environment

Changes in government regulation or the inability to obtain or maintain necessary government approvals could have a material adverse effect on our business, financial condition, and results of operations.

Our products are subject to extensive government regulation, both in the United States and in other countries. To clinically test, manufacture, and market products for human use, we must comply with regulations and safety standards set by the FDA and comparable state and foreign agencies. Regulations adopted by the FDA are wide-ranging and govern, among other things, product design, development, manufacture and control testing, labeling control, storage, advertising, and sales. Generally, products must meet regulatory standards as safe and effective for their intended use before being marketed for human applications. The clearance process is expensive, time-consuming, and uncertain. Failure to comply with applicable regulatory requirements of the FDA can result in an enforcement action, which could include a variety of sanctions, including fines, injunctions, civil penalties, recall or seizure of our products, operating restrictions, partial suspension, or total shutdown of production and criminal

prosecution. The failure to receive or maintain requisite approvals for the use of our products or processes, or significant delays in obtaining such approvals, could prevent us from developing, manufacturing, and marketing products and services necessary for us to remain competitive.

If we develop new products and applications or make any significant modifications to our existing products or labeling, we will need to obtain additional regulatory clearances or approvals. Any modification that could significantly affect a product’s safety or effectiveness, or that would constitute a change in its intended use, will require a new FDA 510(k) clearance, or could require a PMA application. The FDA requires each manufacturer to make this determination initially, but the FDA can review any such decision and can disagree with a manufacturer’s determination. If the FDA disagrees with a manufacturer’s determination, the FDA can require the manufacturer to cease marketing and/or recall the modified device until 510(k) clearance or PMA is obtained. If 510(k) clearance is denied and a PMA application is required, we could be required to submit substantially more data and conduct human clinical testing and would very likely be subject to a significantly longer review period.

Products sold in international markets are also subject to the regulatory requirements of each respective country or region. The regulations of the European Union require that a device have a CE Mark, indicating conformance with European Union laws and regulations before it can be sold in the European Union. The regulatory international review process varies from country to country. We rely on our distributors and sales representatives in the foreign countries in which we market our products to comply with the regulatory laws of such countries. Failure to comply with the laws of such countries could prevent us from continuing to sell products in such countries. In addition, unanticipated changes in existing regulatory requirements or the adoption of new requirements could impose significant costs and burdens on us, which could increase our operating expenses.

Changes in health care regulations in the U.S. and elsewhere could adversely affect the demand for our products as well as the way in which we conduct our business. For example, in 2010, President Obama signed the Affordable Care Act into law, which included various reforms impacting Medicare coverage and reimbursement, including revision to prospective payment systems, any of which could adversely impact any Medicare reimbursements received by our end-user customers. New legislation may be enacted as President Trump and Congress consider further reform. In addition, as a result of the focus on health care reform, there is risk that Congress could implement changes in laws and regulations governing health care service providers, including measures to control costs, and reductions in reimbursement levels. We cannot be sure that government or private third-party payers will cover and reimburse the procedures using our products, in whole or in part, in the future, or that payment rates will be adequate. If providers cannot obtain adequate coverage and reimbursement for our products, or the procedures in which they are used, our business, results of operations, and financial condition could suffer.

We could be subject to or otherwise affected by federal and state health care laws, including fraud and abuse and health information privacy and security laws, and we could face substantial penalties if we are unable to fully comply with such regulations.

We are directly or indirectly, through our customers, subject to extensive regulation by both the federal government and the states and foreign countries in which we conduct our business. The laws that directly or indirectly affect our ability to operate our business include, but are not limited to, the following:

- the Federal Food, Drug, and Cosmetic Act, which regulates the design, testing, manufacture, labeling, marketing, distribution, and sale of prescription drugs and medical devices and which includes the RCHSA, under which the FDA has established reporting, recordkeeping, and performance requirements for laser products;
- state food and drug laws;
- the federal Anti-Kickback Statute, which prohibits persons from knowingly and willfully soliciting, offering, receiving, or providing remuneration, directly or indirectly, to induce the referral for the furnishing of, or the purchase, order, or recommendation of, a good or service, for which payment could be made under FHCPs such as Medicare, Medicaid, and TRICARE;
- state law equivalents to the federal Anti-Kickback Statute, which may not be limited to government reimbursed items;
- state laws that prohibit fee-splitting arrangements;
- the federal Civil False Claims Act, which imposes liability on any person or entity that knowingly presents, or causes to be presented, a false or fraudulent claim for payment to the government, including FHCPs;
- state false claims laws that prohibit anyone from presenting, or causing to be presented, claims for payment to third-party payers that are false or fraudulent;
- federal crimes for knowingly and willfully executing a scheme to defraud any health care benefit program or making false statements in connection with the delivery of or payment for items or services under a health care benefit program;
- federal law prohibiting offering remuneration to a Medicare or Medicaid beneficiary to influence the beneficiary’s selection of a particular provider, practitioner, or supplier;

- the federal Stark Law, which, in the absence of a statutory or regulatory exception, prohibits: (i) the referral of Medicare or Medicaid patients by a physician to an entity for the provision of designated health care services, if the physician or a member of the physician's immediate family has a direct or indirect financial relationship, including an ownership interest in, or a compensation arrangement with, the entity and (ii) submitting a bill to Medicare or Medicaid for services rendered pursuant to a prohibited referral;
- state law equivalents to the Stark Law, which may not be limited to government reimbursed items;
- the Physician Payments Sunshine Act, which requires us to report annually to CMS certain payments and other transfers of value we make to U.S.-licensed physicians, dentists, and teaching hospitals;
- the FCPA, which generally prohibits companies and their intermediaries from paying anything of value to foreign officials to influence any decision of the foreign official in his/her official capacity or to secure any other improper advantage to obtain or retain business;
- HIPAA and HITECH and their implementing regulations, which govern the use, disclosure, and safeguarding of PHI;
- state privacy laws that protect the confidentiality of patient information;
- Medicare and Medicaid laws and regulations that prescribe the requirements for coverage and payment, including the amount of such payment; state laws that prohibit the practice of medicine by non-physicians; and
- the Federal Trade Commission Act and similar laws regulating advertising and consumer protection.

If our past or present operations are found to be in violation of any of the laws described above or the other governmental laws or regulations to which we or our customers are subject, we could be subject to the applicable penalty associated with the violation, which could include civil and criminal penalties, damages, fines, exclusion from FHCPs, and the curtailment or restructuring of our operations. If we are required to obtain permits or licensure under these laws that we do not already possess, we could become subject to substantial additional regulation or incur significant expense. Any penalties, damages, fines, or curtailment or restructuring of our operations could be significant. The risk of potential non-compliance is increased by the fact that many of these laws have not been fully interpreted by applicable regulatory authorities or the courts, and their provisions are open to a variety of interpretations and additional legal or regulatory change. Any action against us for violation of these laws, even if we successfully defend against it, could cause us to incur significant legal expenses, divert our management's attention from the operation of our business, damage our reputation, and cause a material adverse effect on sales, cash collections, and our ability to meet operating cash flow requirements.

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

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

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

The process of obtaining and maintaining regulatory approvals and clearances to market a medical device from the FDA and similar regulatory authorities abroad can be costly and time-consuming, and we cannot provide assurance that such approvals and clearances will be granted. Pursuant to FDA regulations, unless exempt, the FDA permits commercial distribution of a new medical device only after the device has received 510(k) clearance or is the subject of an approved PMA. The FDA will clear marketing of a medical device through the 510(k) process if it is demonstrated that the new product is substantially equivalent to other 510(k)-cleared products. The PMA process is more costly, lengthy and uncertain than the 510(k) process, and must be supported by extensive data, including data from preclinical studies, and human clinical trials. Because we cannot provide assurance that any new products, or any product enhancements, that we develop will be subject to the shorter 510(k) clearance process, significant delays in the introduction of any new products or product enhancement could occur. We cannot provide assurance that the FDA will not require a new product or product enhancement to go through the lengthy and expensive PMA process. Delays in obtaining regulatory clearances and approvals could:

- delay or eliminate commercialization of products we develop;
- require us to perform costly procedures;
- diminish any competitive advantages that we may attain; and
- reduce our ability to collect revenues or royalties.

Although we have obtained 510(k) clearance from the FDA to market our dental laser systems, we cannot provide assurance that we will not be required to obtain new clearances or approvals for modifications or improvements to our products.

Our products are subject to recalls and other regulatory actions after receiving FDA clearance or approval.

The FDA and similar governmental bodies in other countries have the authority to require the recall of our products in the event of material deficiencies or defects in design or manufacture. A government mandated or voluntary recall by us could occur as a result of component failures, manufacturing errors, or design defects, including defects in labeling. Any recall would divert management’s attention and financial resources and harm our reputation with customers. Any recall involving our laser systems would be particularly harmful to us, because our laser systems comprise such an important part of our portfolio of products. However, any recall could have a material adverse effect on our business, financial condition, and results of operations.

Risks Related to Our Stock

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

The liquidity and trading volume of our common stock has at times been low in the past and could again be low in the future. If the liquidity and trading volume of our common stock is low, this could adversely impact the trading price of our shares, our ability to issue stock and our stockholders’ ability to obtain liquidity in their shares. The issuance of common stock by us in 2013, 2014, 2016 and 2017 involved a significant issuance of stock to a limited number of investors, significantly increasing the concentration of our share ownership in a few holders.

Two of our stockholders hold approximately 60% of our outstanding common stock, in the aggregate, as of December 31, 2018. As a result, these stockholders will be able to affect the outcome of, or exert significant influence over, all matters requiring stockholder approval, including the election and removal of directors and any change in control. In particular, this concentration of ownership of our common stock could have the effect of delaying or preventing a

change in control of us or otherwise discouraging or preventing a potential acquirer from attempting to obtain control of us. This, in turn, could have a negative effect on the market price of our common stock. It could also prevent our stockholders from realizing a premium over the market prices for their shares of common stock. Moreover, the interests of this concentration of ownership may not always coincide with our interests or the interests of other stockholders. The concentration of ownership also contributes to the low trading volume and volatility of our common stock.

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

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

- actual or anticipated fluctuations in our operating results or future prospects;
- our announcements or our competitors’ announcements of new products;
- the public’s reaction to our press releases, our other public announcements, and our filings with the SEC;
- strategic actions by us or our competitors, such as acquisitions or restructurings;
- new laws or regulations or new interpretations of existing laws or regulations applicable to our business;
- changes in accounting standards, policies, guidance, interpretations, or principles;
- changes in our growth rates or our competitors’ growth rates;
- developments regarding our patents or proprietary rights or those of our competitors;
- our inability to raise additional capital as needed;
- concerns or allegations as to the safety or efficacy of our products;
- changes in financial markets or general economic conditions;
- sales of stock by us or members of our management team, our Board, our significant stockholders, or certain institutional stockholders; and
- changes in stock market analyst recommendations or earnings estimates regarding our stock, other comparable companies or our industry generally.

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

You could experience substantial dilution of your investment as a result of subsequent exercises of outstanding warrants and outstanding options issued as compensation for services performed by employees, directors, consultants, and others, warrants issued in past sales of our equity, future sales of our equity, or the grant of future equity-based awards. During 2017, we sold approximately 6.9 million shares of common stock in a rights offering and private placement with gross proceeds totaling approximately $22.5 million. During 2016, we sold approximately 0.9 million shares of common stock in private placements with gross proceeds totaling approximately $10.0 million. We did not complete any private placements during 2015. During 2014, we sold approximately 4.5 million shares of common stock in private placements with gross proceeds totaling approximately $52.0 million.

At our annual meeting of stockholders on May 9, 2018 (the “ 2018 Annual Meeting”), our stockholders approved an amendment to our Restated Certificate of Incorporation, as amended, to effect a reverse stock split our common stock, at a ratio ranging from one-for-five (1:5) to one-for-fifteen (1:15), with the final ratio to be determined by the Board. Immediately after the Annual Meeting, the Board approved a one-for-five (1:5) reverse stock split of the outstanding shares of our common stock. On May 10, 2018, we filed an amendment to our Restated Certificate of Incorporation, as amended, with the Secretary of State of the State of Delaware to effect the reverse stock split and reduce the authorized shares of our common stock from 200,000,000 shares to 40,000,000 shares.

As of December 31, 2018, an aggregate of 4,995,365 shares of common stock were reserved for issuance under our equity incentive plans, 1,623,018 of which were subject to options outstanding as of that date at a weighted-average exercise price of $6.54 per share. Of the 4,995,365 stock options and restricted stock units outstanding at December 31, 2018, 1,100,529 stock options were vested and exercisable. In addition, as of December 31, 2018, 1,933,000 shares of our common stock were subject to warrants at a weighted-average exercise price of $6.62 per share. To the extent that outstanding warrants or options are exercised, our existing stockholders could experience dilution. We rely heavily on equity awards to motivate current employees and to attract new employees. The grant of future equity awards by us to our employees and other service providers could further dilute our stockholders' interests in the Company.

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

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

Item 1B. Unresolved Staff Comments

None.

Item 2. Properties

As of December 31, 2018, we owned or leased a total of approximately 60,000 square feet of space worldwide. We lease our corporate headquarters and manufacturing facility, which consists of approximately 57,000 square feet in Irvine, California. Our lease expires on April 30, 2020. We also lease office space in India and Germany. For additional information, see Note 7 to the consolidated financial statements.

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

Item 3. Legal Proceedings

From time to time, we are involved in legal proceedings and regulatory proceedings arising out of our operations. We establish reserves for specific liabilities in connection with legal actions that we deem to be probable and estimable. The ability to predict the ultimate outcome of such matters involves judgments, estimates, and inherent uncertainties. The actual outcome of such matters could differ materially from management's estimates.

Intellectual Property Litigation

On April 24, 2012, CAO Group, Inc. ("CAO") filed a lawsuit against BIOLASE in the District of Utah alleging that BIOLASE's ezlase dental laser infringes on U.S. Patent No. 7,485,116 (the "116 Patent"). On September 9, 2012, CAO amended its complaint, adding claims for (1) business disparagement/injurious falsehood under common law and (2) unfair competition under 15 U.S.C. Section 1125(a). The additional claims stem from a press release that BIOLASE issued on April 30, 2012, which CAO claims contained false statements that are disparaging to CAO and its diode product. The amended complaint sought injunctive relief, treble damages, attorneys' fees, punitive damages, and interest. Until January 24, 2018, this lawsuit was stayed in connection with the USPTO proceedings relating to the 116 Patent, which proceedings ultimately culminated in a January 27, 2017 decision by the United States Court of Appeals for the Federal Circuit, affirming the findings of the Patent Trial and Appeal Board, which were generally favorable to the Company. On January 25, 2018, CAO moved for leave to file a second amended complaint to add certain claims,

which filing the Company is not opposing. The Utah matter has since been transferred to the Central District of California and the two matters have been consolidated with the matter described below.

On January 23, 2018, CAO filed a lawsuit against BIOLASE in the Central District of California alleging that BIOLASE's diode lasers infringe on U.S. Patent Nos. 8,337,097, 8,834,497, 8,961,040 and 8,967,883. The complaint seeks injunctive relief, treble damages, attorneys' fees, punitive damages, and interest.

On January 25, 2019, BIOLASE and CAO entered into a confidential settlement agreement, which provided that the lawsuits and claims therein were dismissed with prejudice with each party to bear its own costs and attorneys' fees. See Notes 7 and 11 to the consolidated financial statements for additional information.

Item 4. Mine Safety Disclosures

Not applicable.

PART II

Item 5. Market for the Registrant's Common Equity, Related Stockholder Matters, and Issuer Purchases of Equity Securities

Market Information

Our common stock is traded on the NASDAQ Capital Market under the symbol "BIOL."

As of March 5, 2019, the closing price of our common stock on the NASDAQ Capital Market was $2.51 per share, and the number of stockholders of record was 149. We believe that the number of beneficial owners is substantially greater than the number of record holders because a large portion of our stock is held of record through brokerage firms in "street name."

Dividend Policy

We intend to retain our available funds from earnings and other sources for future growth and, therefore, do not anticipate paying any cash dividends in the foreseeable future. Additionally, we are prohibited from declaring and paying dividends under our Credit Agreement with SWK. As a result, we do not anticipate paying any stock dividends in 2019. Our dividend policy may be changed at any time, and from time to time, by our Board. We did not pay or declare any dividends in 2016, 2017, or 2018.

Equity Compensation Plan Information

At our 2018 Annual Meeting of stockholders on May 9, 2018, the Company's stockholders approved the BIOLASE, Inc. 2018 Long-Term Incentive Plan (the "2018 Plan"). The purposes of the 2018 Plan are (i) to align the interests of the Company's stockholders and recipients of awards under the 2018 Plan by increasing the proprietary interest of such recipients in the Company's growth and success; (ii) to advance the interests of the Company by attracting and retaining non-employee directors, officers, other employees, consultants, independent contractors and agents; and (iii) to motivate such persons to act in the long-term best interests of the Company and its stockholders. The 2018 Plan replaced the BIOLASE, Inc. 2002 Stock Incentive Plan, (as amended, the "2002 Plan"), with respect to future awards.

The 2002 Plan and the 2018 Plan are designed to attract and retain the services of individuals essential to the Company's long-term growth and success. The following table summarizes information as of December 31, 2018 with respect to the shares of our common stock that may be issued upon exercise of options, warrants or rights under the 2002 Plan and the 2018 Plan.

Plan Category	Number of Securities to be Issued Upon Exercise of Outstanding Options and release of	Weighted Average Exercise Price of Outstanding Options	Number of Securities Remaining Available for Future Issuance Under Equity Compensation Plans (excluding

	Restricted Stock Units		securities reflected in column)*
Equity Compensation Plan Approved by Stockholders	3,600,065	$ 6.54	1,395,300
Equity Compensation Plan Not Approved by Stockholders	—	—	—
Total	3,600,065	$ 6.54	1,395,300

Item 6. Selected Financial Data

As a smaller reporting company, the Company is not required to provide the information called for under this Item.

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

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

Overview

We are a medical device company that develops, manufactures, markets, and sells laser systems in dentistry and medicine and also markets, sells, and distributes dental imaging equipment, including 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 over 8,900 Waterlase MD, MDX, Express and iPlus systems.

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.

Effective October 8, 2018, the Board elected Elaine Wagner to the Board. Dr. Wagner is a retired United States Navy Rear Admiral with 33 years of service. Dr. Wagner most recently served as 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 Norbe as our President and Chief Executive Officer. Mr. Norbe has more than 25 years of experience as a senior executive with companies within the dental industry. John 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. 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 with the resignation of Harold 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 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.

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.

On March 6, 2018, BIOLASE and two of its wholly-owned subsidiaries (such subsidiaries, together with BIOLASE, the "Borrower") entered into a Business Financing Agreement (the "Business Financing Agreement") with Western Alliance Bank ("Western Alliance"), which provided for borrowings of up to $6.0 million. On August 13, 2018, the Borrower and Western Alliance entered into a Business Financing Modification Agreement, pursuant to which Western Alliance waived the Borrower's covenant defaults and provided an advance of $1.5 million, which advance was due by September 27, 2018. In connection with the execution of the Business Financing Agreement, we issued to Western Alliance warrants. See Notes 6 and 8 to the consolidated financial statements for additional information.

On September 27, 2018, the Borrower and Western Alliance entered into a second Business Financing Modification Agreement which reduced the credit limit under the Business Financing Agreement to $2.5 million and extended the due date of the $1.5 million advance to March 6, 2019.

On October 22, 2018, the Borrower and Western Alliance entered into a third Business Financing Modification Agreement, pursuant to which Western Alliance waived BIOLASE's non-compliance with certain financial operating covenants as set forth in the Business Financing Agreement, and the Borrower agreed to certain amended covenants contained in the Business Financing Agreement, including $300,000 minimum unrestricted cash balance covenant and a waiver of reporting items required to be delivered by BIOLASE to Western Alliance under the Business Financing Agreement.

On November 9, 2018, BIOLASE entered into a five-year secured Credit Agreement with SWK Funding LLC ("SWK"), pursuant to which BIOLASE has borrowed $12.5 million (the "SWK Loan"). BIOLASE's 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 LIBOR plus 10%. Approximately, $0.9 million of the proceeds from the SWK Loan were used to repay all amounts owed to Western Alliance under the Business Financing Agreement, 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 its products to drive recurring higher margin consumables revenue.

On November 9, the Business Financing Agreement, as amended on October 22, 2018, was replaced by the Credit Agreement. All outstanding borrowings, accrued interest and fees were paid off with a portion of the proceeds under the Credit Agreement, and the Business Financing Agreement was terminated.

In summary, 2018 was a year of continued transformation for us, positioning ourselves to further execute on our strategic goals of returning BIOLASE to a successful growing company and continuing as the clear worldwide industry leader in the dental laser segment. Although we have made improvements throughout the year, it will take time for the financial statements to reflect the changes and as such, for the three years ended December 31, 2018 we have reported recurring losses from operations and have not generated cash from operations. Our level of cash used in operations, the potential need for additional capital, and the uncertainties surrounding our ability to raise additional capital, raise substantial doubt about our ability to continue as a going concern. As a result, the opinion we have received from our independent registered public accounting firm, on our consolidated financial statements, contains an explanatory paragraph stating that there is a substantial doubt regarding our ability to continue as a going concern.

