

BIOLASE, INC
Form 10-K
March 15, 2013
Table of Contents

UNITED STATES SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 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, 2012

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 000-19627

BIOLASE, INC.

(Exact Name of Registrant as Specified in Its Charter)

Delaware
(State or Other Jurisdiction)

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

Edgar Filing: BIOLASE, INC - Form 10-K

of Incorporation or Organization)

4 Cromwell

Irvine, California 92618

(Address of Principal Executive Offices, including zip code)

(949) 361-1200

(Registrant's Telephone Number, Including Area Code)

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

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

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

None.

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

Indicate by check mark if the registrant is not required to file reports pursuant to Section 13 or Section 15(d) of the Act. Yes No

Indicate by check mark whether the registrant: (1) has filed all reports required to be filed by Section 13 or 15(d) of the Securities Exchange Act of 1934 during the preceding 12 months (or for such shorter period that the registrant was required to file such reports) and (2) has been subject to such filing requirements for the past 90 days. Yes No

Indicate by check mark whether the registrant has submitted electronically and posted on its corporate website, if any, every Interactive Data File required to be submitted and posted pursuant to Rule 405 of Regulation S-T (§ 232.405 of this chapter) during the preceding 12 months (or for such shorter period that the registrant was required to submit and post such files). Yes No

Indicate by check mark if disclosure of delinquent filers pursuant to Item 405 of Regulation S-K is not contained herein, and will not be contained, to the best of registrant's knowledge, in the definitive proxy or information statements incorporated by reference in Part III of this Form 10-K or any amendment to this Form 10-K.

Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, a non-accelerated filer or a smaller reporting company. See definition of large accelerated filer, accelerated filer and smaller reporting company in Rule 12b-2 of the Exchange Act. (Check one):

Large accelerated filer Accelerated filer Non-accelerated filer Smaller Reporting Company

(Do not check if a smaller reporting company)

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

The aggregate market value of the Registrant's common stock held by non-affiliates was \$57,615,816 based on the last sale price of common stock on June 30, 2012.

Edgar Filing: BIOLASE, INC - Form 10-K

As of March 8, 2013, there were 31,343,661 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 2013 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, 2012, are incorporated by reference into Part III of this Annual Report on Form 10-K.

Table of Contents

BIOLASE, INC.

ANNUAL REPORT ON FORM 10-K

FOR THE FISCAL YEAR ENDED DECEMBER 31, 2012

TABLE OF CONTENTS

PART I

Item 1.	<u>Business</u>	2
	<u>Executive Officers of the Registrant</u>	24
Item 1A.	<u>Risk Factors</u>	25
Item 1B.	<u>Unresolved Staff Comments</u>	41
Item 2.	<u>Properties</u>	41
Item 3.	<u>Legal Proceedings</u>	41
Item 4.	<u>Mine Safety Disclosures</u>	42

PART II

Item 5.	<u>Market for Registrant's Common Equity, Related Stockholder Matters and Issuer Purchases of Equity Securities</u>	42
Item 6.	<u>Selected Financial Data</u>	45
Item 7.	<u>Management's Discussion and Analysis of Financial Condition and Results of Operations</u>	46
Item 7A.	<u>Quantitative and Qualitative Disclosures About Market Risk</u>	61
Item 8.	<u>Financial Statements and Supplementary Data</u>	61
Item 9.	<u>Changes in and Disagreements with Accountants on Accounting and Financial Disclosure</u>	61
Item 9A.	<u>Controls and Procedures</u>	62
Item 9B.	<u>Other Information</u>	63

PART III

Item 10.	<u>Directors, Executive Officers and Corporate Governance</u>	63
Item 11.	<u>Executive Compensation</u>	64
Item 12.	<u>Security Ownership of Certain Beneficial Owners and Management and Related Stockholder Matters</u>	64
Item 13.	<u>Certain Relationships and Related Transactions, and Director Independence</u>	64
Item 14.	<u>Principal Accountant Fees and Services</u>	64

PART IV

Item 15.	<u>Exhibits and Financial Statement Schedules</u>	64
----------	---	----

Table of Contents

CAUTIONARY STATEMENT REGARDING FORWARD LOOKING STATEMENTS

This Annual Report on Form 10-K (Form 10-K), particularly in Item 1, Business, and Item 7, Management's Discussion and Analysis of Financial Condition and Results of Operations, and the documents incorporated by reference, includes forward-looking statements that involve risks and uncertainties, as well as assumptions that, if they prove incorrect or never materialize, could cause our results to differ materially and adversely from those expressed or implied by such forward-looking statements. Examples of forward-looking statements include, but are not limited to any statements, predictions and expectations regarding our earnings, revenue, sales and operations, operating expenses, anticipated cash needs, capital requirements and capital expenditures, needs for additional financing, use of working capital, plans for future products and services and for enhancements of existing products and services, anticipated growth strategies, ability to attract customers, sources of net revenue, anticipated trends and challenges in our business and the markets in which we operate, the adequacy of our facilities, the impact of economic and industry conditions on our customers and our business, customer demand, our competitive position, the outcome of any litigation against us, the perceived benefits of any technology acquisitions, critical accounting policies and the impact of recent accounting pronouncements. Additional forward-looking statements include, but are not limited to, statements pertaining to other financial items, plans, strategies or objectives of management for future operations, our financial condition or prospects, and any other statement that is not historical fact. Forward-looking statements are often identified by the use of words such as may, might, will, intend, should, could, can, would, expect, believe, anticipate, estimate, predict, potential, plan, seek and similar expressions and variations or the negativities of these other comparable terminology.

These forward-looking statements are based on the expectations, estimates, projections, beliefs and assumptions of our management based on information currently available to management, all of which is subject to change. Such 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, those identified under Risk Factors in Item 1A in this Form 10-K. We undertake no obligation to revise or update publicly any forward-looking statements to reflect events or circumstances after the date of such statements for any reason except as otherwise required by law.

The information contained in this Form 10-K is not a complete description of our business or the risks associated with an investment in our common stock. We urge you to carefully review and consider the various disclosures made by us in this Annual Report and in our other reports filed with the Securities and Exchange Commission (the SEC).

Table of Contents

PART I

Item 1. Business

Overview

We are a biomedical company that develops, manufactures, and markets lasers in dentistry and medicine and also markets and distributes dental imaging equipment, including cone beam digital x-rays and CAD/CAM intra-oral scanners. Our dental laser systems allow dentists, periodontists, endodontists, oral surgeons, and other specialists to perform a broad range of dental procedures, including cosmetic and complex surgical applications. Our systems are designed to provide clinically superior performance for many types of dental procedures with less pain and faster recovery times than are generally achieved with drills, scalpels, and other dental instruments. We have clearance from the U.S. Food and Drug Administration (the FDA) to sell our laser systems in the United States and also have the necessary approvals to sell our laser systems in Canada, the European Union and various other international markets. Our licensed dental imaging equipment and other related products are designed to improve diagnoses, applications, and procedures in dentistry and medicine.

We offer two categories of laser system products: Waterlase systems and Diode systems. Our flagship product category, the Waterlase system, uses a patented combination of water and laser energy to perform most procedures currently performed using dental 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 currently have approximately 160 issued and 150 pending U.S. and international patents, the majority of which are related to our core Waterlase technology and dental and medical lasers. Since 1998, we have sold over 9,500 Waterlase systems, including more than 5,500 Waterlase MD® and iPlus® systems, and more than 21,600 laser systems in over 60 countries around the world.

We currently operate in a single reportable business segment. We had net revenues of \$57.4 million, \$48.9 million, and \$26.2 million in 2012, 2011, and 2010, respectively, and we had net losses of \$3.1 million, \$4.5 million, and \$12.0 million for the same periods.

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 to BIOLASE, Inc. in 2012. Since 1998, our primary objective has been to be the leading designer, manufacturer and marketer of laser systems for the dental industry.

Recent Developments

Product Offerings

In October 2012, we expanded the line of dental imaging products by executing a definitive five-year agreement with Copenhagen-based 3Shape Corporation (3Shape), making the Company a distributor of 3Shape's TRIOS intra-oral CAD/CAM scanning technologies for digital impression-taking solutions in the U.S. and Canada. Among other capabilities, the TRIOS offers on-screen visualization of the impressions with online communication with dental laboratories. We are currently selling this product as a distributor under the manufacturer's regulatory market clearances.

In September 2012, we introduced the Epic, which received the CE Mark in late September 2012 and which received FDA 510(k) clearance in October 2012. This innovative diode laser provides versatility with soft tissue surgery, teeth whitening, and pain therapy capabilities in a portable and convenient design with pre-set and customizable settings. Weighing only two and a half pounds, the Epic diode laser has 10 Watts of power. The Epic V-Series launching in 2013 is based on the Epic platform with software and delivery adaptations enabling a wide range of veterinary applications, including surgical, dental, and pain therapy procedures. We anticipate further expansion of the Epic diode laser into additional medical markets in 2013.

Table of Contents

In February 2012, we introduced the Waterlase MDX line, a new product line of all-tissue lasers which expands the Company's product offerings and complements the industry-leading Waterlase iPlus all-tissue dental laser system. Two models of the Waterlase MDX are available. The 8-watt Waterlase MDX 300 improves on Biolase's time-tested Waterlase MD platform with an updated user interface, a new laser engine and a new lightweight and more flexible titanium fiber cable. The Waterlase MDX 450 increases the power output to 9-watts and cuts hard-tissue up to 70 percent faster than the Waterlase MDX 300. The Waterlase MDX 300 is upgradeable in the field to the MDX 450 performance level.

In February 2012, we introduced NewTom Cone Beam three-dimensional (3-D) Imaging products, manufactured by Cefla Dental Group, which we distribute in the United States and Canada. The NewTom 3-D product line will complement the Biolase DaVinci Imaging dental imaging devices and provide our dental customers a wider and more comprehensive choice of configurations, range of performance, and price points. The NewTom imaging products are typically used in highly complex dentistry cases by periodontists, endodontists, and oral surgeons where more involved and more accurate images are required. We believe that they are increasingly being adopted by general practitioners for use in placing implants. We are currently selling these products as a distributor under the manufacturer's 510(k) clearances. We initially introduced dental imaging products in July 2011 under the Biolase DaVinci Imaging name.

In January 2011, we introduced the Waterlase iPlus[®], a powerful and intuitive dual wavelength all-tissue dental laser system. We believe the iPlus is our most significant advancement in all-tissue laser technology since we introduced the Waterlase MD in 2005. The Waterlase iPlus received FDA 510(k) clearance in the United States in August 2010 and received European CE mark-approval in February 2011.

Credit Facilities Established

On May 24, 2012, we entered into two revolving credit facility agreements with Comerica Bank (the Credit Agreements), as amended on August 6, 2012, (Amendment No. 1), which provide for borrowings against certain domestic accounts receivable and inventory, as set forth in the \$4.0 million revolving credit facility agreement (the Domestic Revolver), and borrowings against certain export related accounts receivable and inventory, as set forth in the \$4.0 million revolving credit facility agreement (the Ex-Im Revolver), for a combined aggregate commitment of borrowings of up to \$8.0 million. The Credit Agreements mature on May 1, 2014 and are secured by substantially all of our assets now owned or hereinafter acquired. The Credit Agreements require compliance with certain financial and non-financial covenants, as defined therein. If a default occurs, Comerica Bank may declare the amounts outstanding under the Credit Agreements immediately due and payable. As of December 31, 2012, we were in compliance with these covenants.