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

Critical Accounting Policies

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

Revenue Recognition

Revenue for sales of products and services is derived from contracts with customers. The products and services promised in contracts include delivery of laser systems, imaging systems, and consumables as well as certain ancillary services such as product training and support for extended warranties. Contracts with each customer generally state the terms of the sale, including the description, quantity and price of each product or service. Payment terms are stated in the contract and vary according to the arrangement. Because the customer typically agrees to a stated rate and price in the contract that does not vary over the life of the contract, our contracts do not contain variable consideration. We establish a provision for estimated warranty expenses. For further information on warranty, see Warranty Cost discussion below.

At contract inception, we assess the products and services promised in our contracts with customers. We then identify performance obligations to transfer distinct products or services to the customers. In order to identify performance obligations, we consider all of the products or services promised in the contract regardless of whether they are explicitly stated or are implied by customary business practices.

Revenue from products and services transferred to customers at a single point in time accounted for 86%, 85% and 86% of net revenue for the years ended December 31, 2018, 2017, and 2016, respectively. The majority of the revenue recognized at a point in time is for the sale laser systems, imaging systems, and consumables. Revenue from these contracts is recognized when the customer is able to direct the use of and obtain substantially all of the benefits from the product which generally coincides with title transfer during the shipping process.

Revenue from services transferred to customers over time accounted for 14%, 15%, and 14% of net revenue for the years ended December 31, 2018, 2017, and 2016, respectively. The majority of our revenue that is recognized over time relates to training and extended warranties.

The transaction price for a contract is allocated to each distinct performance obligation and recognized as revenue when, or as, each performance obligation is satisfied. For contracts with multiple performance obligations, we allocate the contract's transaction price to each performance obligation using the best estimate of the standalone selling price of each distinct good or service in a contract. The primary method used to estimate standalone selling price is the observable price when the good or service is sold separately in similar circumstances and to similar customers.

Revenue is recorded for extended warranty over time as the customer benefits from the warranty coverage. This revenue will be recognized equally throughout the contract period as the customer receives benefits from our promise to provide such services. Revenue is recorded for training as the customer attends a training program or upon the expiration of the obligation.

We also have contracts that include both the product sales and product training as performance obligations. In those cases, we record revenue for product sales at the point in time when the product has been shipped. The customer obtains control of the product when it is shipped, as all shipments are made FOB shipping point, and after the customer selects its shipping method and pays all shipping costs and insurance. We have concluded that control is transferred to the customer upon shipment.

We perform our obligations under a contract with a customer by transferring products and/or services in exchange for consideration from the customer. We invoice our customers as soon as control of an asset is transferred and a receivable due to us is established. We recognize a contract liability when a customer prepays for goods and/or services and we have not transferred control of the goods and/or services.

Accounts receivable are stated at estimated net realizable value. The allowance for doubtful accounts is based on an analysis of customer accounts and our historical experience with accounts receivable write-offs.

Accounting for Stock-Based Payments. Stock-based compensation expense is estimated at the grant date of the award, is based on the fair value of the award and is recognized ratably over the requisite service period of the award. For restricted stock units we estimate the fair value of the award based on the number of awards and the fair value of our common stock on the grant date and apply an estimated forfeiture rate. For stock options, we estimate the fair value of the option award using the Black-Scholes option pricing model. This option-pricing model requires us to make several assumptions regarding the key variables used to calculate the fair value of its stock options. The risk-free interest rate used is based on the U.S. Treasury yield curve in effect for the expected lives of the options at their grant dates. Since July 1, 2005, we have used a dividend yield of zero, as we do not intend to pay cash dividends on our common stock in the foreseeable future. The most critical assumptions used in calculating the fair value of stock options is the expected life of the option and the expected volatility of our common stock. The expected life is calculated in accordance with the simplified method, whereby for service-based awards, the expected life is calculated

as a midpoint between the vesting date and expiration date. We use the simplified method, as there is not a sufficient history of share option exercises. For performance-based awards, the expected life equals the life of the award. We believe the historic volatility of our common stock is a reliable indicator of future volatility, and accordingly, a stock volatility factor based on the historical volatility of our common stock over a lookback period of the expected life is used in approximating the estimated volatility of new stock options. Compensation expense is recognized using the straight-line method for all service-based employee awards and graded amortization for all performance-based awards. Compensation expense is recognized only for those options expected to vest, with forfeitures estimated at the date of grant based on historical experience and future expectations. Forfeitures are estimated at the time of the grant and revised in subsequent periods as actual forfeitures differ from those estimates. During the year ended December 31, 2018, we applied a forfeiture rate of 7.28% and 45.31% to awards granted to executives and employees, respectively,

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

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

Valuation of Goodwill and Other Intangible Assets. Goodwill and other intangible assets with indefinite lives are not subject to amortization but are evaluated for impairment annually or whenever events or changes in circumstances indicate that the asset might be impaired. We conducted our annual impairment analysis of our goodwill as of June 30, 2018 and concluded there had been no impairment in goodwill. We closely monitor our stock price and market capitalization and perform such analysis when events or circumstances indicate that there may have been a change to the carrying value of those assets.

Warranty Cost. We provide warranties against defects in materials and workmanship of our laser systems for specified periods of time. For the years ended December 31, 2018, 2017, and 2016 laser systems sold were covered by our warranty for a period of up to two years from the date of sale by us or the distributor to the end-user. In 2017, for Waterlase systems sold domestically and purchased in 2017 or later, we decreased the warranty period from two years to one year. Laser systems sold internationally were covered by our warranty for a period of up to 28 months from the date of sale to the international distributor. Estimated warranty expenses are recorded as an accrued liability with a corresponding provision to cost of revenue. This estimate is recognized concurrent with the recognition of revenue on the sale to the distributor or end-user. Warranty expenses expected to be incurred after one year from the time of sale to the distributor are classified as a long-term warranty accrual. Our overall accrual is based on our historical experience and our expectation of future conditions, taking into consideration the location and type of customer and the type of laser, which directly correlate to the materials and components under warranty, the duration of the warranty period, and the logistical costs to service the warranty. Additional factors that may impact our warranty accrual include changes in the quality of materials, leadership and training of the production and services departments, knowledge of the lasers and workmanship, training of customers, and adherence to the warranty policies. Additionally, an increase in warranty claims or in the costs associated with servicing those claims would likely result in an increase in the accrual and a decrease in gross profit. We offer extended warranties on certain imaging products. However, all imaging products are initially covered by the manufacturer's warranties.

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

Income Taxes. Based upon our operating losses during 2018, 2017, and 2016 and the available evidence, management has determined that it is more likely than not that the deferred tax assets as of December 31, 2018 will

not be realized in the near term. Consequently, we have established a valuation allowance against our net deferred tax asset totaling approximately $46.9 million and $40.8 million as of December 31, 2018 and 2017, respectively. In this determination, we considered factors such as our earnings history, future projected earnings, and tax planning strategies. If sufficient evidence of our ability to generate sufficient future taxable income tax benefits becomes apparent, we may reduce our valuation allowance, resulting in tax benefits in our statement of operations and in additional paid-in-capital. Management evaluates the potential realization of our deferred tax assets and assesses the need for reducing the valuation allowance periodically.

Fair Value of Financial Instruments

Our financial instruments, consisting of cash and cash equivalents, accounts receivable, accounts payable, capital lease obligations and accrued liabilities, approximate fair value because of the liquid or short-term nature of these items.

Fair value is defined as the price that would be received to sell an asset or paid to transfer a liability in an orderly transaction between market participants in the principal market (or, if none exists, the most advantageous market) for the specific asset or liability at the measurement date (referred to as the "exit price"). The fair value is based on assumptions that market participants would use, including a consideration of non-performance risk. Under the accounting guidance for value hierarchy, there are three levels of measurement inputs. Level 1 inputs are quoted prices in active markets for identical assets or liabilities. Level 2 inputs are observable, either directly or indirectly. Level 3 inputs are unobservable due to little or no corroborating market data.

Results of Operations

The following table sets forth certain data from our operating results for each of the years ended December 31, 2018, 2017, and 2016, expressed in thousands and as percentages of revenue:

	Years Ended December 31,					
	2018		2017		2016	
Products and services revenue	$46,143	100.0 %	$46,798	99.7 %	$51,661	99.7 %
License fees and royalty revenue	12	— %	128	0.3 %	149	0.3 %
Net revenue	46,155	100.0 %	46,926	100.0 %	51,810	100.0 %
Cost of revenue	29,260	63.4 %	31,800	67.8 %	31,502	60.8 %
Gross profit	16,895	36.6 %	15,126	32.2 %	20,308	39.2 %
Operating expenses:						
Sales and marketing	18,121	39.3 %	16,718	35.6 %	17,018	32.8 %
General and administrative	11,771	25.5 %	9,712	20.7 %	10,453	20.2 %
Engineering and development	5,203	11.3 %	6,229	13.3 %	7,799	15.1 %
Disposal of internally developed software	1,185	2.6 %	505	1.1 %	—	— %
Loss on patent litigation settlement	1,500	3.2 %	—	— %	—	— %
Total operating expenses	37,780	81.9 %	33,164	70.7 %	35,270	68.1 %
Loss from operations	(20,885)	(45.2)%	(18,038)	(38.5)%	(14,962)	(28.9)%
Non-operating (loss) gain, net	(568)	(1.2)%	605	1.3 %	(258)	(0.5)%
Loss before income tax provision	(21,453)	(46.5)%	(17,433)	(37.2)%	(15,220)	(29.4)%
Income tax provision (benefit)	63	0.1 %	(582)	(1.2)%	151	0.3 %
Net loss	$(21,516)	(46.6)%	$(16,851)	(36.0)%	$(15,371)	(29.7)%

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	100.0	%

Non-GAAP Disclosure

In addition to the financial information prepared in conformity with GAAP, we provide certain historical non-GAAP financial information. Management believes that these non-GAAP financial measures assist investors in making comparisons of period-to-period operating results and that, in some respects, these non-GAAP financial measures are more indicative of our ongoing core operating performance than their GAAP equivalents.

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

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

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

	Years Ended December 31,		
	2018	2017	2016
GAAP net loss attributable to common stockholders	$(21,516)	$(20,829)	$(17,555)
Deemed dividend on convertible preferred stock	—	3,978	2,184
GAAP net loss	$(21,516)	$(16,851)	$(15,371)
Adjustments:			
Interest expense (income), net	510	(42)	(74)
Income tax provision (benefit)	63	(582)	151
Depreciation and amortization	945	1,203	1,048
Disposal of internally developed software	1,185	505	—
Loss on patent litigation settlement	1,500	—	—
Stock-based and other non-cash compensation	2,768	2,207	3,065
Non-GAAP net loss	$(14,545)	$(13,560)	$(11,181)

Comparison of Results of Operations

Year Ended December 31, 2018 Compared with Year Ended December 31, 2017

Net Revenue. Net revenue for the year ended December 31, 2018 ("Fiscal 2018") was $46.2 million, a decrease of $0.8 million, or 2%, as compared with net revenue of $46.9 million for the year ended December 31, 2017 ("Fiscal 2017"). Domestic revenues were $28.7 million, or 62% of net revenue, for Fiscal 2018 compared to $29.3 million, or 62% of net revenue, for Fiscal 2017. International revenues for Fiscal 2018 were $17.5 million, or 38% of net revenue, compared to $17.6 million, or 38% of net revenue for Fiscal 2017.

The decrease in year-over-year net revenue resulted from decreases in worldwide imaging systems, services, and royalty revenue and was partially offset by increases of 2% and 13% in worldwide laser system and consumables and other revenue, respectively.

Laser system net revenues increased by approximately $0.6 million, or 2%, in Fiscal 2018 compared to Fiscal 2017. The laser systems revenue increase was driven by a 7% increase in domestic revenue which was partially offset by 3% decline in international revenue. The increase in domestic laser revenues is primarily due to our increased sales efforts in our model markets as well as the rest of the U.S.

Imaging system net revenue decreased by approximately $2.0 million, or 54%, in Fiscal 2018 compared to Fiscal 2017. This decrease was primarily driven by a one-time study club purchase in 2017 and our renewed focus on laser sales in 2018.

Consumables and other net revenue, which includes products such as disposable tips and shipping revenue, increased approximately $1.0 million, or 13%, in Fiscal 2018, as compared to Fiscal 2017. The increase in consumables and other net revenue was primarily driven by an increase of approximately 12% in domestic sales, which is attributed to our growing laser customer base.

License fees and royalty revenue decreased by approximately $0.1 million or 91%, in Fiscal 2018 compared to Fiscal 2017 primarily due to winding down of the previously disclosed Fotona Proizvodnja Optoelektronskih Naprav D.D. and Fotona LLC intellectual property litigation (the “Fotona Litigation”).

Cost of Revenue. Cost of revenue decreased by $2.5 million, or approximately 8%, to $29.3 million, or 63% of net revenue in Fiscal 2018, compared to cost of revenue of $31.8 million, or 68% of net revenue, in Fiscal 2017. The decrease in cost of revenue in Fiscal 2018 as compared to Fiscal 2017 is primarily due to product mix. In Fiscal 2018, we sold fewer imaging systems which have lower profit margin leading to an overall decline in cost of revenue as a percentage of revenue from Fiscal 2017.

Gross Profit. Gross profit as a percentage of revenue typically fluctuates with product and regional mix, selling prices, product costs and revenue levels. Gross profit for Fiscal 2018 was $16.9 million, or 37% of net revenue, an increase of approximately $1.8 million, or 12%, as compared with gross profit of $15.1 million, or 32% of net revenue, for Fiscal 2017. The increase in gross profit reflects new customer growth and a favorable change in product mix with an increase in laser sales, which have higher average selling prices and higher profit margins than our other product offerings.

Operating Expenses. Operating expenses for Fiscal 2018 were $37.8 million, or 82% of net revenue, an increase of approximately $4.6 million, or 14%, as compared with $33.2 million, or 71% of net revenue, for Fiscal 2017. See the following expense categories for further explanations.

Sales and Marketing Expense. Sales and marketing expense for Fiscal 2018 increased by $1.4 million, or 8%, to $18.1 million, or 39% of net revenue, as compared with $16.7 million, or 36% of net revenue, during Fiscal 2017. The increase in Fiscal 2018 was primarily a result of increases in payroll and consulting-related expense of $0.7 million, advertising and marketing expense of $0.4 million, share-based compensation of $0.3 million and commissions of $0.1 million; the increases were partially offset by a decrease in convention related costs of $0.3 million. As we continue efforts to transform and drive revenue growth, we expect sales and marketing expense to decrease as a percentage of revenue in 2019 primarily due to our continued focus on targeted and cost-effective advertising campaigns and marketing events.

General and Administrative Expense. General and administrative expense for Fiscal 2018 increased by $2.0 million, or 21%, to $11.8 million, or 25% of net revenue, as compared with $9.7 million, or 21% of net revenue, for Fiscal 2017. The increase in general and administrative expense was primarily due to increases in patent and legal expense of $0.9 million, payroll and consulting-related expense of $0.5 million, provision for doubtful accounts of $0.4 million, and other general expenses of $0.2 million, while share-based compensation was consistent with Fiscal 2017. We expect general and administrative expenses to decrease as a percentage of revenue in 2019 primarily due to decreased legal expenses.

Engineering and Development Expense. Engineering and development expense for Fiscal 2018 decreased by $1.0 million, or 16%, to $5.2 million, or 11% of net revenue, as compared with $6.2 million, or 13% of net revenue, in Fiscal 2017. The decrease was primarily related to decreased payroll and consulting-related expense of $0.4 million and decreased supplies expense of $0.4 million. The decrease in payroll and consulting-related expense resulted primarily from decreased salaries and wages of $0.3 million. The decrease in supplies expense resulted primarily from decreased operating supplies of $0.3 million. We expect to continue our investment in engineering and development activity. However, our primary focus will be on our sales and marketing efforts. Therefore, we expect engineering and development expenses to a decrease as a percentage of revenue in 2019.

Disposal of internally developed software. In Fiscal 2018, we recognized a $1.2 million loss on disposal of internally developed software costs. During 2018, it was determined that capitalized website development costs were impaired due to the fact that further development of the tools would not be pursued. In Fiscal 2017, we recognized a $0.5 million loss on disposal of internally developed software resulting from our decision to stop implementation of a new

ERP system.

Loss on patent litigation settlement. In Fiscal 2018, we recognized a contingent loss of $1.5 million relating to the patent litigation claim with CAO. Under the Settlement Agreement, CAO agreed to dismiss with prejudice the previously-disclosed lawsuits filed by CAO against BIOLASE and grant BIOLASE 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 that were the subject of the litigation. BIOLASE agreed to pay $500,000 in cash and 500,000 restricted shares of our common stock, which will vest on December 31, 2021. If upon December 31, 2021, the fair value of the shares issued to CAO is less than $1 million, BIOLASE will pay the difference between the value of the stock on December 31, 2021 and $1 million in cash. We expect legal expenses to decrease in 2019 as a result of this settlement.

Non-Operating Income (Loss)

Gain (Loss) on Foreign Currency Transactions. We recognized a $0.1 million loss on foreign currency transactions for Fiscal 2018 compared to a $0.5 million gain for Fiscal 2017, due to exchange rate fluctuations primarily between the U.S. dollar and the Euro.

Interest Income (Expense), Net. Net interest expense increased by $0.6 million to $0.5 million in Fiscal 2018 compared to $0.1 million of net interest income in Fiscal 2017. The increase in interest expense was the result of $0.3 million in interest relating to the SWK Loan and interest expense of $0.2 million relating to the Business Financing Agreement with Western Alliance. We repaid the borrowings under the Business Financing Agreement in the fourth quarter of Fiscal 2018 with the proceeds from the SWK Loan. We expect interest expense to increase in 2019 as a result of having the SWK Loan outstanding for the full year.

Provision (benefit) for Income Taxes. Our provision for income taxes was $0.1 million for Fiscal 2018, an increase of $0.7 million as compared with our benefit for income taxes of $0.6 million in Fiscal 2017. The increase in our provision for 2018 is primarily due to the one-time impact of the Tax Cuts and Jobs Act of 2017 had upon adoption in Fiscal 2017.

Net Loss. For the reasons stated above, our net loss was $21.5 million for Fiscal 2018 compared to a net loss of $16.9 million for Fiscal 2017. The increase in net loss of approximately $4.7 million, or 28%, was primarily due to increased loss from operations of $2.8 million, including non-cash expenses consisting of the $1.5 million loss relating to the CAO patent infringement settlement and the $0.7 million increase in loss on disposal of internally developed software. Net loss for Fiscal 2018 also included increased legal expenses of $0.9 million and an increase in interest expense of $0.6 million, which were offset by decreases in engineering payroll and consulting expenses and supplies costs of $1.0 million.

Year Ended December 31, 2017 Compared with Year Ended December 31, 2016

Net Revenue. Net revenue for the year ended December 31, 2017 was $46.9 million, a decrease of $4.9 million, or 9%, as compared with net revenue of $51.8 million for the year ended December 31, 2016 (“Fiscal 2016”). Domestic revenues were $29.3 million, or 62% of net revenue, for Fiscal 2017 compared to $33.4 million, or 64% of net revenue, for Fiscal 2016. International revenues for Fiscal 2017 were $17.6 million, or 38% of net revenue, compared to $18.4 million, or 36% of net revenue for Fiscal 2016.

The decrease in year-over-year net revenue resulted from decreases in worldwide laser system revenue, international imaging systems revenue, international consumables and other revenue, international services revenue and domestic license fees and royalty revenue, partially offset by increases in domestic imaging systems revenue, domestic consumables and other revenue and domestic services revenue.

Laser system net revenues decreased by approximately $6.0 million, or 17%, in Fiscal 2017 compared to Fiscal 2016. The laser systems revenue decrease was driven by a 28% decline in domestic revenue and a 3% decline in international revenue.

Imaging system net revenue increased by approximately $0.6 million, or 20%, in Fiscal 2017 compared to Fiscal 2016. This increase was due to increased overall market interest in intra-oral scanning devices, and our favorable positioning as a distributor.

Consumables and other net revenue, which includes products such as disposable tips and shipping revenue, increased approximately $0.4 million, or 6%, in Fiscal 2017, as compared to Fiscal 2016. The increase in consumables and other net revenue was primarily a result of auxiliary sales to our growing laser customer base.

License fees and royalty revenue decreased by 14%, to approximately $0.1 million in Fiscal 2017 compared to Fiscal 2016. License fees and royalty revenues are associated with intellectual property related to our laser technologies. The decrease was primarily due to the Fotona Litigation from Fiscal 2015.

Cost of Revenue. Cost of revenue in Fiscal 2017 increased by $0.3 million, or 1%, to $31.8 million, or 68% of net revenue, compared with cost of revenue of $31.5 million, or 61% of net revenue, in Fiscal 2016.

Gross Profit. Gross profit as a percentage of revenue typically fluctuates with product and regional mix, selling prices, product costs and revenue levels. Gross profit for Fiscal 2017 was $15.1 million, or 32% of net revenue, a decrease of approximately $5.2 million, or 26%, as compared with gross profit of $20.3 million, or 39% of net revenue, for Fiscal 2016. The decrease in gross profit was mainly attributable to promotional introductory pricing of Waterlase Express, unabsorbed fixed costs due to lower revenue, and an increase in imaging revenue, which has lower product distribution margins than laser systems revenue.

Operating Expenses. Operating expenses for Fiscal 2017 were $33.2 million, or 71% of net revenue, a decrease of approximately $2.1 million, or 6%, as compared with $35.3 million, or 68% of net revenue, for Fiscal 2016. The year-over-year decrease in expense is primarily due to a $0.7 million decrease in commissions expenses and $0.8 million decrease in stock-based compensation expenses. See the following expense categories for further explanations.

Sales and Marketing Expense. Sales and marketing expenses for Fiscal 2017 decreased by $0.3 million, or 2%, to $16.7 million, or 36% of net revenue, as compared with $17.0 million, or 33% of net revenue, during Fiscal 2016. The decrease was primarily a result of decreased commissions of $0.7 million, partially offset by increased payroll and consulting-related expenses of $0.1 million, increased convention-related expenses of $0.1 million and increased travel and travel-related expenses of $0.2 million. The decrease in commissions was driven by decreased sales in Fiscal 2017 compared to Fiscal 2016. The increase in payroll and consulting-related expenses resulted primarily from increased incentive compensation of $0.3 million, partially offset by a decrease of $0.2 million in stock-based compensation due to fewer grants. In the first quarter of 2017, we participated in the International Dental Show in Cologne, Germany, which led to higher convention-related expenses and travel expenditures.

General and Administrative Expense. General and administrative expenses for Fiscal 2017 decreased by $0.7 million, or 7%, to $9.7 million, or 21% of net revenue, as compared with $10.5 million, or 20% of net revenue, for Fiscal 2016. The overall decrease to general and administrative expenses was primarily due to decreased payroll and consulting-related expenses of $0.8 million, and decreased patent and legal expenses of $0.3 million, partially offset by increased provision for doubtful accounts of $0.2 million and increased bank fees of $0.1 million. The decreased payroll and consulting-related expenses resulted primarily from decreased recruiting fees of $0.3 million and decreased stock-based compensation expense of $0.6 million due to the reassessment of certain performance-based equity awards, partially offset by an increase in salaries and wages of $0.1 million. The decrease in patent and legal expenses resulted from a decrease in legal and litigation fees in the normal course of business of $0.3 million.

Engineering and Development Expense. Engineering and development expenses for Fiscal 2017 decreased by $1.6 million, or 20%, to $6.3 million, or 13% of net revenue, as compared with $7.8 million, or 15% of net revenue, in Fiscal 2016. The decrease was primarily related to decreased payroll, consulting and temporary labor expenses of $0.9 million and decreased supplies expenses of $0.8 million. The decrease in payroll, consulting and temporary labor expenses resulted primarily from decreased consulting fees of $0.9 million. The decrease in supplies expenses resulted primarily from decreased operating supplies of $0.6 million.

Disposal of Internally Developed Software Expense. Disposal of internally developed software expense for Fiscal 2017 was $0.5 million. In 2013, we began our program to deploy a new global enterprise resource planning (“ERP”) system developed by SAP. After careful evaluation, we have concluded that this new ERP system does not fit into our current business model. Accordingly, we have stopped our global ERP deployment and disposed of all related assets.

Non-Operating Income (Loss)

Gain (Loss) on Foreign Currency Transactions. We recognized a $0.6 million gain on foreign currency transactions for Fiscal 2017 compared to a $0.3 million loss for Fiscal 2016, due to exchange rate fluctuations primarily between the U.S. dollar and the Euro.

Interest Income (Expense), Net. Interest income during Fiscal 2017 represented interest recognized from the discounted present value of the settlement in connection with the Fotona Litigation. Interest expense in Fiscal 2017 consisted of interest incurred on our capital lease obligations in connection with the lease of information technology equipment. Interest income, net comprised of approximately 0.1% of net revenue, for Fiscal 2017, which is consistent with interest income of 0.1% of net revenue for Fiscal 2016.

(Benefit) Provision for Income Taxes. Our benefit for income taxes was $0.6 million for Fiscal 2017, a change of $0.7 million, as compared with our provision of income taxes of $0.2 million in Fiscal 2016. The change is due to the

Tax Cuts and Jobs Act of 2017, which decreased the corporate tax rate from 34% to 21%.

Net Loss. For the reasons stated above, our net loss was $16.9 million for Fiscal 2017 compared to a net loss of $15.4 million for Fiscal 2016. The increase in net loss of approximately $1.5 million, or 10%, was primarily due to increased loss from operations of $3.1 million, including a non-cash expense related to the disposal of internally developed software of $0.5 million due to the decision to cancel future deployments of a new ERP system, partially offset by increased gain of foreign currency transactions of $0.9 million and a change in income tax benefit, net of $0.7 million.

Liquidity and Capital Resources

At December 31, 2018, we had approximately $8.4 million in cash and cash equivalents, including restricted cash equivalents. Management defines cash and cash equivalents as highly liquid deposits with original maturities of 90 days or less when purchased. The decrease in our cash and cash equivalents by $3.5 million from December 31, 2017 was primarily due to cash used in operating and investing activities of $14.2 million and $0.5 million, respectively, and the effect of exchange rates on cash of $0.1 million, partially offset by cash provided by financing activities of $11.2 million. The $14.2 million of net cash used in operating activities in 2018 was primarily driven by our net loss of $21.5 million during the year.

At December 31, 2018, we had approximately $17.3 million in working capital. Our principal sources of liquidity at December 31, 2018, consisted of approximately $8.4 million in cash, cash equivalents and restricted cash and $11.1 million of net accounts receivable.

We have reported recurring losses from operations and have not generated cash from operations for the three years ended December 31, 2018. Our level of cash used in operations, the potential need for additional capital, and the uncertainties surrounding our ability to raise additional capital, raise substantial doubt about our ability to continue as a going concern. The accompanying financial statements have been prepared on a going concern basis, which assumes that we will continue in operation for the next 12 months and will be able to realize our assets and discharge our liabilities and commitments in the normal course of business. The financial statements do not include any adjustments that might be necessary if we are unable to continue as a going concern.

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

On November 9, 2018, we entered into a five-year secured Credit Agreement with SWK, pursuant to which BIOLASE has borrowed $12.5 million. The 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 LIBOR plus 10%. Approximately $0.9 million of the proceeds from the SWK Loan were used to pay off all amounts owed to Western Alliance under the Business Financing Agreement, 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. We are in compliance with the debt covenants as of December 31, 2018. For further information regarding our debt financing, see Note 8 of the consolidated financial statements.

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

Concentration of Credit Risk

Financial instruments, which potentially expose us to a concentration of credit risk, consist principally of cash and cash equivalents, restricted cash, and trade accounts receivable. We maintain our cash and cash equivalents and

restricted cash with established commercial banks. At times, balances may exceed federally insured limits. To minimize the risk associated with trade accounts receivable, we perform ongoing credit evaluations of customers' financial condition and maintain relationships with our customers that allow us to monitor changes in business operations so we can respond as needed. We do not, generally, require customers to provide collateral before we sell them our products. However, we have required certain distributors to make prepayments for significant purchases of our products.

Receivables and Allowance for Doubtful Accounts

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

Consolidated Cash Flows

The following table summarizes our statements of cash flows for Fiscal 2018, Fiscal 2017, and Fiscal 2016 (in thousands):

	Years Ended December 31,		
	2018	2017	2016
Net cash (used in) provided by:			
Operating activities	$(14,147)	$(18,412)	$(10,596)
Investing activities	(522)	(747)	(1,414)
Financing activities	11,235	21,618	9,350
Effect of exchange rates on cash	(106)	262	(64)
Net change in cash and cash equivalents	$(3,540)	$2,721	$(2,724)

Fiscal 2018 Compared to Fiscal 2017

Cash used in operating activities for Fiscal 2018 decreased by $4.3 million compared to Fiscal 2017 and was primarily due an increase in net loss of $4.7 million, offset by an increase in adjustments to reconcile net loss to cash and cash equivalents of $3.5 million which included a $1.5 million loss related to the CAO patent litigation settlement, an increase in loss on disposal of internally developed software of $0.7 million, a $0.6 million increase in share-based compensation, and an increase of $0.7 million in deferred income taxes and a $0.5 million decrease in provision for inventory reserves. Additionally, net changes in operating assets and liabilities resulted in an increase of $5.4 million to operating cash flows in Fiscal 2018 driven primarily by $6.8 million change in accounts payable and accrued liabilities from Fiscal 2017 due to the timing of payments made in 2017 as compared to Fiscal 2018. Cash used in operating activities for Fiscal 2017 totaled $18.4 million and was primarily comprised of net loss of $16.9 million, adjustments to reconcile net loss to net cash and cash equivalents of $3.8 million and cash outflow from net changes in assets and liabilities of $5.4 million. The $5.4 million net decrease in our operating assets and liabilities was primarily due to a decrease in accounts payable and accrued liabilities of $5.0 million related to the timing of our payments.

Cash used in investing activities for Fiscal 2018 totaled $0.5 million compared to $0.7 million for Fiscal 2017. The $0.2 million decrease in net cash used in investing activities was due to our continued efforts to effectively manage resources and is in line with expectations. We expect capital expenditures for 2019 to be consistent with Fiscal 2018.

Cash provided by financing activities decreased by $10.4 million compared to Fiscal 2017 and was primarily due to the difference in the net proceeds from the SWK Loan in Fiscal 2018 as compared to the proceeds received from the proceeds from our rights offering in Fiscal 2017. See Notes 6 and 8 to the consolidated financial statements for more information.

The $0.1 million effect of exchange rate on cash for Fiscal 2018 was due to a recognized loss on foreign currency transactions, primarily the Euro currency conversion rates during Fiscal 2018.

Fiscal 2017 Compared to Fiscal 2016

The $7.8 million increase in net cash used in operating activities for Fiscal 2017 compared to Fiscal 2016 was primarily due to an increase in our net loss of $1.5 million, decreased stock-based compensation of $0.9 million and decreased accounts payable and accrued liabilities of $5.0 million. The increased net loss was primarily driven by an increase in loss from operations of $3.1 million, partially offset by a non-operating gain (loss), net of $0.9 million a change in income tax benefit, net of $0.7 million. Cash used in operating activities for Fiscal 2017 totaled $18.4

million and was primarily comprised of net loss of $16.9 million, adjustments to reconcile net loss to net cash and cash equivalents of $3.8 million and cash outflow from net changes in assets and liabilities of $5.4 million. The $5.4 million net decrease in our operating assets and liabilities was primarily due to a decrease in accounts payable and accrued liabilities of $5.0 million related to the timing of our payments.

Cash used in investing activities for Fiscal 2017 totaled $0.7 million compared to $1.4 million for Fiscal 2016. The $0.7 million decrease in net cash used in investing activities was due to a $0.7 million decrease in capital expenditures during Fiscal 2017 compared to Fiscal 2016. The period-over-period decrease was primarily due to capital expenditures for the implementation of a new enterprise resource planning system, which has been put on hold in 2017.

The $21.6 million increase in net cash provided by financing activities for Fiscal 2017 compared to Fiscal 2016 was primarily due to net proceeds from our rights offering in December 2017 and our equity offering in April 2017 totaling $21.6 million. See Note 8 to the consolidated financial statements for more information.

The $0.3 million effect of exchange rate on cash for Fiscal 2017 was due to a recognized gain on foreign currency transactions, primarily the Euro currency conversion rates during 2017.

Contractual Obligations

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

On November 9, 2018, we entered into the Credit Agreement with SWK, which provides us with the SWK Loan, a variable-rate term loan in the amount of $12.5 million. The SWK Loan bears interest at LIBOR plus 10% and is interest-only for the first two years of the five-year loan term, with the possibility of extending the interest-only period beyond two years. Principal repayments will begin in December 2020, and will be approximately $0.7 million per quarter until the loan matures in November 2023.

The following table presents our expected cash requirements for contractual obligations outstanding as of December 31, 2018, for the years ended as indicated below (in thousands):

	Less Than 1 Year	1 to 3 Years	3 to 5 Years	More Than 5 years	Total
Operating lease obligations	$802	$346	$—	$ —	$1,148
Purchase obligations	8,679	425	—	—	9,104
SWK Loan interest [1]	1,598	2,934	1,491	—	6,023
SWK Loan principal	—	3,500	9,000	—	12,500
Total	$11,079	$7,205	$10,491	$ —	$28,775

(1) estimated using LIBOR rates as at December 31, 2018

Purchase obligations relate to purchase orders with suppliers that we expect to complete primarily during the year ended December 31, 2018. In conformity with current GAAP, purchase obligations and operating lease obligations are not reported in the consolidated balance sheet as of December 31, 2018.

Recent Accounting Pronouncements

See Note 2 to the consolidated financial statements included in this in Part IV, Item 15 of this Annual Report on Form 10-K, which is incorporated herein by reference.

Off-Balance Sheet Arrangements

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

Item 8. Financial Statements

All financial statements required by this Item 8, including the report of the independent registered public accounting firm, are listed in Part IV, Item 15 of this Form 10-K, are set forth beginning on Page F-1 of this Form 10-K, and are hereby incorporated herein by reference.

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

None.

Item 9A. Controls and Procedures

Disclosure Controls and Procedures

Our management has evaluated, with the participation of our President and Chief Executive Officer and Chief Financial Officer, the effectiveness of the Company's disclosure controls and procedures (as defined in Rules 13a-15(e) and 15d-15(e) under the Exchange Act) as of the end of the period covered by this report. Based on that evaluation, our President and Chief Executive Officer and Chief Financial Officer have concluded that the Company's disclosure controls and procedures were effective as of December 31, 2018.

Management's Report on Internal Control over Financial Reporting

Our management is responsible for establishing and maintaining adequate internal control over financial reporting, as such term is defined in Rules 13a-15(f) and 15d-15(f) under the Exchange Act. Under the supervision and with the participation of our management, including our principal executive officer and principal financial officer, we conducted an evaluation of the effectiveness of our internal control over financial reporting based on the framework established by the Committee of Sponsoring Organizations of the Treadway Commission entitled "Internal Control — Integrated Framework (2013)" (the "COSO Framework"). Based on our evaluation under the COSO Framework, our management concluded that our internal control over financial reporting was effective as of December 31, 2018. Our internal control over financial reporting was not subject to attestation by our independent registered public accounting firm, as we are not an accelerated filer.

Changes in Internal Control over Financial Reporting

There have been no changes in our internal control over financial reporting that occurred during the Company's fiscal quarter ended December 31, 2018 that have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

Item 9B. Other Information

None.

PART III

Item 10. Directors, Executive Officers and Corporate Governance

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

The Biolase, Inc. Code of Business Conduct and Ethics applies to all of our employees, officers, and directors, including our President and Chief Executive Officer. The Code of Business Conduct can be found on our website at the following address: media.corporate-ir.net/media_files/nsd/blti/corpgov/CodeofConductandEthics.pdf.

Item 11. Executive Compensation

The information set forth under the captions “Executive Compensation” and “Director Compensation” in the Proxy Statement for the Annual Meeting of Stockholders to be filed with the SEC is incorporated by reference herein.

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

The information set forth under the caption “Security Ownership of Certain Beneficial Owners and Management” in the Proxy Statement for the Annual Meeting of Stockholders to be filed with the SEC and the information set forth under the caption “Equity Compensation Plan Information” in Item 5 of this Form 10-K are incorporated by reference herein.

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

The information set forth under the captions “Election of Directors” and “Certain Relationships and Related Transactions” in the Proxy Statement for the Annual Meeting of Stockholders to be filed with the SEC is incorporated by reference herein.

Item 14. Principal Accountant Fees and Services

The information set forth under the caption “Principal Accountant Fees and Services” in the Proxy Statement for the Annual Meeting of Stockholders to be filed with the SEC is incorporated by reference herein.

PART IV

Item 15. Exhibits and Financial Statement Schedules

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

(1) Financial Statements:

	Page
Report of Independent Registered Public Accounting Firm	F-2
Consolidated Balance Sheets as of December 31, 2018 and 2017	F-3
Consolidated Statements of Operations and Comprehensive Loss for the years ended December 31, 2018, 2017, and 2016	F-4
Consolidated Statements of Stockholders' Equity for the years ended December 31, 2018, 2017, and 2016	F-5
Consolidated Statements of Cash Flows for the years ended December 31, 2018, 2017, and 2016	F-6
Notes to Consolidated Financial Statements	F-7

(2) Financial Statement Schedule:

Schedule II — Consolidated Valuation and Qualifying Accounts and Reserves for the years ended December 31, 2018, 2017, and 2016 S-1

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

(3) Exhibits:

The exhibits filed as a part of this Annual Report on Form 10-K are listed in the accompanying Exhibit Index on page 58.

Item 16. Form 10-K Summary

None

BIOLASE, INC.

Index to Exhibits

			Incorporated by Reference			
Exhibit	Description	Filed Herewith	Form	Period Ending/Date of Report	Exhibit	Filing Date
3.1.1	Restated Certificate of Incorporation, including, (i) Certificate of Designations, Preferences and Rights of 6% Redeemable Cumulative Convertible Preferred Stock of the Registrant; (ii) Certificate of Designations, Preferences and Rights of Series A 6% Redeemable Cumulative Convertible Preferred Stock of the Registrant; (iii) Certificate of Correction Filed to Correct a Certain Error in the Certificate of Designation of the Registrant; and (iv) Certificate of Designations of Series B Junior Participating Cumulative Preferred Stock of the Registrant		S-1, Amendment No. 1	12/23/2005	3.1	12/23/2005
3.1.2	Amendment to Restated Certificate of Incorporation		8-K	05/10/2012	3.1	05/16/2012
3.1.3	Second Amendment to Restated Certificate of Incorporation		8-A/A	11/04/2014	3.1.3	11/04/2014
3.1.4	Third Amendment to Restated Certificate of Incorporation		S-3	07/21/2017	3.4	07/21/2017
3.1.5	Fourth Amendment to Restated Certificate of Incorporation		8-K	05/11/2018	3.1	05/11/2018
3.1.6	Certificate of Elimination of Series B Junior Participating Cumulative Preferred Stock		8-K	11/10/2015	3.1	11/12/2015
3.1.7	Certificate of Designations, Preferences and Rights of Series C Participating Convertible Preferred Stock		8-K	08/08/2016	3.1	08/08/2016
3.1.8	Certificate of Elimination of Series C Participating Convertible Preferred Stock		8-K	04/18/2017	3.1	04/20/2017
3.1.9	Certificate of Designations, Preferences and Rights of Series D Participating Convertible Preferred Stock		8-K	04/18/2017	3.2	04/20/2017

3.2	Seventh Amended and Restated Bylaws of the Registrant, adopted on October 8, 2018	8-K	08/08/2018	3.1	08/09/2018
4.1	Form of Warrant issued on November 7, 2014	8-K	11/03/2014	99.1	11/07/2014
4.2	Form of Warrant issued on August 8, 2016	8-K	08/01/2016	99.1	08/02/2016
4.3	Form of Warrant issued on April 18, 2017	DEF14A		D	05/19/2017
4.4	Warrant to Purchase Stock issued on March 6, 2018 to Western Alliance Bank	10-K	12/31/2017	4.4	03/14/2018
4.5	Warrant to Purchase Stock issued on September 27, 2018 to Western Alliance Bank	10-Q	09/30/2018	4.1	11/14/2018
4.6	Warrant to Purchase Stock issued on November 9 to SWK Funding, LLC	10-Q	09/30/2018	4.2	11/14/2018

			Incorporated by Reference			
Exhibit	Description	Filed Herewith	Form	Period Ending/Date of Report	Exhibit	Filing Date
4.7	Standstill Agreement, dated November 10, 2015, by and among the Registrant, Jack W. Schuler, Renate Schuler and the Schuler Family Foundation		8-K	11/10/2015	99.1	11/12/2015
4.8	Standstill Agreement, dated November 10, 2015, by and among the Registrant and Larry N. Feinberg, Oracle Partners, L.P., Oracle Institutional Partners, L.P., Oracle Ten Fund Master, L.P., Oracle Associates, LLC, and Oracle Investment Management, Inc.		8-K	11/10/2015	99.2	11/12/2015
4.9	Amendment to Standstill Agreement, dated August 1, 2016, by and among the Registrant, Jack W. Schuler, Renate Schuler and the Schuler Family Foundation		8-K	08/01/2016	99.2	08/02/2016
4.10	Amendment to Standstill Agreement, dated August 1, 2016, by and among the Registrant, Larry N. Feinberg, Oracle Partners, L.P., Oracle Institutional Partners, L.P., Oracle Ten Fund Master, L.P., Oracle Associates, LLC and Oracle Investment Management, Inc.		8-K	08/01/2016	99.3	08/02/2016
4.11	Amendment to Standstill Agreement, dated November 9, 2017, by and among the Registrant, Jack W. Schuler, Renate Schuler and the Schuler Family Foundation		8-K	11/09/2017	99.1	11/09/2017
4.12	Amendment to Standstill Agreement, dated November 9, 2017, by and among the Registrant, Larry N. Feinberg, Oracle Partners, L.P., Oracle Institutional Partners, L.P., Oracle Ten Fund Master, L.P., Oracle Associates, LLC and Oracle Investment Management, Inc.		8-K	11/09/2017	99.2	11/09/2017
10.1*	2002 Stock Incentive Plan, as amended		DEF 14A		A	04/07/2016
10.2*	Form of Stock Option Agreement under the 2002 Stock Incentive Plan		10-K	12/31/2004	10.26	07/19/2005
10.3*	Form of Option Award Notice for California Employees under the 2002 Stock Incentive Plan		10-Q	09/30/2015	10.2	11/06/2015
10.4*	Form of Option Award Notice for Non-California Employees under the 2002 Stock Incentive Plan		10-Q	09/30/2015	10.3	11/06/2015
10.5*	Form of Option Award Notice for Non-Employee Directors under the 2002 Stock Incentive Plan		10-Q	09/30/2015	10.4	11/06/2015