Termination of Master Distribution Agreement

On September 23, 2010, we entered into a Distribution and Supply Agreement with Henry Schein, Inc. (HSIC), effective August 30, 2010, (the D&S Agreement), which terminated all prior agreements with HSIC. Under the D&S Agreement, we granted HSIC certain non-exclusive distribution rights in North America and several international markets with respect to our dental laser systems, accessories, and related support and services in certain circumstances. In addition, we granted HSIC exclusivity in selected international markets subject to review of certain performance criteria. In connection with the D&S Agreement, HSIC placed two irrevocable purchase orders totaling \$9 million for our products. The first purchase order, totaling \$6 million, was for the purchase of iLase[®] systems and was fully satisfied during the first quarter of 2011. The second purchase order, totaling \$3 million, was for the purchase of a combination of laser systems and was fully satisfied during the third quarter of 2011. The D&S Agreement granted HSIC a security interest in our inventory and assets, including our intellectual property.

On April 12, 2012, we completed a transaction with HSIC (the 2012 Termination Agreement) whereby we purchased HSIC's inventory of Waterlase MD Turbo laser systems for approximately \$1.1 million and HSIC released its liens on our assets, including our inventory and intellectual property. As part of the 2012 Termination Agreement, we reacquired 153 MD Turbo laser systems at a cost well below market. Pursuant to the terms of the

Table of Contents

transaction, the entire purchase price was paid by offsetting certain accounts receivable currently due from HSIC from sales made in the normal course of business. None of the funds used to offset the purchase price were related to the original sales of the MD Turbo laser systems that were purchased. As a result of the transaction, we are no longer required to fulfill certain future service obligations and, accordingly, derecognized approximately \$155,000 of accounts receivable due from HSIC related to support services previously provided and approximately \$142,000 of accrued warranties during the quarter ended March 31, 2012. During the quarter ended June 30, 2012, the Company reversed accrued sales and marketing service liabilities of approximately \$350,000 because the liability was extinguished with the closing of the 2012 Termination Agreement. During the year ended December 31, 2012, we sold all laser systems purchased under this arrangement at margins consistent with our comparable laser products.

Industry Background

General

Dental procedures are performed on hard tissue, such as bone and teeth, and soft tissue, such as gum and other oral tissue.

A 2007 American Dental Association (ADA) Survey of Dental Services Rendered (the ADA Study) has 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. The ADA study also indicated that more than 1.2 million soft tissue procedures are performed annually in the United States. Soft tissue procedures include operations such as gum line alteration. According to statistics compiled in the ADA s study, over 90% of hard tissue procedures and 60% of soft tissue procedures in the United States are performed by general dentists and the rest are performed by oral surgeons, endodontists, periodontists, and other specialists.

The ADA estimated that the demand for dental services in the United States will continue to grow due to population growth and the increased awareness of the benefits associated with preventive dentistry in reducing the incidence of oral and systemic disease.

We believe there is a growing awareness among consumers of the value and importance of a healthy smile and its connections to overall systemic health. As such, the dental industry has entered an era of growth and consideration of advanced technologies that allow dentists to perform simple or complex cosmetic dental procedures with minimal trauma, improved patient acceptance and clinically superior results. We believe our product offerings correspond with this trend, and we expect incremental growth from these pressures in the marketplace.

Traditional Dental Instruments

Dentists and other specialists choose from a variety of instruments depending on the tissue involved and the type of procedure. Most procedures require the use of multiple instruments to achieve the desired result.

High Speed Drills. Most dentists use high speed drills for hard tissue procedures, such as preparing cavities for filling and gaining access for performing root canals or shaving and 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 to the patient s dental structure. The trauma caused to the surrounding tissues can lead to increased 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. Because many dentists do not recommend anesthetizing more than one or two quadrants of the mouth in a single session, patients may need to return several times to complete their treatment plan. Further, based on the results of several recent studies, autoclaving fails to completely decontaminate dental burs and approximately 15% of these sterilized burs carry pathogenic micro-organisms, which may be transferred from patient to patient.

Table of Contents

Cutting Instruments. Soft tissue procedures, such as reshaping gum lines and grafting on new gum tissue, are typically performed by oral surgeons or periodontists using scalpels, scissors, and other cutting tools. Due to the pain and discomfort associated with procedures performed with these instruments, most soft tissue procedures require the use of local anesthetic which results in numbness and discomfort, and often require stitches. The use of scalpels, scissors, and other cutting tools typically cause bleeding, post-operative swelling, and discomfort. 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 patients taking blood-thinning medications.

Film Radiography Equipment. Since the early twentieth century, dentists have 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, and 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 abilities of doctors to enhance or further manipulate images for easier and more accurate analysis and treatment planning. Furthermore, one of the most critical limitations of film is that it is restricted to two-dimensional images, which can potentially lead to misdiagnosis.

Alternative Dental Instruments

Alternative technologies have been developed over the years to address the problems associated with traditional methods used in dentistry. Most alternatives have addressed either hard or soft tissue applications but not both. The predominant alternative technologies are discussed below.

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

Our Solution

Due to the limitations associated with traditional and alternative dental instruments, we believe there is a large market opportunity for all-tissue dental laser systems that provide superior clinical results and help reduce the trauma, pain, and discomfort associated with dental procedures. We also believe there is a large market opportunity for digital radiography systems that improve practice efficiency and accuracy of diagnosis, leading to superior treatment planning, increased practice revenue, and healthier outcomes for patients.

Our Waterlase systems precisely cut hard tissue and soft tissue with minimal or no damage to surrounding tissue and dental structure. Our Diode systems are designed to complement the Waterlase systems, and are used 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.

Table of Contents

The Biolase DaVinci Imaging and Cefla NewTom products are state-of-the-art digital radiography systems that provide both two- and three-dimensional X-ray images as well as intraoral color images that allow doctors to visualize and manipulate significantly more information than previously available with film, without the time delay of film development or cost associated with chemicals and the film itself. These imaging systems have been designed to produce the highest quality images while exposing patients to the least amount of radiation necessary. The Trios intra-oral CAD/CAM scanning product offers diversity in our imaging product line with spray-free, high-speed, 3-D impression capture as well as touch screen and online lab communication capabilities.

A small percentage of dental professionals worldwide currently use lasers. Our laser systems are more expensive than traditional dental tools; however, we believe that the significant clinical advantages of our systems, patient benefits, the potential return on investment that our systems offer practitioners, and the options available to finance the purchase of our systems will enable us to continue to penetrate the global dental market. Laser technologies with similar patient benefits have become standard of care in ophthalmology, dermatology, and other medical specialties. When combined with better information digital imaging, dental lasers will give the doctor the best treatment options to perform more procedures in a minimally invasive manner. This combination of lasers and digital imaging systems makes us the only company to offer high-technology solutions for the diagnosis, treatment planning, and delivery of treatment, in the most minimally invasive manner possible: the Biolase Total Technology Solution .

We believe the demand for our systems will continue to expand as we increase awareness of the benefits to patients and dental professionals.

Benefits to Dental Professionals

Expanded range of procedures and revenue opportunities. Our laser systems often allow general dentists to perform surgical and cosmetic procedures that they are unable or unwilling to perform with conventional methods, and which would typically be referred to a specialist. Our systems allow dentists to perform these procedures easily and efficiently, increasing their range of skills, professional satisfaction, and revenues.

Additional procedures through increased information and efficiency. Our digital imaging systems allow dentists to diagnose and discover cases that they might not be able to detect with film images and/or two-dimensional images, thereby giving them the ability to offer more treatment options for patients. Our laser systems can shorten and reduce the number of patient visits, providing dental professionals with the ability to service more patients. For hard tissue procedures, our Waterlase systems can reduce the need for anesthesia, which enables the dental practitioner to perform multiple procedures in one visit. For soft tissue procedures, the Waterlase and Diode systems allow tissue to be cut more precisely and with minimal bleeding when compared to traditional tools such as scalpels and electrosurge systems. We have FDA clearance for treatment protocols including Deep Pocket Therapy with New Attachment and subgingival calculus removal using the Waterlase System and the patented Radial Firing Perio Tip. This is a non-surgical alternative treatment for moderate to advanced gum disease, the leading cause for tooth loss for adults over age 35 and a condition impacting more than half of Americans over age 55. In addition, the Epic and iLase systems can be used to quickly perform teeth whitening with our proprietary whitening gel and to provide temporary pain relief from myofascial disorders.

Increased loyalty and expanded patient base. We believe the improved patient comfort and convenience offered by our laser systems and the reduction in chair time and radiation exposure of our digital imaging systems will help improve patient retention, attract new patients, increase revenue per patient, increase demand for elective procedures, increase acceptance of treatment plans, and increase word-of-mouth referrals.

Fewer post-operative complications. By providing more complete and accurate information, our digital imaging systems make it possible for the doctor to determine the optimal diagnosis and treatment plan.

Table of Contents

Our laser systems can then be used to reduce trauma, swelling, and general discomfort of the patient, resulting in fewer post-operative complications that require follow up treatment. In addition, our laser systems effectively reduce the risk of cross-contamination that can occur with traditional dental tools. These factors make it possible for practitioners to devote time to new cases, rather than treating complications from prior procedures.

Benefits to Patients

Comfort. The Waterlase system is able to perform various types of dental procedures without causing the heat, vibration, microfractures, trauma, or pressure associated with traditional dental methods, without cross-contamination. Further, in many cases procedures can be performed without the need for local anesthesia.

Convenience. Our Waterlase system does not require anesthesia in many cases, which allows dental practitioners to perform procedures in multiple quadrants of the mouth during a single office visit. Digital images are available almost immediately, so patients will not have to spend extra time in the dental chair waiting for film to be developed and doctors are more efficient. Combined with the diode lasers, these systems offer a variety of solutions for patients.

Reduced trauma. The Waterlase system avoids the thermal heat transfer, vibration, and grinding action associated with high speed dental drills. As a result, our systems can result in less trauma, swelling, bleeding, and general discomfort to the patient.

Broader range of available procedures. Due to the improved comfort and convenience of our Waterlase system, we believe patients are more likely to consider cosmetic and other elective procedures that would generally be time consuming and uncomfortable, including osseous crown lengthening, periodontal surgeries, and numerous other procedures. Since digital images are displayed on computer monitors, doctors can make treatment planning a more personal experience with patients. We believe that this will lead to greater patient case acceptance.