10.6*	Form of Restricted Stock Unit Award Notice for Non-Employee Directors under the 2002 Stock Incentive Plan	10-Q	09/30/2015	10.5	11/06/2015
10.7*	Form of Indemnification Agreement between the Registrant and its officers and directors	10-Q	09/30/2005	10.1	11/09/2005

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Exhibit	Description	Filed Herewith	Incorporated by Reference Form	Period Ending/Date of Report	Exhibit	Filing Date
10.8	Lease, dated January 10, 2006, by and between the Registrant and The Irvine Company LLC		8-K	01/10/2006	10.1	01/17/2006
10.9	Third Amendment to Lease, dated March 16, 2015, by and between the Registrant and The Irvine Company LLC		10-Q	03/31/2015	10.3	05/01/2015
10.10	Securities Purchase Agreement, dated August 1, 2016, among the Registrant and the investors listed on Schedule I thereto		8-K	08/01/2016	99.1	08/02/2016
10.11	Securities Purchase Agreement, dated April 11, 2017, among the Registrant and the investors listed on Schedule I thereto		8-K	04/11/2017	99.1	04/14/2017
10.12*	Employment Agreement, dated May 14, 2015, by and between the Registrant and Harold C. Flynn, Jr.		10-Q	06/30/2015	10.2	08/07/2015
10.13*	Inducement Restricted Stock Unit Award Agreement, dated July 14, 2015, by and between the Registrant and Harold C. Flynn, Jr.		8-K	07/12/2015	10.2	07/15/2015
10.14*	Acknowledgment Letter, dated November 22, 2016, by and between the Registrant and Harold C. Flynn, Jr.		10-K	12/31/2016	10.18	03/10/2017
10.15	Commitment Letter, dated September 26, 2017, between each of Oracle Partners, LP, Oracle Institutional Partners, LP and Oracle Ten Fund Master, LP and the Registrant		S-1	09/29/2017	10.23	09/29/2017
10.16	Commitment Letter, dated September 26, 2017, between each of Renate Schuler, Jack W. Schuler Living Trust and Schuler Family Foundation and the Registrant		S-1	09/29/2017	10.24	09/29/2017
10.17*	Form of Stock Option Agreement for inducement grants made to John R. Beaver on September 30, 2017		8-K	09/30/2017	10.1	10/03/2017
10.18	Business Financing Agreement, dated as of March 6, 2018, by and among the Registrant, Western Alliance Bank, BL Acquisition Corp. and BL Acquisition II Inc.		10-K	12/31/2017	10.26	03/14/2018
10.19	Export-Import Bank of the United States Working Capital Guarantee Program Borrower Agreement, dated as of March 6, 2018, by and between the Registrant in favor of the Export Import Bank of the United States and Western		10-K	12/31/2017	10.29	03/14/2018

	Alliance Bank				
10.20	Export-Import Bank of the United States Working Capital Guarantee Program Borrower Agreement, dated as of March 6, 2018, by and between BL Acquisition Corp. in favor of the Export Import Bank of the United States and Western Alliance Bank	10-K	12/31/2017	10.29	03/14/2018

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Exhibit	Description	Filed Herewith	Incorporated by Reference Form	Period Ending/Date of Report	Exhibit	Filing Date
10.21	Export-Import Bank of the United States Working Capital Guarantee Program Borrower Agreement, dated as of March 6, 2018, by and between BL Acquisition II Inc. in favor of the Export Import Bank of the United States and Western Alliance Bank		10-K	12/31/2017	10.29	03/14/2018
10.22	Waiver and Business Financing Modification Agreement (First Amendment to Business Financing Agreement), dated as of August 13, 2018, by and among the Registrant, Western Alliance Bank, BL Acquisition Corp., and BL Acquisition II, Inc.		10-Q	09/30/2018	10.3	11/14/2018
10.23	Business Financing Modification Agreement (Second Amendment to Business Financing Agreement), dated as of September 27, 2018, by and between Registrant, Western Alliance Bank, BL Acquisition Corp, and BL Acquisition II Inc.		10-Q	09/30/2018	10.4	11/14/2018
10.24	Business Financing Modification Agreement (Third Amendment to Business Financing Agreement), dated as of October 22, 2018, by and among the Registrant, Western Alliance Bank, BL Acquisition Corp., and BL Acquisition II, Inc.		10-Q	09/30/2018	10.5	11/14/2018
10.25	Credit Agreement dated as of November 9, 2018, by and between the Registrant and SWK Funding LLC		10-Q	09/30/2018	10.6	11/14/2018
10.26	Separation Agreement, dated April 30, 2018 by and between the Registrant and Harold C. Flynn, Jr.		8-K/A	04/10/2018	10.1	05/03/2018
10.27	Employment Agreement, dated August 7, 2018, by and between the Registrant and Todd Norbe		8-K	08/07/2018	10.1	08/08/2018
10.28	Confidential Settlement Agreement, dated January 25, 2019, by and between the Registrant and CAO Group, Inc.	X				
21.1	Subsidiaries of the Registrant	X				
23.1	Consent of Independent Registered Public Accounting Firm, BDO USA, LLP	X				
31.1		X				

	Certification of Chief Executive Officer pursuant to Rule 13a-14 and Rule 15d-14(a) of the Securities Exchange Act of 1934, as amended	
31.2	Certification of Chief Financial Officer pursuant to Rule 13a-14 and Rule 15d-14(a) of the Securities Exchange Act of 1934, as amended	X

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Exhibit	Description	Filed Herewith	Incorporated by Reference Form	Period Ending/Date of Report	Exhibit	Filing Date
32.1	Certification of Chief Executive Officer pursuant to 18 U.S.C. 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002	**				
32.2	Certification of Chief Financial Officer pursuant to 18 U.S.C. 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002	**				
101	The following financial information from the Company’s Annual Report on Form 10-K, for the year ended December 31, 2018, formatted in eXtensible Business Reporting Language: (i) Consolidated Balance Sheets, (ii) Consolidated Statements of Operations and Comprehensive Loss, (iii) Consolidated Statements of Stockholders’ Equity (Deficit), (iv) Consolidated Statements of Cash Flows, (v) Notes to Consolidated Financial Statements	X				

†Confidential treatment was granted for certain confidential portions of this exhibit pursuant to Rule 24b-2 under the Securities Exchange Act of 1934. In accordance with Rule 24b-2, these confidential portions were omitted from this exhibit and filed separately with the Securities and Exchange Commission.

*Management contract or compensatory plan or arrangement.

**Furnished herewith.

SIGNATURES

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

BIOLASE, INC.,

a Delaware Corporation
(registrant)

Dated: March 8, 2019 By: /s/ TODD A. NORBE
Todd A. Norbe
President and Chief Executive Officer

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

Signature	Title	Date
/s/ TODD A. NORBE Todd A. Norbe	President and Chief Executive Officer (Principal Executive Officer) and Director	March 8, 2019
/s/ JOHN R. BEAVER John R. Beaver	Executive Vice President and Chief Financial Officer (Principal Financial Officer and Principal Accounting Officer)	March 8, 2019
/s/ JESS ROPER Jess Roper	Director	March 8, 2019
/s/ DR. JONATHAN T. LORD Dr. Jonathan T. Lord	Director	March 8, 2019
/s/ DR. RICHARD B. LANMAN Dr. Richard B. Lanman	Director	March 8, 2019

		March 8, 2019
/s/ GARRETT SATO Garrett Sato	Director	
/s/ DR. ELAINE WAGNER Dr. Elaine Wager	Director	March 8, 2019

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BIOLASE, INC.

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Notes to Consolidated Financial Statements	F-7
SCHEDULE	
Schedule numbered in accordance with Rule 5.04 of Regulation S-X:	
II. Consolidated Valuation and Qualifying Accounts and Reserves for the years ended December 31, 2018, 2017 and 2016	S-1

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

Report of Independent Registered Public Accounting Firm

Shareholders and Board of Directors

BIOLASE, Inc.

Irvine, California

Opinion on the Consolidated Financial Statements

We have audited the accompanying consolidated balance sheets of BIOLASE, Inc. and subsidiaries (collectively, the "Company") as of December 31, 2018 and 2017, the related consolidated statements of operations and comprehensive loss, stockholders' equity, and cash flows for each of the three years in the period ended December 31, 2018, and the related notes and schedule listed in the index appearing under Item 15(a)(2) (collectively referred to as the "consolidated financial statements"). In our opinion, the consolidated financial statements present fairly, in all material respects, the financial position of the Company and subsidiaries at December 31, 2018 and 2017, and the results of their operations and their cash flows for each of the three years in the period ended December 31, 2018, in conformity with accounting principles generally accepted in the United States of America.

Going Concern Uncertainty

The accompanying consolidated financial statements have been prepared assuming that the Company will continue as a going concern. As discussed in Note 1 to the consolidated financial statements, the Company has suffered recurring losses from operations and has negative cash flows from operations for each of the three years in the period ended December 31, 2018. These factors, among others, raise substantial doubt about its ability to continue as a going concern. Management's plans in regard to these matters are also described in Note 1. The consolidated financial statements do not include any adjustments that might result from the outcome of this uncertainty.

Basis for Opinion

These consolidated financial statements are the responsibility of the Company's management. Our responsibility is to express an opinion on the Company's consolidated financial statements based on our audits. We are a public accounting firm registered with the Public Company Accounting Oversight Board (United States) ("PCAOB") and are required to be independent with respect to the Company in accordance with the U.S. federal securities laws and the applicable rules and regulations of the Securities and Exchange Commission and the PCAOB.

We conducted our audits in accordance with the standards of the PCAOB. Those standards require that we plan and perform the audit to obtain reasonable assurance about whether the consolidated financial statements are free of material misstatement, whether due to error or fraud. The Company is not required to have, nor were we engaged to perform, an audit of its internal control over financial reporting. As part of our audits, we are required to obtain an understanding of internal control over financial reporting but not for the purpose of expressing an opinion on the effectiveness of the Company's internal control over financial reporting. Accordingly, we express no such opinion.

Our audits included performing procedures to assess the risks of material misstatement of the consolidated financial statements, whether due to error or fraud, and performing procedures that respond to those risks. Such procedures included examining, on a test basis, evidence regarding the amounts and disclosures in the consolidated financial statements. Our audits also included evaluating the accounting principles used and significant estimates made by management, as well as evaluating the overall presentation of the consolidated financial statements. We believe that our audits provide a reasonable basis for our opinion.

/s/ BDO USA, LLP

We have served as the Company's auditor since 2005.

Costa Mesa, California

March 8, 2019

BIOLASE, INC.

CONSOLIDATED BALANCE SHEETS

(in thousands, except per share data)

	December 31,	
	2018	2017
ASSETS		
Current assets:		
Cash and cash equivalents	$8,044	$11,645
Restricted cash	312	251
Accounts receivable, less allowance of $850 and $802 in 2018 and 2017, respectively	11,112	10,124
Inventory	12,248	12,298
Prepaid expenses and other current assets	1,591	1,732
Total current assets	33,307	36,050
Property, plant, and equipment, net	1,975	3,674
Goodwill	2,926	2,926
Other assets	308	334
Total assets	$38,516	$42,984
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities:		
Accounts payable	$5,953	$5,109
Accrued liabilities	7,538	5,636
Deferred revenue	2,476	2,625
Total current liabilities	15,967	13,370
Deferred income taxes, net	77	104
Warranty accrual	447	70
Other liabilities	100	180
Term loan	10,836	—
Total liabilities	27,427	13,724
Commitments and contingencies —Note 6		
Stockholders' equity:		
Preferred stock, par value $0.001 per share; 1,000 shares authorized, 0 shares issued and outstanding as of December 31, 2018 and 2017, respectively	—	—
Common stock, par value $0.001 per share; 40,000 and 40,000 shares authorized, 21,072 and 20,468 shares issued and outstanding as of December 31, 2018 and 2017, respectively	21	20
Additional paid-in capital	228,430	224,992
Accumulated other comprehensive loss	(670)	(576)
Accumulated deficit	(216,692)	(195,176)
Total stockholders' equity	11,089	29,260

Total liabilities and stockholders' equity	$38,516	$42,984

See accompanying notes to consolidated financial statements.

BIOLASE, INC.

CONSOLIDATED STATEMENTS OF OPERATIONS AND COMPREHENSIVE LOSS

(in thousands, except per share data)

	Years Ended December 31,		
	2018	2017	2016
Products and services revenue	$46,143	$46,798	$51,661
License fees and royalty revenue	12	128	149
Net revenue	46,155	46,926	51,810
Cost of revenue	29,260	31,800	31,502
Gross profit	16,895	15,126	20,308
Operating expenses:			
Sales and marketing	18,121	16,718	17,018
General and administrative	11,771	9,712	10,453
Engineering and development	5,203	6,229	7,799
Disposal of internally developed software	1,185	505	—
Loss on patent litigation settlement	1,500	—	—
Total operating expenses	37,780	33,164	35,270
Loss from operations	(20,885)	(18,038)	(14,962)
(Loss) gain on foreign currency transactions	(58)	563	(332)
Interest (expense) income, net	(510)	42	74
Non-operating (loss) gain, net	(568)	605	(258)
Loss before income tax provision	(21,453)	(17,433)	(15,220)
Income tax provision (benefit)	63	(582)	151
Net loss	(21,516)	(16,851)	(15,371)
Other comprehensive income (loss) items:			
Foreign currency translation adjustments	(94)	300	(75)
Comprehensive loss	$(21,610)	$(16,551)	$(15,446)
Net loss	$(21,516)	$(16,851)	$(15,371)
Deemed dividend on convertible preferred stock	—	(3,978)	(2,184)
Net loss attributable to common stockholders	$(21,516)	$(20,829)	$(17,555)
Net loss per share attributable to common stockholders:			
Basic	$(1.05)	$(1.41)	$(1.45)
Diluted	$(1.05)	$(1.41)	$(1.45)
Shares used in the calculation of net loss per share:			
Basic	20,588	14,752	12,133
Diluted	20,588	14,752	12,133

See accompanying notes to consolidated financial statements.

BIOLASE, INC.

CONSOLIDATED STATEMENTS OF STOCKHOLDERS' EQUITY

(in thousands)

	Common Stock and Additional Paid-in Capital		Convertible Preferred Stock		Accumulated Other Comprehensive Loss	Accumulated Deficit	Total Stockholders' Equity
	Shares	Amount	Shares	Amount			
Balances, January 1, 2016	11,646	$ 188,680	—	$ —	$ (801)	$ (162,954)	$ 24,925
Exercise of stock options, net	—	1	—	—	—	—	1
Stock-based compensation	—	3,065	—	—	—	—	3,065
Issuance of stock from RSUs, net	98	—	—	—	—	—	—
Issuance of Series C participating convertible preferred stock and warrants, net of issuance cost of $480	—	1,092	88	8,428	—	—	1,092
Beneficial conversion feature of Series C participating convertible preferred stock	—	1,092	—	(1,092)	—	—	1,092
Deemed dividend related to beneficial conversion feature of Series C participating convertible preferred stock	—	(2,184)	—	2,184	—	—	(2,184)
Issuance of common stock upon conversion of Series C participating convertible preferred stock	1,769	9,520	(88)	(9,520)	—	—	9,520
Net loss	—	—	—	—	—	(15,371)	(15,371)
Foreign currency translation adjustment	—	—	—	—	(75)	—	(75)
Balances, December 31, 2016	13,513	201,266	—	—	(876)	(178,325)	22,065
Exercise of stock options, net	—	3	—	—	—	—	3

Stock-based compensation	—	2,145	—	—	—	—	2,145
Issuance of stock from RSUs, net	81	—	—	—	—	—	—
Issuance of Series D participating convertible preferred stock and warrants, net of issuance cost of $251	—	2,026	81	8,214	—	—	2,026
Beneficial conversion feature of Series D participating convertible preferred stock	—	1,952	—	(1,952)	—	—	1,952
Deemed dividend related to beneficial conversion feature of Series D participating convertible preferred stock	—	(3,978)	—	3,978	—	—	(3,978)
Issuance of common stock upon conversion of Series D participating convertible preferred stock	1,613	10,240	(81)	(10,240)	—	—	10,240
Issuance of stock from rights offering, net	5,261	11,358	—	—	—	—	11,358
Net loss	—	—	—	—	—	(16,851)	(16,851)
Foreign currency translation adjustment	—	—	—	—	300	—	300
Balances, December 31, 2017	20,468	225,012	—	—	(576)	(195,176)	29,260
Exercise of stock options, net	1	3	—	—	—	—	3
Fees for rights offering	—	(38)	—	—	—	—	(38)
Stock-based compensation	—	2,627	—	—	—	—	2,627
Issuance of stock from RSUs, net	603	—	—	—	—	—	—
Warrant issued in connection with debt instruments	—	847	—	—	—	—	847
Net loss	—	—	—	—	—	(21,516)	(21,516)
Foreign currency translation adjustment	—	—	—	—	(94)	—	(94)
Balances, December 31, 2018	21,072	$ 228,451	—	$ —	$ (670)	$ (216,692)	$ 11,089

See accompanying notes to consolidated financial statements.

BIOLASE, INC.

CONSOLIDATED STATEMENTS OF CASH FLOWS

(in thousands)

	Years Ended December 31,		
	2018	2017	2016
Cash Flows From Operating Activities:			
Net loss	$(21,516)	$(16,851)	$(15,371)
Adjustments to reconcile net loss to net cash and cash equivalents used in operating activities:			
Depreciation and amortization	945	1,203	1,048
Loss (gain) on disposal of assets, net	1,228	505	(2)
Provision (recovery) for bad debts, net	469	40	(118)
Provision for inventory excess and obsolescence	166	623	272
Amortization of discount on debt	202	—	—
Amortization of debt issuance costs	126	—	—
Loss on patent litigation settlement	1,500	—	—
Stock-based compensation	2,768	2,207	3,065
Deferred income taxes	(27)	(694)	60
Earned interest income, net	1	(42)	(70)
Changes in operating assets and liabilities:			
Accounts receivable	(1,458)	(337)	(644)
Inventory	(127)	419	(1,989)
Prepaid expenses and other current assets	(25)	(11)	79
Accounts payable, accrued and other liabilities	1,762	(5,077)	3,338
Deferred revenue	(161)	(397)	(264)
Net cash and cash equivalents used in operating activities	(14,147)	(18,412)	(10,596)
Cash Flows From Investing Activities:			
Purchases of property, plant, and equipment	(558)	(747)	(1,414)
Proceeds from disposal of property, plant, and equipment	36	—	—
Net cash and cash equivalents used in investing activities	(522)	(747)	(1,414)
Cash Flows From Financing Activities:			
Principal payments under capital lease obligation	(46)	(146)	(171)
Borrowings under lines of credit	3,696	—	—
Payments under lines of credit	(3,696)	—	—
Proceeds from term loan	12,500	—	—
Payments of debt issuance costs	(1,058)	—	—
Proceeds from equity offerings, net of expenses	—	21,761	9,520
Payments of equity offering costs	(164)	—	—
Proceeds from exercise of stock options	3	3	1
Net cash and cash equivalents provided by financing activities	11,235	21,618	9,350
Effect of exchange rate changes	(106)	262	(64)
(Decrease) increase in cash and cash equivalents	(3,540)	2,721	(2,724)
Cash, cash equivalents and restricted cash, beginning of year	11,896	9,175	11,899

Cash, cash equivalents and restricted cash, end of year	$8,356	$11,896	$9,175
Supplemental cash flow disclosure - Cash Paid:			
Interest paid	$23	$1	$4
Interest received	$—	$74	$74
Income taxes paid	$44	$164	$76
Supplemental cash flow disclosure - Non-cash investing and financing activities			
Accrued capital expenditures and tenant improvement allowance	$31	$102	$251
Increase in accrued and other liabilities due to loss on patent litigation	$1,500	$—	$—
Warrants issued in connection with debt instruments	$847	$—	$—

See accompanying notes to consolidated financial statements.