Business Strategy

Our objectives are to increase our leadership position in the dental laser market, to establish our laser systems as essential tools in dentistry, and to leverage our existing technology platform into other medical markets where it can provide significant improvements over existing standards of care. Our business strategy consists of the following key elements:

Increasing awareness of our laser systems among dental practitioners and patients. We intend to further penetrate the dental market by educating dental practitioners and patients about the clinical benefits of Waterlase Dentistry. We plan to increase adoption of our laser systems by dental practitioners through our continued participation in key industry trade shows, the World Clinical Laser Institute® (WCL) (which we founded in 2002), dental schools, and other educational forums. We also intend to market our systems to dental practitioners through our laser specialists and advertising. We continue to explore marketing efforts aimed directly at patients.

Expanding sales and distribution capabilities. In the United States and Canada, we distributed our products directly to dental practitioners utilizing a direct sales force through August 2006. From September 2006 to September 2010, we distributed our products in North America exclusively through HSIC, a leading U.S. dental products and equipment distributor. In September 2010, we changed our relationship with HSIC from an exclusive to a non-exclusive distributor of our products in North America and once again sold directly to dental practitioners utilizing a direct sales force. During 2012, we augmented our outside direct sales force by establishing an inside sales organization. The inside sales force is located at our corporate headquarters and is comprised of sales representatives and lead generators who work in partnership with the outside sales team to maximize sales by leveraging the existing installed customer base. In addition to our direct sales force in North America, we also have distribution agreements with various independent distributors to distribute our products in the United

Table of Contents

States, Canada, and various countries in Europe, the Middle East, Latin America, and Asia-Pacific. We are continuing to develop an infrastructure to support growth in sales and marketing both domestically and internationally. This infrastructure includes product management, information technology systems, and personnel to manage our sales force, compile sales and marketing data, and better serve our customers and non-exclusive distributors.

Expanding product platform and applications. We plan to expand our product line and product applications by developing product enhancements and new laser technologies including new products for use in the medical community. To this end, we launched the Epic in September 2012 which improves and expands on certain capabilities previously offered by the Diolase 10 which was launched in late 2009 for use in the medical specialty markets, including sports medicine, orthopedics, podiatry, physical therapy, and chiropractics. We also have an objective to increase our sales of disposable products that are used by dental practitioners when performing procedures using our dental laser systems. Additionally, we may strategically acquire complementary products and technologies. In February 2011, we established a new division, Biolase DaVinci Imaging, to distribute state-of-the-art extra-oral and intra-oral dental imaging devices. We began selling these imaging devices in the second half of 2011. Additionally, in early 2012, we began distributing the NewTom VGi 3-D cone beam and in late 2012 we began distributing the Trios intra-oral scanning system which expands our imaging product line and offers customers a wider and more comprehensive choice of configurations and range of performance.

Expanding our Er,Cr:YSGG and 940 nm diode technologies into the medical field. Our Waterlase and Diode lasers and their delivery systems and accessories have applications in many other medical and veterinary specialties, including ophthalmology, orthopedics, sports medicine, dermatology, and podiatry. We currently hold a strong patent position which is complemented by our FDA-cleared general indications for use of our lasers with ocular tissue. Our patented Er,Cr:YSGG Waterlase technology has the potential to address several areas in ophthalmology including dry eye, glaucoma, and presbyopia, as well as several other major medical applications in dermatology, cosmetic surgery, orthopedics, and urology. During 2011 we established a new subsidiary, Occulase, Inc., for the purpose of consolidating our ophthalmologic-specific intellectual property, which includes over 30 U.S. and international patents and pending patents, as we continue our efforts to expand in this area. We recently launched the Occulase website at www.occulase.com to further our marketing efforts of this laser technology. We plan to commercialize or license these applications in the future and may use distribution partners or other strategic partnerships to enter into these markets.

Continuing high quality manufacturing and customer service. Our manufacturing operations are focused on producing high quality dental laser systems. We intend to continually develop and refine our manufacturing processes to increase both production efficiencies and product quality. We provide high quality maintenance and support services through our support hotline and dedicated staff of in-house and field service personnel. Additionally, we maintain a network of factory-trained service technicians to provide maintenance and support services to customers in markets within and beyond North America.

Strengthening and defending technology leadership. We believe our proprietary Waterlase system and YSGG Laser technology represent significant advancements in dentistry. We will pursue the protection of our intellectual property rights by expanding our existing patent portfolio in the United States and internationally. We intend to strategically enforce our intellectual property rights worldwide.

Strengthening training and development of our laser users. In 2012 we opened our technology and training center at corporate headquarters. The center provides introductory and specialized training sessions for dental professionals seeking proficiency and certification training utilizing our products, and will also be used for ongoing training and clinical education for both outside and inside sales teams and our service professionals. We also have established access to several training facilities around the U.S. through our network of key-opinion leaders and trainers.

Table of Contents

Products

Our Waterlase Dentistry consists of two principal product lines: Waterlase systems and Diode systems. We developed the Waterlase and Diode systems through our own research and development, as well as intellectual property obtained through various acquisitions. During the second half of 2012, we introduced the Epic diode laser system which increases our customer base by providing an exceptional laser at an attractive value proposition. During the second half of 2011, we introduced the Biolase DaVinci Imaging line of imaging products which enabled us to offer high quality digital diagnostic solutions to complement the minimally invasive dental treatment solutions offered by our Waterlase and Diode dental systems. In 2012, we added the distribution of the NewTom 3-D cone beam and Trios intra-oral CAD/CAM scanning system which expanded our imaging product line and provides dental customers with a wider and more comprehensive choice of configurations and range of performance. The integration of our laser products with imaging offers dental professionals the Total Technology Solution which provides imaging capabilities for early diagnosis and minimally invasive treatment with our Waterlase and Diode laser technologies.

Waterlase systems. Our all-tissue Waterlase dental laser systems currently consist of the Waterlase iPlus, the Waterlase MD Turbo, and the Waterlase MDX 300 and 450, both introduced in February 2012. Each of these systems is designed around our patented YSGG Laser technology that refers to the unique laser crystal used in the Waterlase system, which contains the elements erbium, chromium and yttrium, scandium, gallium and garnet (Er, Cr: YSGG). This unique crystal laser produces energy with specific absorption and tissue interaction characteristics optimized for dental applications. HydroPhotonics refers to the interaction of YSGG lasers with water to produce energy to cut tissue. It is minimally invasive and can precisely cut hard tissue, such as bone and teeth, and soft tissue, such as gums or skin, without the heat, vibration, or pressure associated with traditional dental treatments. By eliminating heat, vibration, and pressure, our Waterlase systems reduce and, in some instances, eliminate the need for anesthesia and also result in faster healing times versus traditional methods of treatment.

The Waterlase systems incorporate an ergonomic handpiece and an extensive control panel located on the front of the system with precise preset functionality 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 office.

The original Waterlase MD released in 2005 features white light-emitting diode (LED) handpiece illumination, a full color touch screen improving user friendliness (with a built in user Help system), a refined water spray that improves cutting, and a Windows CE operating system. In 2008, we introduced a new clinical procedure for endodontic root canal disinfection with radial firing tips. The Waterlase MD Turbo All-Tissue Dental Laser System was introduced in the first quarter of 2009 and increased the cutting speed compared to the original Waterlase MD. In 2009, we also obtained FDA clearance for a new treatment protocol called Deep Pocket Therapy with New Attachment using the Waterlase MD and the patented Radial Firing Perio Tip. This is a non-surgical alternative treatment for moderate to advanced gum disease, the leading cause of tooth loss for adults over 35 and a condition impacting more than half of Americans over age 55. The procedure assists in new attachment and subgingival calculus removal, and in most cases provides deep pocket treatments in a single visit without the use of a scalpel, stitches, or the conventional cutting of the gums. The Waterlase iPlus, introduced in January 2011, is our most advanced and powerful, yet most intuitive, dual-wavelength all-tissue dental laser system. It delivers all the benefits of our other Waterlases, but with more power, versatility, and ease of use, including an intuitive user interface and a significant increase in cutting speed that is comparable to a high speed drill. The Waterlase iPlus also incorporates the iLase wireless diode laser that can be utilized for unexpected soft-tissue cases in an adjacent treatment room, controlling bleeding, and temporary pain relief.

Diode systems. Our Diode laser systems in dentistry currently consist of the Epic and iLase, semiconductor diode lasers that perform soft tissue, hygiene, cosmetic procedures, teeth whitening, and temporary pain relief.

Table of Contents

In February 2010, we introduced our iLase diode laser system, the first wireless, affordable dental diode laser that provides minimally invasive solutions for the most common everyday soft tissue surgical and hygiene procedures. Featuring patent-pending finger switch activation, battery power, our unique 940 nm wavelength, and ComfortPulse® cutting modality, we believe the wireless and highly portable iLase is a perfect complement for every dental operatory. In September 2012, we introduced our new Epic diode laser system, a portable touch screen system with applications in soft tissue surgery, dental hygiene, teeth whitening, and temporary pain relief. The iLase and Epic are FDA cleared in the United States and CE mark-approved in Europe.

Imaging systems. Our imaging systems include licensed state-of-the-art extra-oral and intra-oral dental digital imaging devices. Our expansion into digital imaging systems enables us to offer high quality diagnostic solutions to complement the minimally invasive dental treatment solutions offered by our Waterlase and Diode systems. We now provide both high-precision intuitive diagnosis and treatment planning solutions, fundamental to the delivery of quality dentistry, together with truly advanced laser treatment solutions thereby delivering, we believe, the best biological and therapeutic results for dentists and patients. Our Imaging systems include the Cefla NewTom VGi and Biolase DaVinci D3D, 3-D Cone Beam Computed Tomography (CBCT) devices. We are currently selling these products as a distributor under the manufacturer's FDA 510(k) clearance. Our 3-D CBCT devices produce stable and high quality 3-D images with low levels of radiation critical features in dental implant, endodontic, orthodontic, and oral surgery cases.

The first CBCT system introduced to the dental market in 1996 was a NewTom. Since that time, the NewTom brand has been synonymous with providing the clearest, sharpest, and highest quality three-dimensional images. The NewTom VGi is a small-footprint CBCT system that offers medical grade imaging technology at a fraction of the cost and radiation exposure typically associated with medical CT equipment. In addition to producing up to 50% higher image resolution with medical grade rotating anode technology, its proprietary SafeBeam technology automatically adjusts radiation dosage to ensure patient safety.

3Shape Trios CAD/CAM Imaging Systems. 3Shape unveiled this system at the International Dental Show in Germany in 2011. We immediately recognized this system as an advanced dental imaging product designed with technical solutions for the dental practitioner and comfort for patients. The 3Shape system offers a spray-free scanning device for optimal accuracy and patient comfort, high speed technology with accurate digital impression-taking with up to 1000 3-D pictures, a touchscreen interface with live 3-D visualization, online communication capability with labs, and additional benefits. We are currently selling this product as a distributor under the manufacturer's regulatory market clearances.