BIOLASE, INC.

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

NOTE 1 — BASIS OF PRESENTATION

The Company

BIOLASE, Inc. (“BIOLASE” and, together with its consolidated subsidiaries, the “Company”) incorporated in Delaware in 1987, 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 three-dimensional CAD/CAM intra-oral scanners and digital dentistry software.

Use of Estimates

The preparation of these consolidated financial statements in conformity with generally accepted accounting principles in the United States of America (“GAAP”) requires the Company to make estimates and assumptions that affect amounts reported in the consolidated financial statements and the accompanying notes. Significant estimates in these consolidated financial statements include allowances on accounts receivable, inventory, and deferred taxes, as well as estimates for accrued warranty expenses, goodwill and the ability of goodwill to be realized, revenue deferrals, effects of stock-based compensation and warrants, contingent liabilities, and the provision or benefit for income taxes. Due to the inherent uncertainty involved in making estimates, actual results reported in future periods may differ materially from those estimates.

Reclassifications

The Company has reclassified certain immaterial amounts in prior years to conform to current year’s presentation.

Fair Value of Financial Instruments

Fair value is defined as the price that would be received to sell an asset or paid to transfer a liability in an orderly transaction between market participants in the principal market (or, if none exists, the most advantageous market) for the specific asset or liability at the measurement date (referred to as the “exit price”). The fair value is based on assumptions that market participants would use, including a consideration of non-performance risk. Under the accounting guidance for fair value hierarchy, there are three levels of measurement inputs. Level 1 inputs are quoted prices in active markets for identical assets or liabilities. Level 2 inputs are observable, either directly or indirectly. Level 3 inputs are unobservable due to little or no corroborating market data.

The Company’s financial instruments, consisting of cash, cash equivalents, restricted cash, accounts receivable, accounts payable, accrued liabilities, and SWK Loan, approximate fair value because of the liquid or short-term nature of these items.

Reverse Stock Split

At the Company’s annual meeting of stockholders on May 9, 2018 (the “2018 Annual Meeting”), the Company’s stockholders approved an amendment to its Restated Certificate of Incorporation to effect a reverse stock split of its common stock, at a ratio ranging from one-for-five to one-for-fifteen, with the final ratio to be determined by the Company’s board of directors (the “Board”). Immediately after the 2018 Annual Meeting, the Board approved a one-for-five (1:5) reverse stock split of the outstanding shares of the BIOLASE common stock. On May 10, 2018, the

Company filed an amendment (the “Fourth Amendment”) to its Restated Certificate of Incorporation with the Secretary of State of the State of Delaware to effect the reverse stock split and to reduce the authorized shares of common stock from 200,000,000 shares to 40,000,000 shares. Except as the context otherwise requires, all current and prior year share numbers (including common stock warrants) and share price amounts (including exercise prices and closing market prices) contained in these audited financial statements and notes thereto reflect the one-for-five reverse stock split. Additionally, in 2018 the Company recorded a reclassification of $0.1 million between common stock and additional paid-in capital, equal to the reduction in par value.

Concentration of Credit Risk, Interest Rate Risk and Foreign Currency Exchange Rate

Financial instruments which potentially expose the Company to a concentration of credit risk consist principally of cash and cash equivalents, restricted cash, and trade accounts receivable. The Company maintains its cash and cash equivalents and restricted cash with established commercial banks. At times, balances may exceed federally insured limits. To minimize the risk associated with trade accounts receivable, management performs ongoing credit evaluations of customers' financial condition and maintains relationships with the Company's customers that allow management to monitor current changes in business operations so the Company can respond as needed. The Company does not, generally, require customers to provide collateral before it sells them its products. However, the Company has required certain distributors to make prepayments for significant purchases of products.

Substantially all of the Company's revenue is denominated in U.S. dollars, including sales to international distributors. Only a small portion of its revenue and expenses is denominated in foreign currencies, principally the Euro and Indian Rupee. The Company's foreign currency expenditures primarily consist of the cost of maintaining offices, consulting services, and employee-related costs. During the years ended December 31, 2018, 2017, and 2016, the Company did not enter into any hedging contracts. Future fluctuations in the value of the U.S. dollar may affect the price competitiveness of the Company's products outside the U.S.

Liquidity and Management's Plans

The Company has reported losses from operations of $20.9 million, $18.0 million, and $15.0 million for the years ended December 31, 2018, 2017, and 2016, respectively, and has not generated cash from operations for the years ended December 31, 2018, 2017, and 2016. During the years ended December 31, 2017 and 2016, the principal sources of liquidity for the Company were its net proceeds from the December 5, 2017, April 18, 2017 and August 8, 2016 sales by the Company of $11.4 million, $10.2 million, and $9.5 million, respectively, of unregistered shares of the Company's equity securities. During the year ended December 31, 2018, the Company also received liquidity from the Credit Agreement (as defined and described in Note 6) with SWK Funding, LLC which provided borrowings of $12.5 million, and the Business Financing Agreement (as defined and described in Note 6) with Western Alliance Bank, which provided borrowings up to $6.0 million. The Company's recurring losses, level of cash used in operations, potential need for additional capital, and the uncertainties surrounding our ability to raise additional capital, raises substantial doubt about its ability to continue as a going concern. The financial statements do not include any adjustments that might be necessary if the Company is unable to continue as a going concern.

At December 31, 2018, the Company had approximately $17.3 million in working capital. The Company's principal sources of liquidity at December 31, 2018 consisted of approximately $8.4 million in cash, cash equivalents, and restricted cash, and $11.1 million of net accounts receivable.

In order for the Company to continue operations beyond the next 12 months and be able to discharge its liabilities and commitments in the normal course of business, the Company must increase sales of its products, control or potentially reduce expenses and establish profitable operations in order to generate cash from operations or obtain additional funds when needed.

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

NOTE 2 — SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES

Cash and Cash Equivalents

The Company considers all highly liquid investments with maturities of three months or less when purchased, as cash equivalents. Cash equivalents are carried at cost, which approximates fair market value.

Restricted Cash

Restricted cash represents $0.2 million relating to a revolving 90-day certificate of deposit maintained by the Company as collateral in connection with corporate credit cards and $0.1 million relating to its commercial credit card servicing agreement with Western Alliance Bank. At December 31, 2018 and 2017, the restricted cash balance was $0.3 million and $0.3 million, respectively.

The following table provides a reconciliation of cash, cash equivalents, and restricted cash reported in the consolidated balance sheets to the same total reported in the consolidated statements of cash flows (in thousands):

	For the years ended December 31,	
	2018	2017
Cash and cash equivalents	$ 8,044	$ 11,645
Restricted cash	312	251
Total cash, cash equivalents, and restricted cash in the consolidated statement of cash flows	$ 8,356	$ 11,896

Inventory

The Company values inventory at the lower of cost or net realizable value, with cost determined using the first-in, first-out method. The carrying value of inventory is evaluated periodically for excess quantities and obsolescence. Management evaluates quantities on hand, physical condition, and technical functionality as these characteristics may be impacted by anticipated customer demand for current products and new product introductions. The allowance is adjusted based on such evaluation, with a corresponding provision included in cost of revenue. Abnormal amounts of idle facility expenses, freight, handling costs and wasted material are recognized as current period charges, and the Company's allocation of fixed production overhead is based on the normal capacity of its production facilities.

Property, Plant, and Equipment

Property, plant, and equipment is stated at acquisition cost less accumulated depreciation. Maintenance and repairs are expensed as incurred. Upon sale or disposition of assets, any gain or loss is included in the consolidated statements of operations.

The cost of property, plant, and equipment is depreciated using the straight-line method over the following estimated useful lives of the respective assets, except for leasehold improvements, which are depreciated over the lesser of the estimated useful lives of the respective assets or the related lease terms.

Building	30 years
Leasehold improvements	3 to 5 years
Equipment and computers	3 to 5 years
Furniture and fixtures	5 years

Depreciation expense for the years ended December 31, 2018, 2017, and 2016 totaled approximately $0.9 million, $1.2 million and $1.0 million, respectively. The Company recognized losses on impairment of internally developed software of $1.2 million and $0.5 million during the years ended December 31, 2018 and December 31, 2017, respectively.

Goodwill and Other Intangible Assets

Goodwill is not subject to amortization but is evaluated for impairment annually or whenever events or changes in circumstances indicate that the asset might be impaired. The Company operates in one reporting segment and operating unit; therefore, goodwill is tested for impairment at the consolidated level against the fair value of the Company. The fair value of a reporting unit refers to the amount at which the unit as a whole could be bought or sold in a current transaction between willing parties. Quoted market prices in active markets are the best evidence of fair value and are used as the basis for measurement, if available. Management assesses potential impairment on an annual basis on June 30th and compares the Company's market capitalization to its carrying amount, including goodwill. A significant decrease in the Company's stock price could indicate a material impairment of goodwill which, after further analysis, could result in a material charge to operations. Inherent in the Company's fair value determinations are certain judgments and estimates, including projections of future cash flows, the discount rate reflecting the inherent risk in future cash flows, the interpretation of current economic indicators and market valuations, and strategic plans with regard to operations. A change in these underlying assumptions could cause a change in the results of the tests, which could cause the fair value of the reporting unit to be less than its respective carrying amount.

Costs incurred to acquire and successfully defend patents, and costs incurred to acquire trademarks and trade names are capitalized. Costs related to the internal development of technologies that are ultimately patented are expensed as incurred. Intangible assets, except those determined to have an indefinite life, are amortized using the straight-line method or over management's best estimate of the pattern of economic benefit over the estimated useful life of the assets. Intangible assets are reviewed for impairment whenever events or changes in circumstances indicate that the carrying amount of the asset may not be recoverable.

Long-Lived Assets

The carrying values of long-lived assets, including intangible assets subject to amortization, are reviewed when indicators of impairment, such as reductions in demand or significant economic slowdowns, are present. Reviews are performed to determine whether carrying value of an asset is impaired based on comparisons to undiscounted expected future cash flows. If this comparison indicates that there is impairment, the impaired asset is written down to fair value, which is typically calculated using discounted expected future cash flows. Impairment is based on the excess of the carrying amount over the fair value of those assets.

Other Comprehensive (Loss) Income

Other comprehensive (loss) income encompasses the change in equity from transactions and other events and circumstances from non-owner sources and is included as a component of stockholders' equity but is excluded from net (loss) income. Accumulated other comprehensive (loss) income is comprised of foreign currency translation adjustments.

Foreign Currency Translation and Transactions

Transactions of the Company's German, Spanish, Australian, and Indian subsidiaries are denominated in their local currencies which have been determined to be their functional currencies. The results of operations and cash flows are translated at average exchange rates during the period, and assets and liabilities are translated at end-of-period exchange rates. Translation gains or losses are shown as a component of accumulated other comprehensive (loss) income in stockholders' equity. Income and losses resulting from foreign currency transactions which are denominated in a currency other than the entity's functional currency, are included in the consolidated statements of operations.

Revenue Recognition

Contracts with Customers

Revenue for sales of products and services is derived from contracts with customers. The products and services promised in customer contracts include delivery of laser systems, imaging systems, and consumables as well as certain ancillary services such as training and extended warranties. Contracts with each customer generally state the terms of the sale, including the description, quantity and price of each product or service. Payment terms are stated in the contract and vary according to the arrangement. Because the customer typically agrees to a stated rate and price in the contract that does not vary over the life of the contract, the Company's contracts do not contain variable consideration. The Company establishes a provision for estimated warranty expense.

Performance Obligations

At contract inception, the Company assesses the products and services promised in its contracts with customers. The Company then identifies performance obligations to transfer distinct products or services to the customers. In order to identify performance obligations, the Company considers all of the products or services promised in contracts

regardless of whether they are explicitly stated or are implied by customary business practices.

Revenue from products and services transferred to customers at a single point in time accounted for 86%, 85%, and 86% of net revenue for the years ended December 31, 2018, 2017, and 2016, respectively. The majority of the Company’s revenue recognized at a point in time is for the sale laser systems, imaging systems, and consumables. Revenue from these contracts is recognized when the customer is able to direct the use of and obtain substantially all of the benefits from the product which generally coincides with title transfer during the shipping process.

Revenue from services transferred to customers over time accounted for 14%, 15%, and 14% of net revenue for the years ended December 31, 2018, 2017, and 2016, respectively. The majority of our revenue that is recognized over time relates to product training and extended warranties. Deferred revenue attributable to undelivered elements, which primarily consists of product training, totaled approximately $0.7 million and $1.0 million as of December 31, 2018 and 2017, respectively.

Transaction Price Allocation

The transaction price for a contract is allocated to each distinct performance obligation and recognized as revenue when, or as, each performance obligation is satisfied. For contracts with multiple performance obligations, the Company allocates the contract's transaction price to each performance obligation using the best estimate of the standalone selling price of each distinct good or service in a contract. The primary method used to estimate standalone selling price is the observable price when the good or service is sold separately in similar circumstances and to similar customers.

Significant Judgments

Revenue is recorded for extended warranties over time as the customer benefits from the warranty coverage. This revenue will be recognized equally throughout the contract period as the customer receives benefits from the Company's promise to provide such services. Revenue is recorded for product training as the customer attends a training program or upon the expiration of the obligation, which is generally after nine months.

The Company also has contracts that include both the product sales and product training as performance obligations. In those cases, the Company records revenue for product sales at the point in time when the product has been shipped. The customer obtains control of the product when it is shipped, as all shipments are made FOB shipping point, and after the customer selects its shipping method and pays all shipping costs and insurance. The Company has concluded that control is transferred to the customer upon shipment.

Accounts Receivable

Accounts receivable are stated at estimated net realizable value. The allowance for doubtful accounts is based on an analysis of customer accounts and the Company's historical experience with accounts receivable write-offs.

Contract Liabilities

The Company performs its obligations under a contract with a customer by transferring products and/or services in exchange for consideration from the customer. The Company typically invoices its customers as soon as control of an asset is transferred and a receivable for the Company is established. The Company, however, recognizes a contract liability when a customer prepays for goods and/or services and the Company has not transferred control of the goods and/or services. The opening and closing balances of the Company's contract liabilities are as follows (in thousands):

	December 31,	
	2018	2017
Undelivered elements (training, installation, product and support services)	$730	$980
Extended warranty contracts	1,735	1,634

Deferred royalties	11	22
Total deferred revenue	2,476	2,636
Less: long-term portion of deferred revenue	—	11
Deferred revenue – current	$2,476	$2,625

The balance of contract assets was immaterial as the Company did not have a significant amount of uninvoiced receivables in the years ended December 31, 2018 and 2017.

The amount of revenue recognized during the years ended December 31, 2018 that was included in the opening contract liability balance related to undelivered elements was $0.8 million, related to extended warranty contracts was $0.8 million and deferred royalties was $11,000.

Disaggregation of Revenue

The Company disaggregates revenue from contracts with customers into geographical regions and by the timing of when goods and services are transferred. The Company determined that disaggregating revenue into these categories depicts how the nature, amount, timing and uncertainty of revenue and cash flows are affected by regional economic factors.

The Company's revenues related to the following geographic areas were as follows (in thousands):

	Years Ended December 31,		
	2018	2017	2016
United States	$28,661	$29,296	$33,385
International	17,494	17,630	18,425
	$46,155	$46,926	$51,810

Information regarding revenues disaggregated by the timing of when goods and services are transferred is as follows (in thousands):

	For the Year Ended December 31,		
	2018	2017	2016
Revenue recognized over time	6,441	7,123	7,103
Revenue recognized at a point in time	$39,714	$39,803	$44,707
Total	$46,155	$46,926	$51,810

The Company's sales by end market is as follows (in thousands):

	For the Year Ended December 31,		
	2018	2017	2016
End-customer	$30,478	$31,886	$36,060
Distributors	15,677	15,040	15,750
	$46,155	$46,926	$51,810

Shipping and Handling Costs and Revenues

Shipping and freight costs are treated as fulfillment costs. For shipments to end-customers, the customer bears the shipping and freight costs and has control of the product upon shipment. For shipments to distributors, the distributor bears the shipping and freight costs, including insurance, tariffs and other import/export costs.

Provision for Warranty Expense

The Company provides warranties against defects in materials and workmanship of its laser systems for specified periods of time. For the years ended December 31, 2018 and 2017, laser systems sold were covered by the warranty

for a period of up to two years from the date of sale by the Company or the distributor to the end-user. In 2017, for Waterlase systems sold domestically and purchased in 2017 or later, the Company decreased the warranty period from two years to one year. Laser systems sold internationally were covered by the warranty for a period of up to 28 months from the date of sale to the international distributor. Estimated warranty expenses are recorded as an accrued liability with a corresponding provision to cost of revenue. This estimate is recognized concurrent with the recognition of revenue on the sale to the distributor or end-user. Warranty expenses expected to be incurred after one year from the time of sale to the distributor are classified as a long-term warranty accrual. The Company’s overall accrual is based on its historical experience and management’s expectation of future conditions, taking into consideration the location and type of customer and the type of laser, which directly correlate to the materials and components under warranty, the duration of the warranty period, and the logistical costs to service the warranty. Additional factors that may impact the Company’s warranty accrual include changes in the quality of materials, leadership and training of the production and services departments, knowledge of the lasers and workmanship, training of customers, and adherence to the warranty policies. Additionally, an increase in warranty claims or in the costs associated with servicing those claims would likely result in an increase in the accrual and a decrease in gross profit. All imaging products are initially covered by the manufacturer’s warranties. However, the Company offers extended warranties on certain imaging products.

Changes in the initial product warranty accrual and the expenses incurred under the Company's initial and extended warranties for the years ended December 31 are included within accrued liabilities on the Consolidated Balance Sheets and were as follows (in thousands):

	Years Ended December 31,		
	2018	2017	2016
Balance, January 1	$1,190	$1,706	$2,188
Provision for estimated warranty cost	901	492	348
Warranty expenditures	(783)	(1,008)	(830)
Balance, December 31	1,308	1,190	1,706
Less: long-term portion of warranty accrual	447	70	773
Current portion of warranty accrual	$861	$1,120	$933

Advertising Costs

Advertising costs are expensed as incurred and totaled approximately $0.6 million, $0.3 million and $0.4 million for the years ended December 31, 2018, 2017, and 2016, respectively.

Engineering and Development

Engineering and development expenses are generally expensed as incurred and consist of engineering personnel salaries and benefits, prototype supplies, contract services, and consulting fees related to product development.

Stock-Based Compensation

During the years ended December 31, 2018, 2017, and 2016, the Company recognized compensation cost related to stock options of $2.8 million, $2.2 million, and $3.1 million, respectively, based on the grant-date fair value. In 2018, $0.1 million of the total stock compensation cost related to performance-based awards was recognized as a liability. The following table summarizes the income statement classification of compensation expense associated with share-based payments (in thousands):

	Years Ended December 31,		
	2018	2017	2016
Cost of revenue	$420	$207	$226
Sales and marketing	535	235	477
General and administrative	1,440	1,469	2,051
Engineering and development	373	296	311
	$2,768	$2,207	$3,065

As of December 31, 2018 and 2017, the Company had $2.8 million and $3.4 million, respectively, of total unrecognized compensation cost, net of estimated forfeitures, related to unvested share-based compensation arrangements granted under its existing plans. The $2.8 million in cost is expected to be recognized over a weighted-average period of 2.0 years as of December 31, 2018.

Stock-based compensation expense is estimated at the grant date of the award, is based on the fair value of the award and is recognized ratably over the requisite service period of the award. For restricted stock units ("RSUs") the Company estimates the fair value of the award based on the number of awards and the fair value of BIOLASE common stock on the grant date, and applies an estimated forfeiture rate. For stock options, the Company estimates the fair value of the option award using the Black-Scholes option pricing model. This option-pricing model requires the Company to make several assumptions regarding the key variables used to calculate the fair value of its stock options. The risk-free interest rate used is based on the U.S. Treasury yield curve in effect for the expected lives of the options at their grant dates. Since July 1, 2005, the Company has used a dividend yield of zero, as it does not intend to pay cash dividends on its common stock in the foreseeable future. The most critical assumptions used in calculating the fair value of stock options is the expected life of the option and the expected volatility of the Company's common stock. The expected life is calculated in accordance with the simplified method, whereby for service-based awards the expected life is calculated as a midpoint between the vesting date and expiration date. The Company uses the simplified method, as there is not a sufficient history of share option exercises. For performance-based awards, the expected life equals the life of the award. Management believes that the historic volatility of the Company's common stock is a reliable indicator of future volatility, and accordingly, a stock volatility factor based on the historical volatility of the Company's common stock over a lookback period of the expected life is used in approximating the

estimated volatility of new stock options. Compensation expense is recognized using the straight-line method for all service-based employee awards and graded amortization for all performance-based awards. Compensation expense is recognized only for those options expected to vest, with forfeitures estimated at the date of grant based on historical experience and future expectations. Forfeitures are estimated at the time of the grant and revised in subsequent periods as actual forfeitures differ from those estimates. The Company applied a forfeiture rate of 7.28% and 45.31% to awards granted to executives and employees, respectively, during the year ended December 31, 2018.