Medical systems. Our Medical systems include the Diolase 10 Diode Laser for which we received FDA 510(k) clearance in April 2009 to use in our ezlase platform for both dental and medical pain relief applications. In late 2009 we broadened our product scope to include the use of lasers in a variety of health care and therapeutic markets outside of dentistry. The Diolase 10 was launched with a patented handpiece for therapeutic applications, including temporary pain relief, topical heating for the purpose of temporarily relieving minor muscle and joint pain and stiffness, minor arthritis pain, muscle spasm, minor sprains and strains, and minor muscular back pain; temporarily increasing local blood circulation; and temporarily relaxing muscles. The Diolase 10 was our first strategic expansion into the medical market (which includes sports medicine, orthopedics, podiatry, physical therapy, and chiropractics). We initially focused on the chiropractic market and in 2010 we expanded into physical therapy and sports medicine and introduced the Deep Tissue Handpiece. A continuation of our expansion into the medical market is also realized in our Epic diode laser, which was launched in late 2012 and has improved portability and value proposition with applications including temporary pain relief. The Epic V-Series launching in 2013 is based on the Epic platform with software and delivery adaptations enabling a wide range of veterinary applications, including surgical, dental, and pain therapy procedures. We anticipate further expansion of the Epic diode laser into additional medical markets in 2013.

Table of Contents

Related Accessories and Disposable Products

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

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 while our Diode systems warranty is for a period of up to two years from the date of sale to the end-user by us or a distributor. Waterlase systems sold internationally are generally covered by a warranty against defects in material and workmanship for a period of sixteen months while our Diode systems warranty period is up to twenty eight months from date of sale to the international distributor. Our warranty covers parts and service for sales in our North American territories and parts only for international distributor sales. In North America, we sell service contracts to our end users that cover the period after the expiration of our standard warranty coverage for our laser systems. Extended warranty coverage provided under our service contracts varies by the type of system and the level of service desired by the customer. Products or accessories remanufactured, refurbished, or sold by authorized parties, voids all warranties in place for such products and exempts us from liability issues relating to the use of such products. We do not offer warranties on imaging products which are covered by manufacturer s warranties.

Insurance

We maintain product liability insurance on a claims-made-and-reported basis with a limit of \$10 million per occurrence and \$10 million in the aggregate for all occurrences. The insurance is subject to various standard coverage exclusions, including damage to the product itself, losses from recall of our product, and losses covered by other forms of insurance such as workers compensation. We cannot be certain that we will be able to successfully defend any claims against us, nor can we be certain that our insurance will cover all liabilities resulting from such claims. In addition, we cannot assure you that we will be able to obtain such insurance in the future on terms acceptable to us, or at all.

Manufacturing

Our strategy is to manufacture products in-house when it is efficient for us to do so. We currently manufacture, assemble, and test all of our products 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, manufacturing, installation, and servicing of our products. In addition, our U.S. facility is registered with the FDA and is compliant 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: handpieces, laser crystals, and fiber components are each supplied by separate single-source suppliers. In recent years, we have not experienced material delays from the suppliers of these three key components. However, in the event that we experience an unexpected interruption from a single source supplier, manufacturing delays, re-engineering, significant costs, and sales disruptions could occur, any of which could have a material adverse effect on our operations. We are currently in the process of identifying

Table of Contents

and qualifying alternate source suppliers for our key components, including but not limited to those noted above. There can be no assurance, however, that we will successfully identify and qualify an alternate source supplier for any of our key components or that we could enter into an agreement with any such alternate source supplier on terms acceptable to us.

Marketing and Sales

Marketing

We currently market our laser systems in the United States and worldwide. Our marketing efforts are focused on increasing brand and specific product awareness among dental practitioners. We continue to explore methods to increase awareness of the benefits of our products by marketing directly to patients.

Dental Practitioners. We currently market our laser systems to dental practitioners through regional, national and international trade publications, educational events, individual meetings, the internet, and seminars. We also use brochures, direct mailers, press releases, posters, and other promotional materials, as well as print and electronic media news coverage. In 2010, we introduced the Biolase Store for online purchase of lasers, consumables, accessories, and service contracts in North America. In 2002, we founded the WCLI to formalize our efforts to educate and train dental practitioners in laser dentistry. The WCLI conducts and sponsors educational programs domestically and internationally for dental practitioners, researchers, and academicians, including one, two, and three-day seminars and training sessions involving in-depth presentations on the use of lasers in dentistry. In addition, we have developed relationships with research institutions, dental schools, and laboratories which use our products in training and demonstrations. We believe these relationships will increase awareness of our products. In 2012 we formalized a 5 year agreement with Professor Norbert Gutknecht and the Aachen Center for Laser Dentistry (AALZ), the acknowledged leader in dental laser education since its founding in 1992. We expect the AALZ and related World Academy for Laser Education in Dentistry Network (WALED) will expand the availability of postgraduate advanced wavelength clinical laser education to more than 40 countries while also taking major steps toward standardizing laser dental education for all our owners worldwide.

Chiropractors, Sports Medicine. We market to chiropractors, physical therapists, and other pain management specialists through trade advertising, seminars, and trade shows. Our marketing activities are primarily executed by our network of independent sales representatives who are managed by our internal sales management team.

Patients. We market the benefits of our laser systems directly to patients through marketing and advertising programs, including the internet, social networks, print and broadcast media, local television news and radio spots, as well as product placements of our laser systems on television programs. We believe that making patients aware of our laser systems and their benefits will increase demand for our products.

Sales

We currently sell our products primarily to dentists in general practice through our direct sales force and our distributor network. The majority of the dentists in the United States and the majority of our end-user customers are sole practitioners. We expect our laser systems to continue to gain acceptance among periodontists, endodontists, oral surgeons, and other dental specialists as they become better aware of the clinical benefits and new treatment options available through the use of our laser systems. Outside of the dental market, we expect that our initial sales of lasers will be to chiropractors, physical therapists, and other pain management specialists, as well as the veterinary market.

Table of Contents

The following table summarizes our net revenues by category for the years ended December 31, 2012, 2011, and 2010 (dollars in thousands):

	Years Ended December 31,					
	2012(1)		2011(2)		2010(2)	
Waterlase systems	\$ 36,041	63%	\$ 29,288	60%	\$ 8,241	32%
Diode systems	6,307	11%	9,172	19%	7,907	30%
Imaging systems	3,365	6%	238	0%		0%
Consumables and other	5,954	10%	5,236	11%	4,234	16%
Services revenue	5,524	10%	4,485	9%	4,198	16%
Products and services revenue	57,191	100%	48,419	99%	24,580	94%
License fees and royalties	165	0%	439	1%	1,645	6%
Net revenue	\$ 57,356	100%	\$ 48,858	100%	\$ 26,225	100%

(1) The summary of net revenue includes the non-recurring event of approximately \$1.1 million, which if excluded would result in Waterlase systems revenue of \$37.2 million and 64%, total laser systems revenue of \$43.5 million and 74%, and net revenue of \$58.5 million and 100% for the year ended December 31, 2012, and the remaining categorical percentages would decrease correspondingly.

(2) Certain amounts have been reclassified to conform to the current year presentation. Net revenue by geographic location based on the location of customers was as follows (in thousands):

	Years Ended December 31,		
	2012(1)	2011	2010
United States	\$ 40,524	\$ 32,782	\$ 16,900
International	16,832	16,076	9,325
	\$ 57,356	\$ 48,858	\$ 26,225

(1) The net revenue by geography includes the non-recurring event of \$1.1 million, which if excluded would result in U.S. net revenue of \$41.7 million, for the year ended December 31, 2012. International revenue accounts for a significant portion of our total revenue and accounted for approximately 29%, 33%, and 36% of our net revenue in 2012, 2011, and 2010, respectively. No individual country outside the United States represented more than 10% of net revenue during the years ended December 31, 2012, 2011, and 2010.

For financial information about our long-lived assets, see Note 2 and Note 9 to the *Notes to the Consolidated Financial Statements - Summary of Significant Accounting Policies* and *Segment Information*.

North American Sales. Effective September 1, 2006, we commenced selling our products into the U.S. and Canadian markets exclusively through HSIC. As part of this agreement, HSIC purchased products from us at negotiated distributor pricing, and invoiced the customer directly at the customer's purchase order price.

On September 23, 2010, we entered into a Distribution and Supply Agreement with HSIC, effective August 30, 2010, (the "D&S Agreement"), which terminated all prior agreements with HSIC. Under the D&S Agreement, we granted HSIC certain non-exclusive distribution rights in North America and several international markets with respect to our dental laser systems, accessories, and related support and services in certain

circumstances. In addition, we granted HSIC exclusivity in selected international markets subject to review of certain performance criteria. In connection with the D&S Agreement, HSIC placed two irrevocable purchase orders totaling \$9 million for our products. The first purchase order, totaling \$6 million, was for the purchase of iLase systems and was fully satisfied during the first quarter of 2011. The second purchase order, totaling \$3 million, was for the purchase of a combination of laser systems and was fully satisfied during the third quarter of 2011. The D&S Agreement granted HSIC a security interest in our inventory and assets, including our intellectual property.

Table of Contents

On April 12, 2012, we completed a transaction with HSIC (the 2012 Termination Agreement) whereby we purchased HSIC's inventory of Waterlase MD Turbo laser systems for approximately \$1.1 million and HSIC released its liens on our assets, including our inventory and intellectual property. As part of the 2012 Termination Agreement, we reacquired 153 MD Turbo laser systems at a cost well below market. Pursuant to the terms of the transaction, the entire purchase price was paid by offsetting certain accounts receivable currently due from HSIC from sales made in the normal course of business. None of the funds used to offset the purchase price were related to the original sales of the MD Turbo laser systems that were purchased. As a result of the transaction, we are no longer required to fulfill certain future service obligations and, accordingly, derecognized approximately \$155,000 of accounts receivable due from HSIC related to support services previously provided and approximately \$142,000 of accrued warranties during the quarter ended March 31, 2012. During the quarter ended June 30, 2012, the Company reversed accrued sales and marketing service liabilities of approximately \$350,000 because the liability was extinguished with the closing of the 2012 Termination Agreement. During the year ended December 31, 2012, the Company sold all laser systems purchased under this arrangement at margins consistent with our comparable laser products.

International Sales. Through 2008, we sold products in Germany, Spain, Australia, and New Zealand through direct sales forces from our sales and service locations in those respective countries. In the first quarter of 2009, we transitioned sales in these countries from direct sales to distribution through HSIC and a network of other independent distributors. 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 and distributors for cause or non-performance. In some select territories we have granted certain distributors the right to be our exclusive distributor in that territory. These distributors are generally required to satisfy certain minimum purchase requirements to maintain their exclusivity. In 2011, we began selling our products directly to end users in Germany and other countries where we have non-exclusive distribution arrangements. In 2012, we began selling our products directly to end users in India and neighboring countries.

Customer Concentration. From 2007 through 2010, we were substantially dependent on our distributor, HSIC, for purchases of our products. For the years ended December 31, 2012, 2011, and 2010, sales to HSIC worldwide accounted for approximately 3%, 19%, and 38%, respectively, of our net revenue. HSIC no longer distributes our products on an exclusive basis. Instead we sell our products through our direct sales force and non-exclusive distributor relationships. However, our relationship with HSIC remains significant and they are our largest non-exclusive distributor in the U.S. and certain other countries.