The stock option fair values were estimated using the Black-Scholes option-pricing model with the following weighted-average assumptions:

	For the years ended December 31,		
	2018	2017	2016
Expected term (years)	5.87	5.51	5.96
Volatility	81 %	79 %	86 %
Annual dividend per share	$—	$—	$—
Risk-free interest rate	2.54%	1.99%	1.39%

Income Taxes

Differences between accounting for income taxes for financial statement purposes and accounting for tax return purposes are stated as deferred tax assets or deferred tax liabilities in the accompanying consolidated financial statements. The provision for income taxes represents the tax payable for the period and the change during the period in deferred tax assets and liabilities. The Company establishes a valuation allowance when it is more likely than not that the deferred tax assets will not be realized.

The income tax provisions for the years ended December 31, 2018, 2017, and 2016 were calculated using the discrete year-to-date method. See Note 5 for additional disclosures related to the Company’s income taxes.

Net Loss Per Share — Basic and Diluted

Basic net income (loss) per share is computed by dividing income (loss) available to common stockholders by the weighted-average number of common shares outstanding for the period. In computing diluted net income (loss) per share, the weighted average number of shares outstanding is adjusted to reflect the effect of potentially dilutive securities.

Outstanding stock options, restricted stock units and warrants to purchase approximately 5,862,000, 3,384,000, , and 4,107,000 shares were not included in the calculation of diluted loss per share amounts for the years ended December 31, 2018, 2017, and 2016, respectively, as their effect would have been anti-dilutive.

Recent Accounting Pronouncements

Changes to GAAP are established by the Financial Accounting Standards Board (“FASB”) in the form of accounting standards updates (“ASUs”) to the FASB’s Accounting Standards Codification (“ASC”).

The Company considers the applicability and impact of all ASUs. ASUs not listed below were assessed and determined not to be applicable or are expected to have minimal impact on the Company’s consolidated financial position and results of operations.

Adopted Accounting Standards

In May 2014, the FASB issued ASU No. 2014-09, Revenue from Contracts with Customers ("ASU 2014-09"). The core principle of ASU 2014-09 is to recognize revenues when promised goods or services are transferred to customers in an amount that reflects the consideration to which an entity expects to be entitled for those goods or services. The standard is effective for annual periods beginning after December 15, 2017, and interim periods therein.

ASU 2014-09 supersedes existing guidance on revenue recognition with a five-step model for recognizing and measuring revenue from contracts with customers. The objective of the new standard is to provide a single, comprehensive revenue recognition model for all contracts with customers to improve comparability within industries, across industries, and across capital markets. The underlying principle is that an entity will recognize revenue to depict the transfer of goods or services to customers at an amount that the entity expects to be entitled to in exchange for those goods or services. The guidance also requires a number of disclosures regarding the nature, amount, timing, and uncertainty of revenue and the related cash flows. The guidance can be applied retrospectively to each prior reporting period presented (full retrospective method) or retrospectively with a cumulative effect adjustment to retained earnings for initial application of the guidance at the date of initial adoption (modified retrospective method). The Company adopted the new standard effective January 1, 2018 using the modified retrospective method applied to those contracts that were not completed or substantially completed as of January 1, 2018. The timing and measurement of revenue recognition under the new standard is not materially different than under the old standard. The adoption of the new standard did not have an impact on the Company’s consolidated financial statements.

In August 2016, the FASB issued ASU 2016-15, Statement of Cash Flows (Topic 230) (“ASU 2016-15”). The updated standard addresses eight specific cash flow issues with the objective of reducing diversity in practice. ASU 2016-15 is effective for public business entities for annual reporting periods beginning after December 15, 2017, including interim periods within those annual reporting periods. Early adoption is permitted. The Company adopted ASU 2016-15 as of January 1, 2018. The adoption of ASU 2016-15 did not have an impact on the Company’s consolidated financial statements.

In November 2016, the FASB issued ASU 2016-18, Statement of Cash Flows (Topic 230) (“ASU 2016-18”). The updated standard requires that a statement of cash flows explain the change during the period in the total of cash, cash equivalents, and amounts generally described as restricted cash or restricted cash equivalents. Therefore, amounts generally described as restricted cash and restricted cash equivalents should be included with cash and cash equivalents when reconciling the beginning-of-period and end-of-period total amounts shown on the statement of cash flows. ASU 2016-18 is effective for public business entities for annual reporting periods beginning after December 15, 2017, including interim periods within those annual reporting periods. The Company adopted ASU 2016-18 as of January 1, 2018. The adoption of ASU 2016-18 did not have a material effect on the Company’s consolidated financial statements.

In May 2017, the FASB issued ASU 2017-09, Compensation – Stock Compensation (Topic 718) (“ASU 2017-09”). The updated standard clarifies when an entity must apply modification accounting to changes in the terms or conditions of a share-based payment award. ASU 2017-09 is effective for public business entities for annual reporting periods beginning after December 15, 2017, including interim periods within those annual reporting periods. Early adoption is permitted. The Company adopted ASU 2017-09 as of January 1, 2018. The adoption of ASU 2017-09 did not have a material effect on the Company’s consolidated financial statements.

In July 2017, FASB issued ASU 2017-11 (Part I) Accounting for Certain Financial Instruments with Down Round Features, (Part II) Replacement of the Indefinite Deferral for Mandatorily Redeemable Financial Instruments of Certain Nonpublic Entities and Certain Mandatorily Redeemable Noncontrolling Interests with a Scope Exception (“ASU 2017-11”). The new standard simplifies the accounting for certain financial instruments with down round features. Part I of ASU 2017-11 changes the classification analysis of certain equity-linked financial instruments, such as warrants and embedded conversion features, such that a down round feature is disregarded when assessing whether the instrument is indexed to an entity’s own stock under Subtopic 815-40, Contracts in Entity’s Own Equity. As a result, a down round feature, by itself, no longer requires an instrument to be remeasured at fair value through earnings each period, although all other aspects of the indexation guidance under Subtopic 815-40 continue to apply. Part II of ASU 2017-11 recharacterizes the indefinite deferral of certain provisions of Topic 480, Distinguishing Liabilities from Equity, (currently presented as pending content in the Codification) as a scope exception. In the fourth

quarter of 2018, the Company early-adopted ASU 2017-11 using the modified-retrospective method, which resulted in the reclassification of previously liability classified warrants of approximately $0.8 million to Additional Paid-In Capital and no cumulative effect adjustment to retained earnings. These warrants were issued in connection with the Company's debt financing activities in 2018. For further information on these warrants see Notes 6 and 8. The amendments in Part II have no accounting impact and therefore do not have an associated effective date.

Accounting Standards Not Yet Adopted

In February 2016, the FASB established ASU Topic 842 – Leases, by issuing ASU Topic No. 2016-02, which requires lessees to recognize lease on-balance sheet and disclose key information about leasing arrangements. Topic 842 was subsequently amended by ASU Topic 2018-11 – Targeted Improvements. The new standard establishes a right-of-use model ("ROU") that requires a lessee to recognize a ROU asset and a lease liability for all leases with a term longer than 12 months. Leases will be classified as finance or operating, with classification affecting the pattern and classification of expense recognition in the statement of operations. The new standard is effective for the Company on January 1, 2019, with early adoption permitted. The Company expects to adopt the new standard on its effective date. A modified retrospective transition method is required, applying the new standard to all leases existing

at the date of initial application. An entity may choose to use either (1) the effective date or (2) the beginning of the earliest comparative period presented in the financial statements as its date of initial application. If an entity chooses the second option, the transition requirements for existing leases also apply to leases entered into between the date of initial application and the effective date. The entity must also recast its comparative period financial statements and provide disclosures required by the new standard for the comparative periods. The Company expects to adopt the new standard on January 1, 2019 and use the effective date as the date of initial application. Consequently, financial information will not be updated and the disclosures required under the new standard will not be provided for dates and periods before January 1, 2019.

The new standard provides a number of optional practical expedients in transition. The Company expects to elect the practical expedients which permits the Company to not reassess under the new standard its prior conclusions about lease identification, lease classification, and initial direct costs.

The Company expects this standard to have a material effect on our financial statements. While the Company assesses all of the effects of adoption, it currently believes the most significant effects relate to (1) the recognition of new ROU assets and lease liabilities on its balance sheet for its real property. The Company does not expect a significant change in its leasing activities between now and its adoption.

On adoption, we currently expect to recognize additional operating liabilities ranging from $0.8 million to $1.0 million with corresponding ROU assets of the same amount based on the present value of the remaining minimum rental payments under current leasing standards for existing operating leases. Our conclusions are preliminary and subject to change as we finalize our analysis. Changes in our lease population or changes in incremental borrowing rates may alter these estimates. We will expand our consolidated financial statements disclosure upon adoption of the new standard.

In June 2016, the FASB issued a new standard to replace the incurred loss impairment methodology under current GAAP with a methodology that reflects expected credit losses and requires consideration of a broader range of reasonable and supportable information to inform credit loss estimates. The Company will be required to use a forward-looking expected credit loss model for accounts receivables, loans, and other financial instruments. Credit losses relating to available-for-sale debt securities will also be recorded through an allowance for credit losses rather than as a reduction in the amortized cost basis of the securities. The standard will be effective for the Company beginning January 1, 2020, with early adoption permitted beginning January 1, 2019. We are currently evaluating the impact of this standard on the Company’s consolidated financial statements, including accounting policies, processes, and systems.

NOTE 3 — SUPPLEMENTARY BALANCE SHEET INFORMATION

Accounts Receivable, net:

	December 31,	
(in thousands):	2018	2017
Trade	$10,990	$10,047
Royalties	71	71
Other	51	6
Total receivables, net	$11,112	$10,124

Accounts receivable is net of allowances for doubtful accounts of approximately $0.9 million and $0.8 million and sales returns of approximately $0.2 and $0.2 million at December 31, 2018 and 2017, respectively.

Inventory:

	December 31,	
(in thousands):	2018	2017
Raw materials	$3,590	$3,953
Work-in-process	1,435	1,162
Finished goods	7,223	7,183
Inventory	$12,248	$12,298

Inventory includes write-downs for excess and obsolete inventory totaling approximately $1.1 million and $1.9 million at December 31, 2018 and 2017, respectively.

Property, Plant, and Equipment, net:

(in thousands):	December 31, 2018	2017
Building	$213	$220
Leasehold improvements	2,004	2,005
Equipment and computers	7,277	6,883
Furniture and fixtures	634	634
Construction in progress	25	1,182
Total property, plant, and equipment before depreciation and land	10,153	10,924
Less: accumulated depreciation	(8,344)	(7,426)
Total property, plant, and equipment, net before land	1,809	3,498
Land	166	176
Property, plant, and equipment, net	$1,975	$3,674

The cost basis of assets held under capital lease was $0.4 million, which was fully depreciated as of December 31, 2018.

During 2018 and 2017, the Company recognized a non-cash, pre-tax charge related to the disposal of internally developed software of $1.2 million and $0.5 million, respectively, primarily due to the decision to cancel future deployments of a global enterprise resource planning system and certain other web-based tools originally intended to customize such systems.

Accrued Liabilities:

	December 31, 2018	2017
Payroll and benefits	$2,400	$2,115
Warranty accrual, current portion	861	1,120
Taxes	714	544
Accrued professional services	1,044	584
Accrued insurance premium	328	870
Customer deposits	21	27
Patent litigation settlement	1,500	—
Other	670	376
Accrued liabilities	$7,538	$5,636

NOTE 4 — INTANGIBLE ASSETS AND GOODWILL

The Company conducted its annual impairment test of goodwill as of June 30, 2018 and determined that there was no impairment. The Company also tests its intangible assets and goodwill between the annual impairment test if events occur or circumstances change that would more likely than not reduce the fair value of the Company or its assets below their carrying amounts. For intangible assets subject to amortization, the Company performs its impairment test

when indicators, such as reductions in demand or significant economic slowdowns, are present. No events have occurred that triggered further impairment testing of the Company's intangible assets and goodwill during the years ended December 31, 2018 and 2017.

As of December 31, 2018 and 2017, the Company had goodwill (indefinite life) of $2.9 million. As of December 31, 2018 and 2017, all intangible assets have been fully amortized and there was no amortization expense for the respective years. The amortization expense for the year ended December 31, 2016 was $51,000.

The following table presents the details of the Company’s intangible assets, related accumulated amortization and goodwill (in thousands):

	As of December 31, 2018 and 2017			
	Gross	Accumulated Amortization	Impairment	Carrying Value
Patents (4-10 years)	$1,914	$ (1,914)	$ —	$ —
Trademarks (6 years)	69	(69)	—	—
Other (4 to 6 years)	817	(817)	—	—
Total	$2,800	$ (2,800)	$ —	$ —
Goodwill (indefinite life)	$2,926			$ 2,926

NOTE 5 — INCOME TAXES

The Company accounts for income taxes under the asset and liability method, whereby deferred tax assets and liabilities are recognized for the future tax consequences attributable to differences between the financial statement carrying amounts of existing assets and liabilities and their respective tax bases. Deferred tax assets and liabilities are measured using enacted tax rates expected to apply in the years in which those temporary differences are expected to be recovered or settled. The effect on deferred tax assets and liabilities of a change in tax rates is recognized in income in the period that includes the enactment date. Management evaluates the need to establish a valuation allowance for deferred tax assets based upon the amount of existing temporary differences, the period in which they are expected to be recovered, and expected levels of taxable income. A valuation allowance to reduce deferred tax assets is established when it is “more likely than not” that some or all of the deferred tax assets will not be realized. Based on the Company’s net losses in prior years, management has determined that a full valuation allowance against the Company’s net deferred tax assets is appropriate.

The following table presents the current and deferred provision for income taxes for the years ended December 31 (in thousands):

	2018	2017	2016
Current:			
Federal	$—	$—	$—
State	14	19	22
Foreign	90	93	69
	104	112	91
Deferred:			
Federal	(41)	(694)	60
State	—	—	—
Foreign	—	—	—
	(41)	(694)	60
	$63	$(582)	$151

The provision for income taxes differs from the amount that would result from applying the federal statutory rate as follows for the years ended December 31:

	2018	2017	2016
Statutory regular federal income tax rate	(21.0)%	(34.0)%	(34.0)%
Change in valuation allowance	28.6 %	(90.6)%	40.4 %
State tax benefit (net of federal benefit)	(3.1)%	(3.2)%	(3.0)%
Research credits	(1.7)%	(1.7)%	(3.4)%
Foreign amounts with no tax benefit	— %	— %	0.2 %
Non-deductible expenses	0.3 %	1.0 %	0.6 %
Effect of change in rate from federal Tax Reform	0.5 %	127.1 %	0.5 %
Other	(3.3)%	(2.0)%	(0.2)%
Total	0.3 %	(3.4)%	1.1 %

The components of the deferred income tax assets and liabilities as of December 31 (in thousands):

	2018	2017
Capitalized intangible assets for tax purposes	$(42)	$(21)
Reserves not currently deductible	1,666	1,130
Deferred revenue	38	5
Stock options	4,153	3,600
State taxes	5	6
Income tax credits	3,820	2,640
Inventory	549	495
Property and equipment	126	165
Other comprehensive income	120	—
Unrealized gain on foreign currency	85	84
Net operating losses	37,205	33,451
Total deferred tax assets	47,725	41,555
Valuation allowance	(46,967)	(40,866)
Net deferred tax assets	758	689
Capitalized intangible assets	(629)	(608)
Other	(206)	(185)
Total deferred tax liabilities	(835)	(793)
Net deferred tax liabilities	$(77)	$(104)

Based upon the Company's operating losses incurred for each of three years ended December 31, 2018, and the available evidence, the Company has established a valuation allowance against its net deferred tax assets in the amount of $47.0 million as of December 31, 2018. Management considered factors such as the Company's earnings history, future projected earnings, and tax planning strategies. If sufficient evidence of the Company's ability to generate sufficient future taxable income tax benefits becomes apparent, the valuation allowance may be reduced, thereby resulting in tax benefits in the statement of operations and additional paid-in-capital. Management evaluates the potential realization of the Company's deferred tax assets and assesses the need for reducing the valuation allowance periodically.

The reversal of valuation allowance is primarily due to reduction in corporate income tax rate resulting from the enactment of the Tax Cuts Jobs Act further discussed below.

As of December 31, 2018, the Company had net operating loss ("NOL") carryforwards for federal and state purposes of approximately $164.6 million and $98.6 million, respectively, which expire in 2019 through 2038. The utilization of NOL and credit carryforwards may be limited under the provisions of the Internal Revenue Code ("IRC") Section 382 and similar state provisions. IRC Section 382 generally imposes an annual limitation on the amount of NOL carryforwards that may be used to offset taxable income where a corporation has undergone significant changes in stock ownership. As of December 31, 2018, the Company had research and development tax credit carryforwards for federal and state purposes of approximately $2.1 million and $2.0 million, respectively, which will begin to expire in 2019 through 2038 for federal purposes and will carry forward indefinitely for state purposes. An updated analysis may be required at the time the Company begins utilizing any of its net operating losses to determine if there is an IRC Section 382 limitation.

The following table summarizes the activity related to the Company's unrecognized tax benefits during the year ended December 31, 2018 (in thousands):

Balance at January 1, 2018	$568
Additions for tax positions related to the prior year	—
Lapse of statute of limitations	—
Balance at December 31, 2018	$568

The Company expects resolution of unrecognized tax benefits, if created, would occur while the full valuation allowance of deferred tax assets is maintained. The Company does not expect to have any unrecognized tax benefits that, if recognized, would affect the effective tax rate. As of December 31, 2018 and 2017, the Company does not have liability for potential penalties or interest. The Company does not expect its unrecognized tax benefits to change significantly over the next 12 months.

The Company files U.S., state and foreign income tax returns in jurisdictions with varying statutes of limitations. The 2014 through 2018 tax years generally remain subject to examination by federal and most state tax authorities. In foreign jurisdictions, the 2012 through 2018 tax years remain subject to examination by their respective tax authorities.

On December 22, 2017, the U.S. President signed the Tax Cuts and Jobs Act (the “2017 Act”) into law. The 2017 Act will have pervasive financial reporting implications for all companies with U.S. operations. The Company has reviewed and incorporated the 2017 Act implications in the 2018 consolidated financial statements for the year ended December 31, 2018. The primary change is the remeasurement of deferred taxes at the new corporate tax rate of 21%, which reduced the Company’s net deferred tax assets for the year ended December 31, 2017, before valuation allowance, by $21.7 million. Due to full valuation allowance, the change in deferred taxes was fully offset by the change in valuation allowance other than deferred tax liability recorded against indefinite-lived intangible assets. In connection with the 2017 Act, net operating losses generated subsequent to December 31, 2017 have an indefinite carryforward period with a limitation on utilization to 80% of taxable income in any given year. In addition, the 2017 Act limits the interest expense deduction to 30% of adjusted taxable income and any excess interest expenses are carried forward indefinitely. Accordingly, up to 30% of deferred tax assets generated with respect to a balance of excess interest carryforward and up to 80% of deferred tax assets related to NOL generated with indefinite carryforward periods are available to offset deferred tax liability related to indefinite lived intangibles (“naked credit”). As of December 31, 2018, the Company had $0.5 million of deferred tax assets available to offset a naked credit balance of $0.6 million, resulting in net deferred tax liability of $0.1 million.

U.S. income taxes or withholding taxes were provided for all the distributed earnings for the Company’s foreign subsidiaries as of December 31, 2018. At December 31, 2018, unremitted earnings of foreign subsidiaries were approximately $0.6 million and have been included in our computation of the transition tax associated with the enactment of the 2017 Act. We do not provide for U.S. taxes on our unremitted earnings of foreign subsidiaries that have not been previously taxed since we intend to invest such undistributed earnings indefinitely outside of the U.S.

The 2017 Act subjects a U.S, stockholder to current tax on global intangible low-taxed income (GILTI) earned by certain foreign subsidiaries. The FASB Staff Q&A, Topic 740 No. 5, Accounting for Global Intangible Low-Taxed Income, states that an entity can make an accounting policy election to either recognize deferred taxes for temporary differences expected to reverse as GILTI in future years or provide for the tax expense related to GILTI in the year the tax is incurred. We have elected to recognize the tax on GILTI as a period expense in the period the tax is incurred. The current income related to the GILTI inclusion in 2018 is $0.1 million.

NOTE 6 — DEBT

The following table presents the details of the principal outstanding and unamortized discount (in thousands):

	December 31,	
	2018	2017
Term loan	$12,500	$ —
Discount and debt issuance costs on term loan	(1,664)	—
Total long-term debt, net	$10,836	$ —

Line of Credit

On March 6, 2018, the Company and two of its wholly-owned subsidiaries (such subsidiaries, together with BIOLASE, the “Borrower”) entered into the Business Financing Agreement (the “Business Financing Agreement” with

Western Alliance Bank ("Western Alliance"). Pursuant to the terms and conditions of the Business Financing Agreement, Western Alliance has agreed to provide the Borrower a secured revolving line of credit permitting the Borrower to borrow or receive letters of credit up to the lesser of $6.0 million (the "Domestic Revolver") (subject to a $6.0 million credit limit relating to domestic eligible accounts receivable (the "domestic credit limit") and a $3.0 million credit limit relating to export-related (the "EXIM Revolver") eligible accounts receivable (the "EXIM credit limit")) and the borrowing base, which is defined as the sum of the domestic borrowing base (up to 75% of the Borrower's eligible domestic accounts receivable less such reserves as Western Alliance may deem proper and necessary) and the export-related borrowing base (up to 85% of the Borrower's eligible export-related accounts receivable less such reserves as Western Alliance may deem proper and necessary). The Business Financing Agreement was set to expire on March 6, 2020, and the Borrower's obligations thereunder were secured by a security interest in all of the Borrower's assets.