Customer Service. We provide maintenance and support services through our support hotline, field and factory service technicians, and our network of factory-trained third-party service technicians. We currently provide maintenance and support services in the United States and Canada through our employee service technicians. We maintain a network of service technicians who provide maintenance and support services in all other countries where we do business. 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. Many dentists finance their purchases through third-party leasing companies, banks, or lessors. In the United States and Canada, third-party customers enter into a lease with a lessor who purchases the product from us or one of our distributors. We are not party to these leases, so if the customer agrees to pay the lessor in installments, we do not bear the credit risk that the dentist might not make payments. The leasing companies and banks 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 at the end of the lease.

Seasonality. Historically, we have experienced fluctuations in revenue from quarter to quarter due to seasonality. Revenue in the first quarter typically is lower than average and revenue in the fourth quarter typically is stronger than average due to the buying patterns of dental professionals. 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.

Table of Contents

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 research and product development group consists of approximately 13 individuals with medical device and laser development experience, including two Ph.Ds. During the years ended December 31, 2012, 2011, and 2010, our engineering and product development expenses totaled approximately \$4.7 million, \$4.3 million and \$3.8 million, respectively. Our current engineering and product development activities are focused on improving our existing products and technology and extending our product range in order to provide dental practitioners and patients with less painful and clinically superior laser systems. Some examples of the improvements we are pursuing for our dental lasers include faster cutting speed, ease of use, less need for anesthesia injections, interconnectivity, and an expanded portfolio of consumable products for use with our laser systems.

We also devote engineering and development resources toward markets outside of dentistry in which we might exploit our technology platform and capabilities. We believe our laser technology and developments capabilities could be applicable in several other medical markets, including ophthalmology, orthopedics, podiatry, pain management, aesthetics/dermatology, veterinary, and consumer products.

In May 2010, we entered into a License Agreement (the "2010 P&G Agreement") with Procter & Gamble Company ("P&G"), which replaced an existing license agreement between us and P&G (the "2006 P&G Agreement"). Pursuant to the 2010 P&G Agreement, we agreed to continue granting P&G an exclusive license to certain of our patents to enable P&G to develop products aimed at the consumer market and P&G agreed to pay royalties based on sales of products developed with such intellectual property. The prepaid royalty payments previously paid by P&G were applied to the new exclusive license period from January 1, 2009 through December 31, 2010. At this time, we had deferred royalty revenue totaling \$1.9 million from the 2006 P&G Agreement. The 2010 P&G Agreement permitted us to recognize \$1.5 million in royalty revenue for the year ended December 31, 2010 related to the 2009 and 2010 exclusivity period. As of December 31, 2010, \$375,000 remained in long term deferred revenue. On June 28, 2011, we entered into an amendment to the 2010 P&G Agreement (the "2011 P&G Amendment") which extended the effective period for the 2010 P&G Agreement from December 31, 2010 through June 30, 2011, and resulted in us recognizing the previously deferred \$375,000 of revenue as royalty revenue during the quarter ended June 30, 2011.

The 2011 P&G Amendment also provided that effective January 1, 2011, P&G's exclusive license to our patents converted to a non-exclusive license unless P&G paid us a license payment in the amount of \$187,500 by the end of the third quarter of 2011, and at the end of each quarter thereafter, throughout the term of the 2010 P&G Agreement. As a result of P&G not making any payments to us in the third or fourth quarters of the year ended December 31, 2011, their license converted to a non-exclusive license. We are currently engaged in an active collaboration with P&G to commercialize a consumer product utilizing our patents.

Intellectual Property and Proprietary Rights

We believe that in order to maintain a competitive advantage in the marketplace, we must develop and maintain protection of the proprietary aspects of our technology. We rely on a combination of patents, trademarks, trade secrets, copyrights and other intellectual property rights to protect our intellectual property. We have developed a patent portfolio internally, and to a lesser extent through acquisitions and licensing, that covers many aspects of our product offerings. As of December 31, 2012, we had approximately 160 issued patents and 150 pending patent applications in the United States, Europe and other countries around the world. 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: five in 2013, four in 2014, 21 in 2015, 18 in 2016, and six in 2017,

Table of Contents

with the majority having expiration dates ranging from 2018 to 2032. With approximately 150 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.

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

Competition

We compete with a number of companies that market traditional dental products, such as dental drills, as well as other companies that market laser technologies in dental and other medical markets. In the domestic hard tissue dental market, we believe our Waterlase systems primarily compete with laser systems manufactured by Lares Dental Research, the U.S. distributor of Fotona d.d. In the international market, our Waterlase systems compete primarily with products manufactured by several companies, including Fotona d.d., KaVo Dental GmbH, Lambda SpA, J Morita Manufacturing Corp., Syneron Medical Ltd, and Deka Laser Technologies, Inc. Our Waterlase systems also compete with non-laser based systems, including traditional high and low-speed dental drills and air abrasion systems that are used for dental procedures.

Our Diode laser systems, including the Epic, ezlase and iLase, compete with other semiconductor diode lasers manufactured by Ivoclar Vivadent, Inc., Sirona Dental Systems, Inc., KaVo Dental GmbH, AMD Lasers, LLC, (which was acquired by Dentsply, Inc. in July 2011), ARC, GIGA, Zila and DenMat, as well as with scalpels, scissors and a variety of other cutting tools that have been traditionally used to perform soft tissue procedures. We also expect other domestic and foreign laser manufacturers to enter this market in the future. Our new Epic and iLase lasers were specifically designed to compete in this growing market with key differentiating features and performance. Unlike the Epic and ezlase, none of the lasers in this category have FDA clearance for use in both pain management therapy and teeth whitening, in addition to a full range of soft tissue indications. Our Epic and ezlase system 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.

Traditional and commonly used cutting tools are less expensive for performing dental procedures. For example, a high speed handpiece or an electrosurge device, not including the cost of replacement disposables, can be purchased for less than \$2,500 each. In addition, our systems are not designed to perform certain functions that high speed drills can perform, such as cutting metal fillings and certain polishing and grinding functions. Our systems are not intended to replace all of the applications of the high speed drill and a drill may be required for certain procedures.

We believe that the principal competitive factors for companies that market laser technologies in the dental and other medical markets include:

acceptance by leading dental 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.

Edgar Filing: BIOLASE, INC - Form 10-K

Some of the manufacturers that develop competing laser systems 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 laser systems.

Table of Contents

Because of the large size of the potential market for our products, we anticipate that new or existing competitors may develop competing products, procedures, or clinical solutions which 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, loss of market share, or may render our products obsolete.

Government Regulation

FDA's Premarket Clearance and Approval Requirements

Unless an exemption applies, each medical device that we wish to market in the U.S. must first receive either 510(k) clearance, by filing a 510(k) pre-market notification, or PMA approval, by filing a Premarket Approval Application (PMA) from the FDA pursuant to the Federal Food, Drug, and Cosmetic Act. The FDA's 510(k) clearance process usually takes from four to twelve months, but it can take longer. The process of obtaining PMA approval is much more costly, lengthy, and uncertain. It generally takes from one to three years or even longer. We cannot be sure that 510(k) clearance or PMA approval will ever be obtained for any product we propose to market.

The FDA decides whether a device must undergo either the 510(k) clearance or PMA approval process based upon statutory criteria. These criteria include the level of risk that the agency perceives is associated with the device and a determination of whether the product is a type of device that is similar to devices that are already legally marketed. Devices deemed to pose relatively less risk are placed in either Class I or II, which generally requires the manufacturer to submit a pre-market notification requesting 510(k) clearance, unless an exemption applies.

Class I devices are those for which safety and effectiveness can be assured by adherence to the FDA's general regulatory controls (General Controls) for medical devices, which include compliance with the applicable portions of the FDA's Quality System Regulation (QSR) facility registration and product listing, reporting of adverse medical events, and appropriate, truthful and non-misleading labeling, advertising, and promotional materials. Some Class I devices also require premarket clearance by the FDA through the 510(k) premarket notification process.

Class II devices are subject to the FDA's General Controls, and any other special controls as deemed necessary by the FDA to ensure the safety and effectiveness of the device. Premarket review and clearance by the FDA for Class II devices is accomplished through the 510(k) premarket notification procedure. All of our current regulated devices are Class II devices and all have qualified for 510(k) clearance.

Class III devices are those devices deemed by the FDA to pose the greatest risk, such as life-sustaining, life-supporting, or implantable devices, or deemed not substantially equivalent to a legally marketed predicate device. The safety and effectiveness of Class III devices cannot be assured solely by the General Controls and the other requirements described above. These devices almost always require formal clinical studies to demonstrate safety and effectiveness and must be approved through the premarket approval process described below. Premarket approval applications, and supplemental premarket approval applications, are subject to significantly higher user fees under Medical Device User Fee and Modernization Act of 2002, or MDUFMA, than are 510(k) premarket notifications, and generally take much longer for the FDA to review.

To obtain 510(k) clearance, a company must submit a premarket notification demonstrating that the proposed device is substantially equivalent in intended use and in technological and performance characteristics to a legally marketed predicate device that is either in Class I, Class II, or is a Class III device that was in commercial distribution before May 28, 1976, for which the FDA has not yet called for submission of a PMA application. Pursuant to the MDUFMA and the MDUFMA II provisions of the Food and Drug Amendments Act of 2007, unless a specific exemption applies, 510(k) premarket notification submissions are subject to user fees. After a device receives 510(k) clearance, any modification that could significantly affect its

Table of Contents

safety or effectiveness, or that would constitute a major change in its intended use, requires a new 510(k) clearance or could require a PMA approval. The FDA requires each manufacturer to make this determination in the first instance, but the FDA can review any decision. If the FDA disagrees with a manufacturer's decision not to seek a new 510(k) clearance, the agency may retroactively require the manufacturer to seek 510(k) clearance or PMA approval. The FDA also can require the manufacturer to cease marketing and/or recall the modified device until 510(k) clearance or PMA approval is obtained. We have made and plan to continue to make additional product enhancements to our laser systems that we believe will not require new 510(k) clearances. We cannot assure you that the FDA would agree with any of our decisions not to seek additional 510(k) clearances or even PMA approval for these or future device modifications. If the FDA requires us to seek 510(k) clearance or PMA approval for any modification, we also may be required to cease marketing and/or recall the modified device until we obtain a new 510(k) clearance or PMA approval.

Class III devices are required to undergo the PMA approval process in which the manufacturer must establish the safety and effectiveness of the device to the FDA's satisfaction. A PMA application must provide extensive preclinical and clinical trial data as well as information about the device and its components regarding, among other things, device design, manufacturing and labeling. Also during the review period, an advisory panel of experts from outside the FDA may be convened to review and evaluate the application and provide recommendations to the FDA as to the approvability of the device. In addition, the FDA will conduct a preapproval inspection of the manufacturing facility to ensure compliance with the QSR. A new PMA or a PMA Supplement is required for modifications that affect the safety or effectiveness of the device, including, for example, certain types of modifications to the device's indications for use, manufacturing process, manufacturing facility, labeling and design. PMA Supplements often require submission of the same type of information as an original PMA application, except that the supplement is limited to information needed to support any changes from the device covered by the original PMA application, and may not require as extensive clinical data or the convening of an advisory panel. None of our products are currently approved under a PMA.