The Business Financing Agreement required the Company to maintain compliance with certain financial and non-financial covenants, as defined therein. Western Alliance had the right to declare the amounts outstanding under the Business Financing Agreement immediately due and payable upon a default.

Amounts outstanding under the Business Financing Agreement bore interest at a per annum floating rate equal to the greater of 4.5% or the “Prime Rate” published in the Money Rates section of the Western Edition of The Wall Street Journal (or such other rate of interest publicly announced from time to time by Western Alliance as its “Prime Rate”), plus 1.5% with respect to advances made under the line of credit, plus an additional 5.0% during any period that an event of default has occurred and is continuing. The commitment fee under the Business Financing Agreement was 0.25% of the domestic credit limit and 1.75% of the EXIM credit limit, payable on March 6, 2018 and each anniversary thereof.

Pursuant to the Business Financing Agreement, the Company paid the first of two annual commitment fees totaling $67,500, being 0.25% of the aggregate $6.0 million commitment for the Domestic Revolver and 1.75% of the aggregate $3.0 million commitment for the EXIM Revolver. The commitment fees and the legal costs associated with acquiring the credit facilities were capitalized and were amortized on a straight-line basis as interest expense over the term of the Business Financing Agreement.

As additional consideration for the lines of credit, the Company also issued the Western Alliance Warrants. For additional information on the Western Alliance Warrants, see Note 8 to the consolidated financial statements. The fair value of the Western Alliance Warrants was estimated using the Black-Scholes option-pricing model with the following assumptions: expected term of 10 years; volatility of 91.49%; annual dividend per share of $0.00; and risk-free interest rate of 2.88%; and resulted in an estimated fair value of $0.1 million, which was recorded as a liability and resulted in a discount to the credit facilities at issuance. The discount was expensed to interest expense at the time the Business Financing Agreement was terminated, as discussed below.

On August 13, 2018, the Borrower and Western Alliance entered into a Waiver and Business Financing Modification Agreement, pursuant to which Western Alliance waived certain of the Borrower’s covenants under the Business Financing Agreement and provided an advance of $1.5 million, which advance was due by September 27, 2018.

On September 27, 2018, the Borrower and Western Alliance entered into a Business Financing Modification Agreement which reduced the credit limit under the Business Financing Agreement to $2.5 million and extended the due date of the $1.5 million advance to March 6, 2019.

On October 22, 2018, the Borrower and Western Alliance entered into a new Business Financing Modification Agreement, pursuant to which Western Alliance waived BIOLASE’s non-compliance with certain financial operating covenants as set forth in the Business Financing Agreement, and the Borrower agreed to certain amended covenants contained in the Business Financing Agreement, including $300,000 minimum unrestricted cash balance covenant and a waiver of reporting items required to be delivered by BIOLASE to Western Alliance under the Business Financing Agreement.

On November 9, 2018, all outstanding borrowings, accrued interest and fees under the Business Financing Agreement were repaid with a portion of the proceeds under the Credit Agreement, and the Business Financing Agreement was terminated. The Company recorded approximately $0.1 million of interest expense including unamortized debt issuance costs that were written-off upon extinguishment of the debt. As of December 31, 2018, the warrants held by Western Alliance remain outstanding and are classified in equity in the consolidated balance sheet upon the adoption of ASU 2017-11 in the fourth quarter of 2018 and as of December 31, 2018.

Term Loan

On November 9, 2018, the Company entered into a five-year secured Credit Agreement ("Credit Agreement") with SWK Funding LLC ("SWK"), pursuant to which the Company has borrowed $12.5 million ("SWK Loan"). The Company's obligations under the Credit Agreement are secured by substantially all of the Company's assets. Under the terms of the Credit Agreement, repayment of the loan is interest-only for the first two years, paid quarterly with the option to extend the interest-only period. Principal repayments will begin in the first quarter of 2021 and will be approximately $0.7 million quarterly until the loan matures in the fourth quarter of 2023. The loan bears interest at London Interbank Bank Offered Rate ("LIBOR") plus 10% or another index that approximates LIBOR as close as possible if and when LIBOR no longer exists. Approximately $0.9 million of the proceeds from the SWK Loan were used to pay off all amounts owed to Western Alliance under the Business Financing Agreement. The Company plans to use the remaining proceeds to provide additional working capital to fund its growth initiatives, such as broadening its customer base and increasing the utilization of its products to drive recurring higher margin consumables revenue.

The Credit Agreement contains financial and non-financial covenants requiring the Company to, among other things, (i) maintain unencumbered liquid assets of no less than $1.5 million or (B) the sum of aggregate cash flow from operations less capital expenditures, ii) achieve certain revenue and EBITDA levels during the first two years of the loan, (iii) limit future borrowing, investments and dividends, and (iv) submit monthly and quarterly financial reporting. The Company was in compliance with these debt covenants as of December 31, 2018.

In connection with the SWK Loan, the Company paid approximately $1.0 million in debt issuance costs, including a $0.2 million loan origination fee, a $0.4 million finder's fee, and $0.4 million in legal and other fees. These costs were recognized as a discount on the SWK Loan and are being amortized on a straight-line basis over the loan term which approximates the effective-interest method.

The Company recognized approximately $0.2 million in interest expense relating to the SWK Loan for the year ended December 31, 2018. The weighted-average interest rate for the year ended December 31, 2018 was approximately 12.8%.

SWK Warrants

In connection with the Credit Agreement, the Company issued warrants to SWK (the "SWK Warrants") on November 9, 2018, to purchase up to 372,023 shares of the Company's common stock. The SWK Warrants are immediately exercisable and expire on November 9, 2026. The exercise price of the SWK Warrants is $1.34, which was the average closing price of the Company's common stock for the ten trading days immediately preceding November 9, 2018. These warrants contain down-round features that require the Company to adjust the exercise price proportionately should the Company issue shares at a price per share less than the exercise price. The fair value of the SWK Warrants was estimated using the Black-Scholes option-pricing model with the following assumptions: expected term of 8 years; volatility of 81.79%; annual dividend per share of $0.00; and risk-free interest rate of 3.13%; and resulted in an estimated fair value of $0.4 million. See Note 8 for additional information.

DPG Warrants

In connection with the SWK Loan, the Company paid a finder's fee to Deal Partners Group of $0.4 million cash and issued warrants to purchase up to 279,851 shares of common stock (the "DPG Warrants"). The warrants were issued on November 14, 2018, were exercisable immediately, and expire on November 9, 2026. The exercise price of the DPG Warrants is $1.34 which was the average closing price of the Company's common stock for the ten trading days immediately preceding November 9, 2018. These warrants contain down-round features that require the Company to adjust the exercise price proportionately should the Company issue shares at a price per share less than the exercise price. The fair value of the DPG Warrants of $0.3 million was estimated using the Black Scholes option pricing model with the following assumptions: expected term of 8 years; volatility of 81.79%; annual dividend per share of $0.00; and risk-free interest rate of 3.13%. See Note 8 for additional information.

The value of both warrants was recognized as a discount on the term loan and are being amortized on a straight-line basis over the loan term which approximates the effective-interest method over the loan term of five years. Additionally, based on the adoption of ASU 2017-11 in the fourth quarter of 2018, these warrants are classified as equity in the consolidated balance sheet as of December 31, 2018.

The future minimum principal payments as of December 31, 2018, are as follows (in thousands):

	Principal	Interest (1)
2019	$—	$1,598

2020	700	1,590
2021	2,800	1,344
2022	2,800	986
2023	6,200	505
Total future payments	$ 12,500	$ 6,023

(1) Estimated using LIBOR rates as at December 31, 2018

NOTE 7 — COMMITMENTS AND CONTINGENCIES

Leases

The Company leases its 57,000 square foot corporate headquarters and manufacturing facility located at 4 Cromwell, Irvine, California. In March 2015, the corporate headquarters and manufacturing facility lease was amended to extend the term through April 30, 2020, modify provisions for tenant improvement allowance of up to $398,000, and adjust the basic rent terms. Future minimum rental commitments under operating lease agreements with non-cancelable terms greater than one year for the years ending December 31 are listed below. The Company also leases additional office space and certain office equipment under various operating lease arrangements.

Future minimum rental commitments under lease agreements, as of December 31, 2018, with non-cancelable terms greater than one year for each of the years ending December 31 are as follows (in thousands):

2019	$802
2020	313
2021	33
2022 and thereafter	—
Total future minimum lease obligations	$1,148

Rent expense totaled approximately $0.8 million, $1.0 million and $1.0 million in each of the years ended December 31, 2018, 2017, and 2016, respectively.

Employee Arrangements and Other Compensation

Certain members of management are entitled to severance benefits payable upon termination following a change in control, which would approximate $3.0 million and $1.7 million at December 31, 2018 and 2017, respectively. The Company also has agreements with certain employees to pay bonuses based on targeted performance criteria. As of December 31, 2018 and 2017, approximately $0.3 million and $0.1 million was accrued for performance bonuses, which is included in accrued liabilities in the consolidated balance sheets. See Note 8 for additional information relating to specific stock-based compensation awards.

Purchase Commitments

The Company generally purchases components and subassemblies for its products from a limited group of third-party suppliers through purchase orders. The Company had $8.7 million of purchase commitments as of December 31, 2018, for which the Company has not received the goods or services and which is expected to be purchased primarily within one year. These purchase commitments were made to secure better pricing and to ensure the Company will have the necessary parts to meet anticipated near term demand. Although open purchase orders are considered enforceable and legally binding, the Company may be able to cancel, reschedule, or adjust requirements prior to supplier fulfillment.

Litigation

The Company discloses material loss contingencies deemed to be reasonably possible and accrues for loss contingencies when, in consultation with its legal advisors, management concludes that a loss is probable and reasonably estimable. The ability to predict the ultimate outcome of such matters involves judgments, estimates, and inherent uncertainties. The actual outcome of such matters could differ materially from management's estimates.

Intellectual Property Litigation

On April 24, 2012, CAO Group, Inc. (“CAO”) filed a lawsuit against BIOLASE in the District of Utah alleging that BIOLASE’s ezlase dental laser infringes on U.S. Patent No. 7,485,116 (the “116 Patent”). On September 9, 2012, CAO amended its complaint, adding claims for (1) business disparagement/injurious falsehood under common law and (2) unfair competition under 15 U.S.C. Section 1125(a). The additional claims stem from a press release that BIOLASE issued on April 30, 2012, which CAO claims contained false statements that are disparaging to CAO and its diode product. The amended complaint sought injunctive relief, treble damages, attorneys’ fees, punitive damages, and interest. Until January 24, 2018, this lawsuit was stayed in connection with United States Patent and Trademark Office proceedings relating to the 116 Patent, which proceedings ultimately culminated in a January 27, 2017 decision by the United States Court of Appeals for the Federal Circuit, affirming the findings of the Patent Trial and Appeal Board, which were generally favorable to the Company. On January 25, 2018, CAO moved for leave to file a second amended complaint to add certain claims, which filing the Company is not opposing.

On January 23, 2018, CAO filed a lawsuit against BIOLASE in the Central District of California alleging that BIOLASE’s diode lasers infringe on U.S. Patent Nos. 8,337,097, 8,834,497, 8,961,040 and 8,967,883. The complaint seeks injunctive relief, treble damages, attorneys’ fees, punitive damages, and interest.

On January 25, 2019, the Company and CAO entered into a confidential settlement agreement, 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 Note 11 for additional information.

NOTE 8 — STOCKHOLDERS’ EQUITY

Preferred Stock

The Board, without further stockholder authorization, may issue from time to time up to 1,000,000 shares of the Company’s preferred stock. Of the 1,000,000 shares of preferred stock, 500,000 shares are designated as Series B Junior Participating Cumulative Preferred Stock. As of December 31, 2018 and 2017, no shares of the Company’s preferred stock were issued or outstanding.

Common Stock

At December 31, 2018, 21,072,491 shares of the Company’s common stock were issued and outstanding. On May 10, 2018, the Company filed the Fourth Amendment to its Restated Certificate of Incorporation to reduce the authorized shares of common stock from 200,000,000 shares to 40,000,000 shares. See Note 1 for further information on the reverse stock split.

Stock Dividends

There were no dividends paid or declared in 2018, 2017 or 2016.

Warrants

The Company issues warrants for the sale of its common stock as approved by its Board. In 2018, the Company issued 708,212 warrants to purchase common stock at a weighted-average exercise price of $1.40, including the SWK Warrants, the DPG Warrants and the Western Alliance Warrants, excluding those warrants issued and canceled as a result of the Bridge Bank loan amendment. Warrants to purchase up to an aggregate of 785,174 unregistered shares of common stock at an exercise price of $9.00 per share were issued in connection with the Company’s April 2017

private placement. The debt-related warrants and the private placements are accounted for within stockholders' equity in the consolidated balance sheets upon adoption of ASU 2017-11 in the fourth quarter and as of December 31, 2018.

The following table summarizes warrant activity (in thousands, except per share data):

	Shares	Weighted-Average Exercise Price Per Share
Warrants outstanding, January 1, 2016	2,018	$ 20.90
Granted/Issued	407	$ 10.00
Exercised	—	$ —
Forfeited, cancelled, or expired	(144)	$ 32.50
Warrants outstanding, December 31, 2016	2,281	$ 20.90
Granted/Issued	785	$ 9.00
Exercised	—	$ —
Forfeited, cancelled, or expired	(1,841)	$ 20.00
Warrants outstanding, December 31, 2017	1,225	$ 9.65
Granted/Issued	760	$ 2.23
Exercised	—	$ —
Forfeited, cancelled, or expired	(52)	$ 2.35
Warrants outstanding, December 31, 2018	1,933	$ 6.62
Warrants exercisable, December 31, 2018	1,906	$ 6.43
Vested warrants expired during the 12 months ended December 31, 2018	—	$ —

On March 6, 2018, in connection with the execution of the Original Business Financing Agreement, the Company issued to Western Alliance warrants (the “Original Western Alliance Warrants”) to purchase up to the number of shares of common stock equal to $120,000 divided by the applicable exercise price at the time such warrants are exercised. The Original Western Alliance Warrants are fully vested and exercisable. The Original Western Alliance Warrants may be exercised with a cash payment from Western Alliance, or, in lieu of a cash payment, Western Alliance may convert the warrants into a number of shares, in whole or in part. The initial exercise price of the warrants was $2.35 per share, which was the Reverse Stock Split-adjusted closing market price of BIOLASE common stock on March 6, 2018. On September 27, 2018, the Company entered into the Second Modification Agreement to amend the Original Business Financing Agreement. In connection with the Second Modification Agreement, the Original Western Alliance Warrants were terminated, and the Company issued new warrants (the “Western Alliance Warrants”) to purchase up to the number of shares of common stock equal to $120,000 divided by the exercise price of $2.13, which was the closing price of the Company’s common stock on September 27, 2018. The Western Alliance Warrants are immediately exercisable and expire on September 27, 2028. These warrants contain down-round features that require the Company to adjust the exercise price proportionately should the Company issue shares at a price per share less than the exercise price. As a result of the early-adoption of ASU 2017-11, the value of these warrants has been recognized in equity in the consolidated balance sheets as of December 31, 2018.

On November 9, 2018, in connection with the Credit Agreement, BIOLASE issued to SWK, LLC or its assignees (collectively with SWK, the “Holder”) warrants to purchase up to 372,023 shares of common stock. The exercise price of the SWK Warrants is $1.34 per share, which was the average closing price of common stock for the ten trading days immediately preceding November 9, 2018. The SWK Warrants are immediately exercisable, expire on November 9, 2026 and contain a “cashless exercise feature.” Subject to certain limitations, the Holder has certain piggyback registration rights with respect to the shares that are issued upon exercise of the SWK Warrants. These warrants contain down-round features that require the Company to adjust the exercise price proportionately should the Company issue shares at a price per share less than the exercise price. As a result of the early-adoption of ASU 2017-11, the value of these warrants has been recognized in equity in the consolidated balance sheets as of December 31, 2018.

On November 14, 2018, in connection with the SWK Loan, the Company issued to DPG warrants to purchase up to 279,851 shares of common stock. The exercise price of the DPG Warrants is $1.34 per share, which was the average closing price of common stock for the ten trading days immediately preceding November 9, 2018. The DPG Warrants are immediately exercisable, expire on November 9, 2026 and contain a “cashless exercise feature.” Subject to certain limitations, the Holder has certain piggyback registration rights with respect to the shares that are issued upon exercise of the DPG Warrants. These warrants contain down-round features that require the Company to adjust the exercise price proportionately should the Company issue shares at a price per share less than the exercise price. As a result of the early-adoption of ASU 2017-11, the value of these warrants has been recognized in equity in the consolidated balance sheet as of December 31, 2018.

Stock Options

2002 Stock Incentive Plan

The 2002 Stock Incentive Plan (as amended effective as of May 26, 2004, November 15, 2005, May 16, 2007, May 5, 2011, June 6, 2013, October 30, 2014, April 27, 2015, and May 6, 2016, the "2002 Plan") was replaced by the 2018 Plan (as defined below) with respect to future equity awards. Persons eligible to receive awards under the 2002 Plan included officers, employees, and directors of the Company, as well as consultants. As of December 31, 2018, a total of 3,110,000 shares have been authorized for issuance under the 2002 Plan, of which 961,982 shares of common stock have been issued pursuant to options that were exercised, 1,724,264 shares of common stock have been reserved for options and restricted stock units that are outstanding, and 0 shares of common stock remain available for future grants.

2018 Stock Incentive Plan

At the 2018 Annual Meeting, the Company's stockholders approved the 2018 Long-Term Incentive Plan (as amended, the "2018 Plan") which was amended by Amendment No. 1 to the 2018 Long Term Incentive Plan, approved by the Company's stockholders at a special meeting on September 21, 2018. The purposes of the 2018 Plan are (i) to align the interests of the Company's stockholders and recipients of awards under the 2018 Plan by increasing the proprietary interest of such recipients in the Company's growth and success; (ii) to advance the interests of the Company by attracting and retaining non-employee directors, officers, other employees, consultants, independent contractors and agents; and (iii) to motivate such persons to act in the long-term best interests of the Company and its stockholders.

As of December 31, 2018, a total of 3,271,101 shares of common stock have been authorized for issuance under the 2018 Plan, of which 1,875,801 shares of common stock have been reserved for outstanding options and unvested RSUs, and 1,395,300 shares of common stock remain available for future grants.

Stock options may be granted as incentive or non-qualified options; however, no incentive stock options have been granted to date. The exercise price of options is at least equal to the market price of the stock as of the date of grant. Options may vest over various periods but typically vest on a quarterly basis over four years. Options expire after five years, ten years, or within a specified time from termination of employment, if earlier. The Company issues new shares of common stock upon the exercise of stock options. The following table summarizes option activity under the 2002 Plan and the 2018 Plan (in thousands, except per share data):

	Shares	Weighted-Average Exercise Price Per Share	Weighted-Average Remaining Contractual Term (Years)	Aggregate Intrinsic Value(1)
Options outstanding, January 1, 2016	898	$ 15.15		
Granted at fair market value	622	$ 7.10		
Exercised	—	$ —		
Forfeited, cancelled, or expired	(198)	$ 15.05		
Options outstanding, December 31, 2016	1,322	$ 13.60		

Granted at fair market value	446	$ 5.15		
Exercised	—	$ 4.30		
Forfeited, cancelled, or expired	(421)	$ 9.15		
Options outstanding, December 31, 2017	1,347	$ 8.99		
Granted at fair market value	611	$ 1.98		
Exercised	(1)	$ 2.10		
Forfeited, cancelled, or expired	(334)	$ 10.68		
Options outstanding, December 31, 2018	1,623	$ 6.54	5.94	$ —
Options exercisable, December 31, 2018	1,101	$ 7.88	4.98	$ —
Vested options expired during the twelve months ended December 31, 2018	102	$ 18.06		

(1) The intrinsic value calculation does not include negative values. This can occur when the fair market value on the reporting date is less than the exercise price of a grant.