A clinical trial may be required in support of a 510(k) submission and generally is required for a PMA application. These trials generally require an Investigational Device Exemption (IDE) application approved in advance by the FDA for a specified number of patients, unless the product is deemed a non-significant risk device eligible for certain exemptions from the IDE requirements. The IDE application must be supported by appropriate data, such as animal and laboratory testing results. Clinical trials may begin if the IDE application is approved by the FDA and the appropriate institutional review boards at the clinical trial sites. Even if a trial is completed, the results of clinical testing may not adequately demonstrate the safety and efficacy of the device or may otherwise not be sufficient to obtain FDA clearance to market the product in the U.S.

In the future, we may be required to make additional 510(k) submissions to the FDA to address new claims, uses, or products. We cannot assure you that the FDA will not deem one or more of our future products, or those of our OEM partners, to be a Class III device subject to the more burdensome PMA approval process. The FDA also may not approve or clear these products for the indications that are necessary or desirable for successful commercialization. Indeed, the FDA may refuse our requests for 510(k) clearance or PMA of new products, new intended uses or modifications to existing products.

Pervasive and Continuing FDA Regulation

After a device is placed on the market, numerous regulatory requirements continue to apply. Those regulatory requirements include:

product listing and establishment registration, which helps facilitate FDA inspections and other regulatory action;

QSR, which requires manufacturers, including third-party manufacturers, to follow stringent design control, testing, change control, documentation, and other quality assurance procedures during all aspects of the manufacturing process;

Table of Contents

labeling control and advertising regulations which include FDA prohibitions against the promotion of products for uncleared, unapproved, or off-label uses or indications;

clearance of product modifications that could significantly affect safety or efficacy or that would constitute a major change in intended use of one of our cleared devices;

approval of product modifications that affect the safety or effectiveness of one of our future approved devices;

medical device reporting (MDR), regulations, which require that manufacturers comply with FDA requirements to report if their device may have caused or contributed to a death or serious injury, or has malfunctioned in a way that would likely cause or contribute to a death or serious injury if the malfunction of the device or a similar device were to recur;

post-approval restrictions or conditions, including post-approval study commitments;

post-market surveillance requirements, which apply when necessary to protect the public health or to provide additional safety and effectiveness data for the device;

the FDA's recall authority, whereby it can ask, or under certain conditions order, device manufacturers to recall from the market a product that is in violation of governing laws or regulations or other conditions under which the product was approved;

regulations pertaining to voluntary recalls; and

notices of corrections or removals.

We will need to invest significant time and other resources to ensure ongoing compliance with FDA QSR and other post-market regulatory requirements.

We have registered with the FDA as a medical device manufacturer and we have obtained a manufacturing license from the California Department of Health Services. As a manufacturer, we are subject to announced and unannounced facility inspections by the FDA and the California Department of Health Services to determine our compliance with various regulations. Our subcontractors manufacturing facilities are also subject to inspection.

If the FDA finds that we have failed to comply, the agency can institute a wide variety of enforcement actions, ranging from a public warning letter to more severe sanctions such as:

finances and civil penalties;

unanticipated expenditures to address or defend such actions;

delays in clearing or approving, or refusal to clear or approve, our products;

Edgar Filing: BIOLASE, INC - Form 10-K

withdrawal or suspension of approval of our products or those of our third-party suppliers by the FDA or other regulatory bodies;

product recall or seizure;

interruption of production;

operating restrictions;

injunctions; and

criminal prosecution.

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

Table of Contents

Advertising and promotion of medical devices, in addition to being regulated by the FDA, are also regulated by the Federal Trade Commission (FTC) and by state regulatory and enforcement authorities. Recently, promotional activities for FDA-regulated products of other companies have been the subject of enforcement action brought under healthcare 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, it 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, injunction, seizure, civil fine, or criminal penalties. In that event, our reputation could be damaged and adoption of the products could be impaired.

We are also subject to regulation under the Radiation Control for Safety and Health Act of 1968 (the Safety Act), which is administered by the FDA. The Safety Act regulates the energy emissions of light and sound and electronic waves from electronic products. Regulations implementing the Safety Act require a laser manufacturer to file new product and annual reports; to maintain quality control, product testing, and sales records; to distribute product operation manuals; to incorporate certain design and operating features in lasers sold to end users; and to certify and label each laser sold to end users as one of four classes of lasers based on the level of radiation emitted from the laser. In addition, various warning labels must be affixed to the product and certain protective features must be installed, depending upon the class of product.

Foreign Regulation

Many foreign countries in which we market or may market our products have regulatory bodies and restrictions similar to those of the FDA. International sales are subject to foreign government regulation, the requirements of which vary substantially from country to country. The time required to obtain approval by a foreign country may be longer or shorter than that required for FDA clearance and the requirements may differ. Companies are now required to obtain the CE Mark prior to sale of medical devices within the European Union. During this process, the sponsor must demonstrate compliance with the International Organization for Standardization's manufacturing and quality requirements. We have received CE Marking for our Waterlase and Diode laser systems. We cannot assure you that we will be able to obtain necessary foreign government approvals or successfully comply with foreign regulations. Our failure to do so could hurt our business, financial condition, and results of operations.

Other U.S. Regulation

We and subcontractors also must comply with numerous federal, state and local laws relating to matters such as safe working conditions, manufacturing practices, environmental protection, fire hazard control and hazardous substance disposal. We 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 hurt our business, financial condition and results of operations. Unanticipated changes in existing regulatory requirements or adoption of new requirements could hurt 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.

Table of Contents

Health Care Fraud and Abuse

In the U.S., there are federal and state anti-kickback laws that generally prohibit the payment or receipt of kickbacks, bribes, or other remuneration in exchange for the referral of patients or other health-related business. For example, the Federal Health Care Programs Anti-Kickback Law (42 U.S.C. § 1320a-7b(b)) prohibits anyone from, among other things, knowingly and willfully offering, paying, soliciting or receiving any bribe, kickback or other remuneration intended to induce the referral of patients for, or the purchase order, or recommendation of, health care products and services reimbursed by a federal health care program, including Medicare and Medicaid. Recognizing that the federal anti-kickback law is broad and potentially applicable to many commonplace arrangements, Congress and the Office of Inspector General within the Department of Health and Human Services (OIG) has created statutory exceptions and regulatory safe harbors. Exceptions and safe harbors exist for a number of arrangements relevant to our business, including, among other things, payments to bona fide employees, certain discount and rebate arrangements, and certain payment arrangements. Although an arrangement that fits into one or more of these exceptions or safe harbors is immune from prosecution, arrangements that do not fit squarely within an exception or safe harbor do not necessarily violate the law and the OIG or other government enforcement authorities will examine the practice to determine whether it involves the sorts of abuses that the statute was designed to combat. Violations of this federal law can result in significant penalties, including imprisonment, monetary fines and assessments, and exclusion from Medicare, Medicaid and other federal health care programs. Exclusion of a manufacturer, like us, would preclude any federal health care program from paying for its products. In addition to the federal anti-kickback law, many states have their own laws that parallel and implicate anti-kickback restrictions analogous to the federal anti-kickback law, but may apply regardless of whether any federal health care program 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 (31 U.S.C. § 3729 et seq.) imposes liability on any person or entity who, among other things, knowingly and willfully presents, or causes to be presented, a false or fraudulent claim for payment by a federal health care program, including Medicaid and Medicare. Some suits filed under the False Claims Act, known as *qui tam* actions, can be brought by a whistleblower, or 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 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. Sanctions under these federal and state laws may include civil monetary penalties, exclusion of a manufacturer's products from reimbursement under government programs, and imprisonment.

The Health Insurance Portability and Accountability Act of 1996 (HIPAA) created two new federal crimes: 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, imprisonment or exclusion from government sponsored programs. 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 health care benefits, items or services. A violation of this statute is a felony and may result in fines and imprisonment.

The Foreign Corrupt Practices Act and similar worldwide anti-bribery laws in non-U.S. jurisdictions generally prohibit companies and their intermediaries from making improper payments to non-U.S. officials for the purpose of obtaining or retaining business.

Table of Contents

Due to the breadth of some of these laws, it is possible that some of our current or future practices might be challenged under one or more of these laws. In addition, there can be no assurance that we would not be required to alter one or more of our practices to be in compliance with these laws. Evolving interpretations of current laws or the adoption of new federal or state laws or regulations could adversely affect many of the arrangements we have with customers and physicians. Our risk of being found in violation of these laws is increased by the fact that some of these laws are broad and open to interpretation. 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 most healthcare (including dental) facilities that purchase and use our products. The HIPAA Privacy Rule restricts the use and disclosure of patient information, and requires covered entities to safeguard that information and to provide certain rights to individuals with respect to that information. The HIPAA Security Rule establishes elaborate requirements for safeguarding patient information transmitted or stored electronically. We are not a covered entity but due to activities that we perform for or on behalf of covered entities, we are sometimes deemed to be a business associate of covered entities.

In certain circumstances, the HIPAA rules require covered entities to contractually bind us, as a business associate, to protect the privacy and security of health information we may encounter during activities like training customers on the use of our products or investigating product performance. The Health Information Technology for Economic and Clinical Health Act (HITECH) enacted in February 2009, made significant amendments to the HIPAA Privacy and Security Rules. Most provisions of HITECH were effective February 17, 2010; however, the new federal health data breach notice provision which requires business associates to notify covered entities of any breach of unsecured health information went into effect in September 2009. Prior to February 17, 2010, our business was not directly subject to the HIPAA Privacy and Security Rules. As a business associate, our privacy and security related obligations were solely contractual in nature and governed by the terms of each business associate agreement. HITECH fundamentally changed a business associate s obligations by imposing a number of HIPAA Privacy Rule requirements and a majority of HIPAA Security Rule provisions directly on business associates and making business associates directly subject to HIPAA civil and criminal enforcement and the associated penalties for violation of the Privacy and Security Rule requirements. HITECH increased civil penalty amounts for violations of HIPAA by either covered entities or business associates and requires the U.S. Department of Health and Human Services to conduct periodic audits to confirm compliance. In addition, HITECH authorizes state attorneys general to bring civil actions in response to violations of HIPAA Privacy and Security Rules that threaten the privacy of state residents. Due to the very recent enactment of HITECH and expected implementing regulations, we are unable to predict what the extent of the impact on our business will be, but these new HITECH requirements may require us to incur additional costs and may restrict our business operations.

The HIPAA standards also apply to the use and disclosure of health information for research, and require the covered entity performing the research to obtain the written authorization of the research subject (or an appropriate waiver) before providing that subject s health information to sponsors like us for purposes related to the research. These covered entities also typically impose contractual limitations on our use and disclosure of the health information they disclose to us. We may be required to make costly system modifications to comply with the privacy and security requirements that will be imposed on us and our failure to comply may result in liability and adversely affect our business.

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 various laws in many cases are not preempted by the HIPAA rules and may be subject to varying interpretations by the courts and government

Table of Contents

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 and these laws could create liability for us or increase our cost of doing business.