The following table summarizes additional information for those options that are outstanding and exercisable as of December 31, 2018 (in thousands, except per share data):

	Options Outstanding			Exercisable	
Range of Exercise Prices	Number of Shares	Weighted-Average Exercise Price	Weighted-Average Remaining Life (Years)	Number of Shares	Weighted-Average Exercise Price
$1.17 - $2.13	416	$ 1.95	9.19	105	$ 2.10
$ 2.14 - $6.57	273	$ 4.06	7.20	204	$ 4.30
$6.58 - $7.50	391	$ 7.17	3.06	320	$ 7.16
$7.51 - $11.10	283	$ 9.15	6.32	213	$ 9.43
$11.11 - $20.35	260	$ 12.69	3.30	259	$ 12.69
Total	1,623	$ 6.54	5.94	1,101	$ 7.88

Cash proceeds, along with fair value disclosures related to grants, exercises, and vesting options, are as follows for the years ended December 31 (in thousands, except per share amounts):

	Years Ended December 31,		
	2018	2017	2016
Proceeds from stock options exercised	$2	$3	$1
Tax benefit related to stock options exercised(1)	N/A	N/A	N/A
Intrinsic value of stock options exercised(2)	$—	$1	$—
Weighted-average fair value of options granted	$1.38	$3.45	$5.15
Total fair value of shares vested during the year	$1,191	$1,286	$1,728

(1) Excess tax benefits received related to stock option exercises are presented as operating cash inflows. For the periods presented, the Company did not receive a tax benefit related to the exercise of stock options due to its net operating losses.

(2) The intrinsic value of stock options exercised is the amount by which the market price of the stock on the date of exercise exceeded the market price of the stock on the date of grant.

2018 Stock Option Activity

Effective January 25, 2018, the Compensation Committee of the Board awarded 360,000 non-qualified stock options to purchase shares of common stock to certain employees of the Company. These awards were valued at $2.11 per share and expire 10 years from the grant date. The options vest ratably over the 36-month period, commencing on February 25, 2018.

Additional options were granted during 2018, none of which were individually material.

2017 Stock Option Activity

- Effective February 6, 2017, the Compensation Committee of the Board issued 122,200 non-qualified stock options to purchase shares of the Company’s common stock to certain employees of the Company. These awards were issued at $7.75 per share, the closing market price of the Company’s common stock on the grant date, and expire 10 years from the grant date. Vesting periods for options are as follows: (i) for the 117,200 options awarded to existing employees, one-half vest on the first anniversary of grant date and one-half vest on the second anniversary of the grant date and (ii) for the 5,000 options awarded to new employees, 25% vest on February 6, 2018 and the remainder vest ratably over the 36-month period, commencing on March 6, 2018.
- On May 10, 2017, non-employee directors of the Company were granted a total of 105,105 non-qualified stock options to purchase shares of common stock. These awards were issued at $6.05 per share, the closing market price of common stock on the grant date, and expire 10 years from the grant date. The total grant vests in equal installments over a consecutive 12-month period, commencing on June 10, 2017.

- On September 1, 2017, Paul N. Clark resigned from the Board, effective September 11, 2017, and as Chairman of the Board, effective September 1, 2017. Effective September 1, 2017, Dr. Jonathan T. Lord was appointed Chairman of the Board. On September 11, 2017, the Compensation Committee of the Board approved a modification to expiration dates applicable to Mr. Clark's vested options. As a result of the modification, the Company recognized additional compensation expense of $44,000 for the year ended December 31, 2017. On September 11, 2017, Dr. Lord was granted 13,077 non-qualified stock options to purchase shares of common stock at $2.70 per share, the closing market price of the Company's common stock on the grant date, and expiring 10 years from the grant date. On September 12, 2017, Dr. Lord was granted 13,178 non-qualified stock options to purchase shares of common stock at $3.05 per share, the closing market price of common stock on the grant date, and expiring 10 years from the grant date. Both grants vest in equal installments over an eight-month period, commencing on October 10, 2017.
- On October 27, 2017, Frederic H. Moll, M.D. resigned from the Board, effective November 11, 2017. On November 11, 2017, the Compensation Committee of the Board approved a modification to expiration dates applicable to Dr. Moll's vested options. As a result of the modification, the Company recognized additional compensation expense of $22,000 for the year ended December 31, 2017. Also, on October 27, 2017 the Board elected Richard B. Lanman, M.D. to the Board. In connection with his election to the Board, on November 1, 2017, Dr. Lanman was granted 27,066 non-qualified stock options to purchase shares of common stock at $3.75 per share, the closing market price of the Company's common stock on the grant date, and expiring 10 years from the grant date.
    - Effective November 7, 2017, the Compensation Committee of the Company's Board issued 85,200 non-qualified stock options to purchase shares of common stock to certain employees of the Company. These awards were issued at $3.00 per share, the closing market price of the Company's common stock on the grant date, and expire 10 years from the grant date. Vesting periods for options are as follows: one-half vest on the first anniversary of the grant date and one-half vest ratably monthly commencing thirteen months after the grant date through the twenty-fourth month.

2016 Stock Option Activity

- On February 26, 2016, the Compensation Committee of the Board awarded to certain employees and consultants of the Company a total of 59,000 non-qualified stock options to purchase shares of common stock. These awards were issued at $4.30 per share, the closing market price of the Company's common stock on the grant date, and expire 10 years from the grant date. Vesting periods for options are as follows: (i) 37,000 options, awarded to existing employees, vest ratably over a 48 month period, commencing one month from the grant date, and (ii) 22,000 options, awarded to new 2016 employees, vest 25% on the one-year anniversary of the grant date and the remainder ratably over the 36-month period, commencing 13 months after of the grant date.
- On April 18, 2016, in connection with the hiring of the two new Vice Presidents, the Compensation Committee of the Board awarded 65,000 non-qualified stock options to purchase shares of common stock. These awards were issued at $7.15 per share, the closing market price of the Company's common stock on the grant date, and expire 10 years from the grant date. Vesting periods for the options are as follows: (i) one-half of the total grant is subject to time vesting, with 25% vesting as of April 18, 2017 and the remaining 75% vesting ratably monthly over a 36-month period commencing on April 18, 2017, and (ii) one-half of the total grant is subject to specific 2016 and 2017 performance criteria, with vesting upon completion of the applicable performance criteria. As of December 31, 2016, 48,750 non-qualified stock options to purchase shares of the Company's common stock remain outstanding.
- On May 6, 2016, non-employee directors of the Company were granted a total of 119,551 non-qualified stock options to purchase shares of common stock. These awards were issued at $7.05 per share, the closing market price of the Company's common stock on the grant date, and expire 10 years from the grant date. The total grant vests in equal installments over a consecutive 12-month period, commencing on June 6, 2016.
- On August 29, 2016, in connection with the hiring of a new Senior Director, the Compensation Committee of the Board awarded 12,000 non-qualified stock options to purchase shares of common stock. This award was issued at $8.25 per share, the closing market price of the Company's common stock on the grant date, and expires 10 years from the grant date. Vesting periods for the options are as follows: (i) one-half of the total grant is subject to ratable time vesting over a 48-month period commencing on September 29, 2016, and (ii) one-half of the total grant is

subject to specific 2017 performance criteria, with vesting upon completion of the applicable performance criteria. As of December 31, 2016, 12,000 non-qualified stock options to purchase shares of the Company's common stock remain outstanding.

- On September 15, 2016, in connection with the hiring of a new Vice President, the Compensation Committee of the Board awarded 50,000 non-qualified stock options to purchase shares of common stock. This award was issued at $8.90 per share, the closing market price of the Company's common stock on the grant date, and expires 10 years from the grant date. Vesting periods for the options are as follows: (i) one-half of the total grant is subject to time vesting with 25% vesting as of September 15, 2017 and the remaining 75% vesting ratably monthly over a 36-month period commencing on September 15, 2017, and (ii) one-half of the total grant is subject to specific 2017 and 2018 performance criteria, with vesting upon completion of the applicable performance criteria. As of December 31, 2016, 50,000 non-qualified stock options to purchase shares of the Company's common stock remain outstanding.
- On October 3, 2016, in connection with the hiring of a new Vice President, the Compensation Committee of the Board awarded 25,000 non-qualified stock options to purchase shares of common stock. This award was issued at $8.60 per share, the closing market price of the Company's common stock on the grant date, and expires 10 years from the grant date. Vesting periods for the options are as follows: (i) one-half of the total grant is subject to time vesting with 25% vesting as of October 3, 2017 and the remaining 75% vesting ratably monthly over a 36-month period commencing on October 3, 2017, and (ii) one-half of the total grant is subject to specific 2017 through 2019 performance criteria, with vesting upon completion of the applicable performance criteria. As of December 31, 2016, 25,000 non-qualified stock options to purchase shares of the Company's common stock remain outstanding.
- During the year ended December 31, 2016, the Compensation Committee of the Board granted non-qualified stock options to purchase 280,000 shares of common stock to the Company's President and Chief Executive Officer. The exercise price of such options ranged from $7.20-$7.25 per share, vest over two to four years, and expire 10 years from the grant date.

Restricted Stock Units

2018 Restricted Stock Units Activity

- Under the 2002 Plan, effective January 26, 2018, the Board issued 40,000 RSUs to the Company's President and Chief Executive Officer. This award was valued at $2.00 per share, the reverse stock split adjusted closing market price of the Company's common stock on the grant date, and will vest upon the achievement of specific annual Company performance criteria.

Effective September 10, 2018 and September 21, 2018, respectively, the Compensation Committee of the Board granted the following:

- 650,000 shares to the Company's President and Chief Executive Officer. These awards were valued at $2.17 per share, the closing price of the Company's common stock on the grant date. Vesting periods for the awards are as follows: (i) 54% of the total grant is subject to time vesting with 33% vesting on August 7, 2019 and the remaining 67% vesting ratably semi-annually over the two-year period commencing on February 7, 2020; and (ii) 46% of the awards is subject to specific 2019, 2020 and 2021 performance criteria, with vesting upon satisfaction of the applicable performance criteria, subject to continued service through the applicable vesting dates.
- 30,388 shares to certain employees of the Company. These awards were valued at $2.06 per share, the closing price of the Company's common stock on the grant date. Vesting periods for the awards are as follows: (i) 50% of 24,271 shares vest on September 10, 2019 and the remaining 50% vest on September 10, 2020; and (ii) 6,117 shares fully vest on March 15, 2019, subject to continued service through the applicable vesting dates.

Effective May 14, 2018, the Compensation Committee of the Board granted the following:

- 1,193,850 shares to certain Board members, employees and consultants of the Company. These awards were valued at $1.45 per share, the closing price of the Company's common stock on the grant date, and vest 40% on December 31, 2018 and 60% on December 31, 2019, subject to continued service through the applicable vesting dates.
- 398,275 shares to certain Board members of the Company. These awards were valued at $1.45 per share, the closing price of BIOLASE common stock on the grant date, and fully vest on the first anniversary of the grant date, subject

to continued service through the applicable vesting date.

- 10,127 shares to certain employees of the Company. These awards were valued at $1.45 per share, the closing price of the Company's common stock on the grant date, and were fully vested on the grant date, subject to continued service through the applicable vesting date.

Effective June 15, 2018, the Board granted 155,000 RSUs to two new Board members. These awards were valued at $1.25 per share, the closing price of the Company's common stock on the grant date, and vest fully on May 9, 2019.

2017 Restricted Stock Units Activity

Effective February 6, 2017, the Compensation Committee of the Board approved the grant of the following awards:

- 16,000 restricted stock units ("RSUs") were awarded to an employee of the Company as part of the employee's 2017 compensation. These awards were valued at $7.75 per share, the closing market price of the Company's common stock on the grant date, and vest as follows: (i) 6,000 of the RSUs vested on March 14, 2017, (ii) 4,000 of the RSUs vested on September 14, 2017, and (iii) 6,000 of the RSUs vest on May 10, 2018.
- 200,000 stock-settled RSUs were awarded to the Company's President and Chief Executive Officer as part of his 2017 compensation. These RSUs were valued at $7.75 per share, the closing market price of the Company's common stock on the grant date. These RSUs vest as follows: (i) one-quarter of the RSUs vest on February 6, 2019, (ii) one-eighth of the RSUs vest on February 6, 2020, (iii) one-eighth of the RSUs vest on February 6, 2021, and (iv) one-half of the RSUs vest upon the achievement of specific interim and annual Company performance criteria.
- On May 9, 2017 and in connection with the Company's 2017 compensation plan, 100,000 RSUs were awarded to certain employees and consultants of the Company. These awards were valued at $6.10 per share, the closing market price of the Company's common stock on the grant date. The RSUs vest as follows: (i) one-half of the total grant is subject to time vesting with 50% vesting on May 9, 2018 and the remaining 50% vesting on May 9, 2019, and (ii) one-half of the total grant is subject to specific 2017 and 2018 performance criteria, with vesting upon satisfaction of the applicable performance criteria.
- On May 10, 2017, non-employee directors of the Company were granted a total of 35,032 RSUs valued at $6.05 per share, the closing market price of the Company's common stock on the grant date. These awards vest on May 10, 2018. On September 1, 2017, Paul N. Clark resigned from the Board, effective September 11, 2017, and as Chairman of the Board, effective September 1, 2017. On September 11, 2017, the Compensation Committee of the Board approved a modification to the vesting criteria applicable to Mr. Clark's unvested RSUs. As a result of the modification, the Company recognized additional compensation expense of $12,000 for the year ended December 31, 2017. On October 27, 2017, Frederic H. Moll, M.D. resigned from the Board, effective November 11, 2017. On November 11, 2017, the Compensation Committee of the Board approved a modification to the vesting criteria applicable to Dr. Moll's unvested RSUs. As a result of the modification, the Company recognized additional compensation expense of $10,000 for the year ended December 31, 2017.

2016 Restricted Stock Units Activity

Under the 2002 Plan, effective February 26, 2016, the Compensation Committee of the Board granted the following awards:

- 77,700 restricted stock units ("RSUs") were awarded to certain employees and consultants of the Company. These awards were valued at $4.30 per share, the closing market price of common stock on the grant date, and fully vested on July 1, 2016.
- 28,000 RSUs were awarded to certain employees and consultants of the Company as part of their compensation plan. These awards were valued at $4.30 per share, the closing market price of the Company's common stock on the grant date, and vest 25% on each of the first, second, third, and fourth anniversaries of the grant date.
- In connection with the President and Chief Executive Officer's employment agreement, the maximum performance bonus was awarded, consisting of (i) $100,000 paid in cash during the nine months ended September 30, 2016, and (ii) the grant of 11,904 RSUs, valued at $4.30 per share, the closing market price of the Company's common stock on the grant date. Half of these RSUs vested on March 30, 2016 and half of these RSUs vested on February 18, 2017.

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- On March 10, 2016, the Compensation Committee of the Board approved the grant of 14,000 RSUs to the Company's Chief Financial Officer as part of his 2015 compensation. These awards were valued at $6.15 per share, the closing market price of the Company's common stock on the grant date, and fully vested on July 1, 2016.
- On May 6, 2016, as compensation for their service during the current year, non-employee directors of the Company were granted a total of 49,750 RSUs valued at $7.05 per share, the closing market price of common stock on the grant date. These awards vest on May 6, 2017.

The following table summarize RSU activity under the 2002 and 2018 Plans (in thousands):

	Shares
Unvested restricted stock units, January 1, 2016	—
Granted	181
Vested	(97)
Forfeited or cancelled	—
Unvested restricted stock units, December 31, 2016	84
Granted	470
Vested	(81)
Forfeited or cancelled	(115)
Unvested restricted stock units, December 31, 2017	358
Granted	2,836
Vested	(604)
Forfeited or cancelled	(427)
Unvested restricted stock units, December 31, 2018	2,163

Inducement Stock-Based Awards

2018 Inducement Activity

There were no new grants relating to inducements for the year ended December 31, 2018. Approximately 124,000 options were canceled and 328,500 remain outstanding at December 31, 2018.

2017 Inducement Activity

- On March 13, 2017, and as amended on April 19, 2017, in connection with the hiring of a new Vice President of Sales, the Compensation Committee of the Board awarded non-qualified stock options to purchase 80,000 shares of BIOLASE common stock. This award was issued at $5.85 per share, the closing market price of the Company's common stock on the grant date, and expires 10 years from the grant date. Vesting periods for the options are as follows: (i) two-fifths of the total grant is subject to time vesting with 25% vesting as of March 13, 2018 and the remaining 75% vesting ratably monthly over a 36-month period commencing on March 13, 2018, and (ii) three-fifths of the total grant is subject to specific 2017 and 2018 performance criteria, with vesting upon satisfaction of the applicable performance criteria. This award was forfeited upon the departure of the Vice President of Sales in November 2017.
- On March 27, 2017, in connection with the hiring of a new Senior Vice President and Chief Financial Officer, the Compensation Committee of the Board awarded non-qualified stock options to purchase 120,000 shares of common stock. This award was issued at $6.40 per share, the closing market price of the Company's common stock on the grant date, and expires 10 years from the grant date. Vesting periods for the options are as follows: (i) two-thirds of the total grant is subject to time vesting with 25% vesting as of March 27, 2018 and the remaining 75% vesting

ratably monthly over a 36-month period commencing on March 27, 2018, and (ii) one-third of the total grant is subject to specific 2017 and 2018 performance criteria, with vesting upon satisfaction of the applicable performance criteria. This award was forfeited upon the departure of the Senior Vice President and Chief Financial Officer in May 2017.

• On October 2, 2017, in connection with the hiring of a new Senior Vice President and Chief Financial Officer, the Compensation Committee of the Board awarded non-qualified stock options to purchase 120,000 shares of common stock. This award was issued at $2.95 per share, the closing market price of the Company' common stock on the grant date, and expires 10 years from the grant date. Vesting periods for the options are as follows: (i) two-thirds of the total grant is subject to time vesting with 25% vesting as of October 2, 2018 and the remaining 75% vesting ratably monthly over a 36-month period commencing on October 2, 2018, and (ii) one-third of the total grant is subject to specific 2018 and 2019 performance criteria, with vesting upon satisfaction of the applicable performance criteria.

NOTE 9 — SEGMENT INFORMATION

The Company currently operates in a single business segment. Management uses one measurement of profitability and does not segregate its business for internal reporting. Sales to customers located in the United States accounted for approximately 62%, 62%, and 64% of net revenue and international sales accounted for approximately 38%, 38%, and 36% of net revenue for the years ended December 31, 2018, 2017, and 2016, respectively. No individual international country represented more than 10% of net revenue during the years ended December 31, 2018, 2017, and 2016.

Long-lived assets by geographic location was as follows (in thousands):

	Years Ended December 31,		
	2018	2017	2016
United States	$1,673	$3,347	$4,175
International	302	327	303
	$1,975	$3,674	$4,478

NOTE 10 — CONCENTRATIONS

Revenue from the Company's products for the years ended December 31, 2018, 2017 and 2016 are as follows:

	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	%
License fees and royalties	12	—	%	128	0.3	%	149	0.3	%
Total revenue	$46,155	100.0	%	$46,926	100.0	%	$51,810	100.0	%

The Company maintains its cash and cash equivalent accounts with established commercial banks. Such cash deposits periodically exceed the Federal Deposit Insurance Corporation insured limit.

One individual customer represented approximately 12% of the Company’s accounts receivable at December 31, 2018. No individual customer represented more than 10% of the Company’s accounts receivable at December 31, 2017.

The Company currently purchases certain key components of its products from single suppliers. Although there are a limited number of manufacturers of these key components, management believes that other suppliers could provide similar key components on comparable terms. A change in suppliers, however, could cause delays in manufacturing and a possible loss of sales, which could adversely affect the Company’s business, results of operations and financial condition.

NOTE 11 — SUBSEQUENT EVENTS (unaudited)

Patent Litigation

On January 25, 2019 (the "Effective Date"), BIOLASE, Inc. (the "Company") entered into a settlement agreement (the "Settlement Agreement") with CAO Group, Inc. ("CAO"). Pursuant to the Settlement Agreement, CAO has 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 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, 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 has 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 (the "Stock Consideration"), 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 considered this a Type I subsequent event and recognized a $1.5 million contingent loss on patent litigation settlement in its statement of operations for the year ended December 31, 2018.

Equity Awards

Restricted Stock Units

Effective February 22, 2019, the Compensation Committee of the Board issued to certain employees of the Company a total of approximately 0.9 million non-qualified RSUs as part of the Company's 2019 performance bonus program. Vesting of these awards will occur quarterly based on the achievement of specific Company performance criteria. These awards expire 10 years from the grant date and were valued at $2.26 per share, the closing market price of the Company's common stock on the grant date.

BIOLASE, INC.

Schedule II — Consolidated Valuation and Qualifying Accounts and Reserves

For the Years Ended December 31, 2018, 2017, and 2016

(in thousands)

	Balance at Beginning of Year	Charges (Reversals) to Cost or Expenses	Deductions	Balance at End of Year
Year Ended December 31, 2018:				
Allowance for doubtful accounts	$ 802	$ 469	$ (421)	$ 850
Allowance for sales returns	210	—	—	210
Allowance for tax valuation	40,866	6,101	—	46,967
Year Ended December 31, 2017:				
Allowance for doubtful accounts	$ 1,209	$ (401)	$ (6)	$ 802
Allowance for sales returns	210	—	—	210
Allowance for tax valuation	54,310	(13,444)	—	40,866
Year Ended December 31, 2016:				
Allowance for doubtful accounts	$ 1,765	$ (438)	$ (118)	$ 1,209
Allowance for sales returns	210	—	—	210
Allowance for tax valuation	49,514	4,796	—	54,310

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