New health information standards, whether implemented pursuant to HIPAA, congressional action or otherwise, could have a significant effect on the manner in which we must handle health care related data, 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 healthcare providers that purchase our products generally rely on third-party payers, including the Medicare and Medicaid programs and private payers, such as indemnity insurers and managed care plans, to cover and reimburse all or part of the cost of the products and the procedures in which they are used. As a result, demand for our products is dependent in part on the coverage and reimbursement policies of these payers. No uniform coverage or reimbursement policy for medical technology exists among all third-party payers, and coverage and reimbursement can differ significantly from payer to payer.

The Patient Protection and Affordable Care Act (the Affordable Care Act), enacted in March 2010, is intended to expand health insurance coverage to uninsured persons in the U.S. The impact of this expansion of coverage on the sales of our products is currently unknown. The Affordable Care Act includes Medicare reimbursement policy, payment and health care delivery system, and coverage reforms, including development, implementation, and revision to prospective payment systems, any of which may adversely impact third-party reimbursements received by our end-user customers. Centers for Medicare and Medicaid Services (CMS), the federal agency responsible for administering the Medicare program, along with its contractors, establish coverage and reimbursement policies for the Medicare program. In addition, private payers, whom often follow the coverage and reimbursement policies of Medicare, and employer-sponsored health care plans, are subject to rules and penalties under the Affordable Care Act which may also adversely impact third-party reimbursements received by our end-user customers. We cannot assure you 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 and we continue to assess the impact of the Affordable Care Act on our business.

In general, we expect Medicare will continue to cover a medical product or procedure when the product or procedure is reasonable and necessary for the diagnosis or treatment of an illness or injury, or to improve the functioning of a malformed body part. Even if the medical product or procedure is considered medically necessary and coverage is available, Medicare may place restrictions on the circumstances where it provides coverage.

Medicare payments also are frequently made under a prospective payment system based on the ambulatory payment classifications (APCs), under which individual items and procedures are categorized. Providers of outpatient services typically receive reimbursement the applicable APC payment rate for a procedure regardless of the actual cost for such treatment. Some outpatient services for which our products may be used do not receive separate reimbursement. Rather, their reimbursement is deemed packaged into the APC for an associated procedure, and the payment for that APC does not vary depending on whether the packaged procedure is performed. Some procedures also are paid through Composite APCs, which are APCs that establish a payment rate that applies when a specific combination of services is provided. 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.

Because payments through the prospective payment system are based on predetermined rates and may be less than a provider's actual costs in furnishing care, providers have incentives to lower their operating costs by

Table of Contents

utilizing products that will decrease labor or otherwise lower their costs. 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, 2012, the Company employed approximately 219 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 organizational meeting of the Board of Directors, which follows the annual meeting of stockholders, and at other Board of Directors meetings, as appropriate.

At March 15, 2013, the executive officers of the Company were as follows:

Name	Age	Position
Federico Pignatelli	60	Chief Executive Officer and Chairman of the Board
Frederick D. Furry	45	Chief Financial Officer and Chief Operating Officer

Federico Pignatelli has served as our Chief Executive Officer (CEO) and Chairman of the Board since September 30, 2010. He served as Chairman of our Board from 1994 until March 2006, at which point he resigned as Chairman of the Board and became Chairman Emeritus. Mr. Pignatelli served as our President from January 2008 until June 2010. From November 2007 to January 2008, Mr. Pignatelli served as interim CEO. He has served as a director since 1991. He is the Founder, and has served as President, of Art & Fashion Group since 1992. Art & Fashion Group is a holding company of an array of businesses providing services to the advertising industry, including the world's largest complex of digital and film still photography studios for production and post-production. Previously, Mr. Pignatelli was a Managing Director at Gruntal & Company, an investment banking and brokerage firm, and was a Managing Director of Ladenburg, Thalmann & Co., an investment banking and brokerage firm.

Frederick Furry has served as our Chief Financial Officer (CFO) since November 2010 and our Chief Operating Officer (COO) since October 2011. From July 2004 to December 2009, Mr. Furry served as an audit partner of Windes & McClaughry. Mr. Furry is a certified public accountant (inactive) and has significant experience working with manufacturing and high technology companies with more than 18 years with public accounting firms, including PricewaterhouseCoopers. He holds a master's of business administration from the A. Gary Anderson Graduate School of Management at the University of California, Riverside.

Available Information

Our Annual Report on Form 10-K, Quarterly Reports on Form 10-Q, Current Reports on Form 8-K and amendments to reports filed or furnished pursuant to Sections 13(a) and 15(d) of the Securities Exchange Act of 1934, as amended, 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 Securities and Exchange Commission. 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.

Table of Contents

Additional Information

BIOLASE®, ZipTip®, ezlase®, eztips®, MD Flow®, Comfortpulse®, Waterlase®, iLase®, iPlus®, WCLI®, World Clinical Laser Institute®, Waterlase MD®, Waterlase Dentistry®, Proprietary MD®, and EZLase It's So Easy® are registered trademarks of Biolase, Inc., and Diolase®, HydroPhotonics®, LaserPal®, MD Gold®, Waterlase MD Turbo®, HydroBeam®, Occulase®, Diolase 10®, Body Contour®, Radial Firing Perio Tips®, Deep Pocket Therapy with New Attachment®, 2R®, Intuitive Power®, Comfortprep®, Rapidprep®, Bondprep®, Intuitive Power®, Occulase iPlus®, Flavorflow®, Occulase MD®, Epic Diode®, Epic Diode Laser®, Biolase Epic®, Epic Laser®, Epic®, Dermalase®, Deltalaser®, Delta®, iStarlaser®, iStar®, Biolase DaVinci® Imaging®, Oculase®, Waterlase MDX®, Total Technology Solution®, Geyserslaser®, Geysers®, eplus®, and iLase® are trademarks of BIOLASE, Inc. All other product and company names are registered trademarks or trademarks of their respective owners.

Item 1A. Risk Factors

The following risk factors and other information included in this Form 10-K should be carefully considered. The risks and uncertainties described below are not the only ones we face. Additional risks and uncertainties not presently known to us or that we presently deem less significant may also impair our business operations. If any of the following risks come to fruition, our business, financial condition, results of operations and future growth prospects would likely be materially and adversely affected. In these circumstances, the market price of our stock could decline, and you could lose all or part of your investment.

Risks Related to Our Revenue

Continued global economic uncertainty and volatility in financial markets may continue to adversely affect our liquidity, operating results, and financial condition.

Our business is highly sensitive to changes in general economic conditions as a seller of capital equipment to end users in dental professional practices. Financial markets inside the United States and internationally have experienced extreme disruption in recent times, including, among other things, extreme volatility in security prices, severely diminished liquidity and credit availability, and declining valuations of investments. These disruptions are likely to have an ongoing adverse effect on the world economy. A continuing economic downturn and financial market disruptions may:

- reduce demand for our products and services, increase order cancellations and result in longer sales cycles and slower adoption of new technologies;

- increase the difficulty of collecting accounts receivable and the risk of excess and obsolete inventories;

- increase price competition in our served markets; and

- result in supply interruptions, which could disrupt our ability to produce our products.

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

We have an accumulated deficit of approximately \$112.3 million at December 31, 2012. We recorded net losses of approximately \$3.1 million, \$4.5 million, and \$12.0 million for the years ended December 31, 2012, 2011, and 2010, respectively. In order to achieve profitability, we must control our costs and increase net revenue through new sales. Failure to increase our net revenue and decrease our costs could cause our stock price to decline.

Our business is capital intensive and the failure to obtain capital could require that we curtail capital expenditures.

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

Table of Contents

infrastructure as we increase sales domestically and internationally. If cash generated from our operations is insufficient to fund such growth, we may be required to raise additional funds through further debt or equity financings, which may dilute the percentage ownership of existing holders of common stock and which may have rights, preferences or privileges senior to those of the holders of our common stock or may be issued at a discount to the market price of our common stock thereby resulting in dilution to our existing stockholders. If we raise additional funds through debt financing, we may be subject to debt covenants which could place limitations on our operations. We may not be able to raise additional capital on reasonable terms, or at all, or we may use capital more rapidly than anticipated. If we cannot raise the required capital when needed, we may not be able to satisfy the demands of existing and prospective customers and may lose revenue and market share.

The following factors, among others, could affect our ability to obtain additional financing on favorable terms, or at all:

our results of operations;

general economic conditions and conditions in the dental or medical device industries;

the perception of our business in the capital markets;

our ratio of debt to equity;

our financial condition;

our business prospects; and

interest rates.

If we are unable to obtain sufficient capital in the future, we may have to curtail our capital expenditures. Any curtailment of our capital expenditures could result in a reduction in net revenue, reduced quality of our products, increased manufacturing costs for our products, harm to our reputation, reduced manufacturing efficiencies or other harm to our business.

Our distributors may cancel, reduce or delay orders of our products, any of which could reduce our revenue.

We rely on exclusive and non-exclusive independent distributors for a declining portion of our sales in North America and a majority of our sales in countries outside of the United States and Canada. For the fiscal years ended December 31, 2012, 2011, and 2010 revenue from distributors accounted for approximately 23%, 42% and 60% of our total net revenue, respectively. Our ability to maintain or increase our revenue will depend in large part on our success in developing and maintaining relationships with our current distributors and developing relationships with new distributors. Our distributors have significant discretion in determining the efforts and resources they apply to the sale of our products. Our distributors may not commit the necessary resources to market and sell our products to the level of our expectations and, regardless of the resources they commit, they may not be successful. From time to time, we may face competition or pricing pressure from one or more of our non-exclusive distributors in certain geographic areas where those distributors are selling inventory to the same customer base as us. Additionally, most of our distributor agreements can be terminated with limited notice, and we may not be able to replace any terminating distributor in a timely manner or on terms agreeable to us, if at all. If we are not able to maintain our distribution network, if our distribution network is not successful in marketing and selling our products, or if we experience a significant reduction in, cancellation or change in the size and timing of orders from our distributors, our revenues could decline significantly.

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

Edgar Filing: BIOLASE, INC - Form 10-K

Our dental laser systems represent relatively new technologies in the dental market. Currently, only a small percentage of dentists use lasers to perform dental procedures. Our future success will depend on our ability to

Table of Contents

increase demand for our products by demonstrating the potential performance advantages of our laser systems over traditional methods of treatment and over competitive laser systems to a broad spectrum of dentists and patients. Historically, we have experienced long sales cycles because dentists have been, and may continue to be, slow to adopt new technologies on a widespread basis. As a result, we generally are required to invest a significant amount of time and resources to educate dentists about the benefits of our products in comparison to competing products and technologies before completing a sale, if any.

Factors that may inhibit adoption of laser technologies by dentists include cost and concerns about the safety, efficacy and reliability of lasers. In order to invest in a Waterlase system, a dentist generally needs to invest time to understand the technology, consider how patients may respond to the new technology, assess the financial impact the investment may have on the dentist's practice and become comfortable performing procedures with our products. Absent an immediate competitive motivation, a dentist may not feel compelled to invest the time required to learn about the potential benefits of using a laser system. Dentists may not accept or adopt our products until they see additional clinical evidence supporting the safety and efficiency of our products or recommendations supporting our laser systems by influential dental practitioners. In addition, economic pressure, caused, for example, by an economic slowdown, changes in healthcare reimbursement or by competitive factors in a specific market, may make dentists reluctant to purchase substantial capital equipment or invest in new technologies. Patient acceptance will depend on the recommendations of dentists and specialists, as well as other factors, including without limitation, the relative effectiveness, safety, reliability and comfort of our systems as compared to other instruments and methods for performing dental procedures. The failure of dental lasers to achieve broad market acceptance would limit sales of our products and have an adverse effect on our business and results of operations.

Any failure in our efforts to train dental practitioners could reduce the market acceptance of Waterlase Dentistry and reduce our revenues.

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

If future data proves to be inconsistent with our clinical results or if competitors' products present more favorable results our revenues may decline.

If new studies or comparative studies generate results that are not as favorable as our clinical results, our revenues may decline. Additionally, if future studies indicate that our competitors' products are more effective or safer than ours, our revenues may decline. Furthermore, physicians may choose not to purchase our laser systems until they receive additional published long-term clinical evidence and recommendations from prominent physicians 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 have established stronger reputations with target customers than ours.

Table of Contents

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 healthcare industry may lead to the entry of new competitors, particularly if dental and medical lasers gain increasing market acceptance. If we do not compete successfully, our revenue and market share may decline.

Our long-term success depends upon our ability to (i) distinguish our products through improving our product performance and pricing, protecting our intellectual property, continuously 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 existing dental and medical lasers.

If our customers cannot obtain third party reimbursement for their use of our products, they may be less inclined to purchase our products.

Our products are generally purchased by dental or medical professionals who have various billing practices and patient mixes. Such practices range from primarily private pay to those who rely heavily on third party payors, such as private insurance or government programs. In the United States, third party payors review and frequently challenge the prices charged for medical services. In many foreign countries, the prices for dental services are predetermined through government regulation. Payors may deny coverage and reimbursement if they determine that the procedure was not medically necessary or that the device used in the procedure was investigational. 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. 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 of future healthcare reforms or changes in financing for health and dental plans. Any such changes could have an adverse effect on the ability of a dental or medical professional to generate a return on investment using our current or future products. Such changes could act as disincentives for capital investments by dental and medical professionals and could have a negative impact on our business and results of operations.

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

Section 382 of the Internal Revenue Code (IRC) of 1986 generally imposes an annual limitation on the amount of net operating loss carryforwards that may be used to offset taxable income when a corporation has undergone significant changes in its stock ownership. In 2006, we completed an analysis to determine the applicability of the annual limitations imposed by IRC Section 382 caused by previous changes in our stock ownership and determined that such limitations should not be significant. Based on our analysis, we believe that, as of December 31, 2012, approximately \$67.0 million of net operating loss carryforwards were available to us for federal income tax purposes. A detailed analysis will be required at the time we begin utilization of any net operating losses to determine if there is an IRC Section 382 limitation. In addition, any ownership changes qualifying under IRC Section 382 including changes resulting from or affected by our public offering or our stock repurchase plan may adversely affect our ability to use our remaining net operating loss carryforwards. If we lose our ability to use net operating loss carryforwards, any income we generate will be subject to tax earlier than it would be if we were able to use net operating loss carryforwards, resulting in lower profits.

Risks Related to Our Intellectual Property

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

Our future success will depend, 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

Table of Contents

of others. We rely on patents to establish and maintain proprietary rights in our technology and products. We currently possess a number of issued patents and patent applications with respect to our products and technology; however, we cannot assure that any additional patents will be issued, that the scope of any patent protection will be effective in helping us address our competition or that any of our patents will be held valid if subsequently challenged. It is also possible that our competitors may independently develop similar or more desirable products, duplicate our products or design products that circumvent our patents. Additionally, 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 are numerous proposed changes to the patent laws and rules of the U.S. Patent and Trademark Office which, if enacted, may have a significant impact on our ability to protect our technology and enforce our intellectual property rights. For example, Congress is considering several significant changes to the U.S. patent laws, including (among other things) changing from a first to invent to a first inventory to file system, limiting the time for which a patentee may file a patent suit, requiring the apportionment of patent damages, and creating a post-grant opposition process to challenge patents after they have issued. If we fail to protect our intellectual property rights adequately, our competitive position and financial condition may be adversely affected.

If third parties claim that we infringe their intellectual property rights, we may incur liabilities and costs and may have to redesign or discontinue selling certain products.

We face substantial uncertainty regarding the impact that other parties' intellectual property positions will have on the markets for dental and other medical lasers. 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 expect to continue to receive, notices of claims of infringement, misappropriation or misuse of other parties' proprietary rights. Some of these claims may lead to litigation. We may not prevail in any future intellectual property infringement litigation given the complex technical issues and inherent uncertainties in litigation. Any claims, with or without merit, may be time-consuming and distracting to management, result in costly litigation or cause product shipment delays. Adverse determinations in litigation could subject us to significant liability and could result in the loss of proprietary rights. A successful lawsuit against us could also force us to cease selling or redesign products that incorporate the infringed intellectual property. Additionally, we could be required to seek a license from the holder of the intellectual property to use the infringed technology, and it is possible that we may not be able to obtain a license on acceptable terms, or at all. Any of the foregoing adverse events could seriously affect our business.

Risks Related to Our Regulatory Environment

Changes in government regulation or the inability to obtain or maintain necessary government approvals could harm our business.

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

Should 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 to market such products.

Table of Contents

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 pre-market approval application is required, we could be required to submit substantially more data, may be required to conduct human clinical testing and would very likely be subject to a significantly longer review period.

Products sold in international markets are also subject to the regulatory requirements of each respective country or region. The regulations of the European Union require that a device have a CE Mark, indicating conformance with European Union laws and regulations before it can be sold in that market. 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 have a material adverse effect on our operations and, at the very least, 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 and harm our financial condition.

Changes in the health care industry in the U.S. and elsewhere could adversely affect the demand for our products as well as the way in which we conduct our business. Significantly, President Obama signed health care reform legislation into law that will require most individuals to have health insurance, establish new regulations on health plans, and create insurance pooling mechanisms and other expanded public health care measures. In general, an expansion in government's role in the U.S. health care industry may lower reimbursements for our products or the procedures for which our products are used, reduce demand for innovative products, reduce volumes for dental and medical procedures and adversely affect our business and results of operations, possibly materially. In addition, as a result of the focus on health care reform, there is risk that Congress may implement changes in laws and regulations governing health care service providers, including measures to control costs, or reductions in reimbursement levels.

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

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

the Federal Food, Drug, and Cosmetic Act, which regulates the design, testing, manufacture, labeling, marketing, distribution and sale of prescription drugs and medical devices;

state food and drug laws;

the federal Anti-Kickback Law, which prohibits persons from knowingly and willfully soliciting, offering, receiving or providing remuneration, directly or indirectly, in cash or in kind, to induce either;

the referral of an individual, or furnishing or arranging for a good or service, for which payment may be made under federal healthcare programs such as the Medicare and Medicaid Programs;

Medicare laws and regulations that prescribe the requirements for coverage and payment, including the amount of such payment, and laws prohibiting false claims for reimbursement under Medicare and Medicaid;

the federal physician self-referral prohibition, commonly known as the Stark Law, which, in the absence of a statutory or regulatory exception, prohibits the referral of Medicare patients by a physician to an

Table of Contents

entity for the provision of designated healthcare 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 also prohibits that entity from submitting a bill to a federal payor for services rendered pursuant to a prohibited referral;

federal provisions of HIPAA that established 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 health care benefits, items or services;

federal and 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;

state laws that prohibit the practice of medicine by non-physicians and fee-splitting arrangements between physicians and non-physicians, as well as state law equivalents to the Anti-Kickback Law and the Stark Law, which may not be limited to government reimbursed items; 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 regulations to which we or our customers are subject, we may be subject to the applicable penalty associated with the violation, including civil and criminal penalties, damages, fines, exclusion from the Medicare and Medicaid programs and the curtailment or restructuring of our operations. If we are required to obtain permits or licensure under these laws that we do not already possess, we may become subject to substantial additional regulation or incur significant expense. Any penalties, damages, fines, curtailment or restructuring of our operations would adversely affect our ability to operate our business and our financial results. The risk of our being found in violation of these laws is increased by the fact that many of them have not been fully interpreted by applicable regulatory authorities or the courts, and their provisions are open to a variety of interpretations and additional legal or regulatory change. Any action against us for violation of these laws, even if we successfully defend against it, could cause us to incur significant legal expenses, divert our management's attention from the operation of our business and damage our reputation.

Product sales or introductions may be delayed or canceled as a result of the FDA regulatory process which could cause our sales or profitability to decline.

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

delay or eliminate commercialization of products we develop;

require us to perform costly procedures;

diminish any competitive advantages that we may attain; and

reduce our ability to collect revenues or royalties.

Table of Contents

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

Our products are subject to recall even after receiving FDA clearance or approval; any recalls would harm our reputation, business and financial results.

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 our business and financial results because the laser systems compose such an important part of our portfolio of products.

Our business and results of operations may be adversely affected by provisions of the Affordable Care Act.

Under the Affordable Care Act, we are subject to a 2.3% excise tax payable semi-monthly on U.S. revenues of certain medical devices beginning in January 2013. These taxes are imposed on us whether or not we earn a profit. A significant portion of our product sales to customers located in the U.S. will be subject to this tax. This tax may adversely impact our operating results if we are not able to offset the cost by raising laser sales prices or through other cost improvements. The Affordable Care Act also contains reporting requirements of certain payments made by us to medical and dental practitioners and teaching hospitals (the Physician Payment Sunshine Act) which will be published on a publicly available website annually beginning in 2014. This requirement is expected to increase the administrative costs for both manufacturers and health care providers and may result in a decline in our collaborative efforts. A decline in these collaborations may adversely affect advances in our laser technology or may reduce attendance at events at which our technology is demonstrated, which could reduce demand for our products and lead to sales price pressures.

Additionally, the Affordable Care Act may adversely impact third-party reimbursements received by our end-user customers, which may reduce demand for our products. There may be other provisions in the law that could adversely affect our business, and we cannot predict with any certainty the full impact this legislation may have on our business.

Risks Related to Our Business and Operations

Any failure to significantly expand sales of our products with our distribution partners will negatively impact our business.

We currently handle a significant portion of the marketing, distribution, and sales of our products. We also utilize our relationships with domestic and international distributors to market, distribute, and sell our products. We face significant challenges and risks in expanding, training, managing, and retaining our sales and marketing teams, including managing geographically dispersed operations. We rely on independent distributors to market and sell our products in a number of countries outside of the United States. These distributors may not commit the necessary resources to effectively market and sell our products, and they may terminate their relationships with us at any time with limited notice. If we are unable to expand our sales and marketing capabilities domestically and internationally, or if the relationship with our distribution partners does not produce the expected results, we may not be able to effectively commercialize our products, which could harm our business and cause the price of our common stock to decline.

We may incur problems in manufacturing our products which may harm our business.

In order to grow our business, we must expand our manufacturing capabilities to produce the systems and accessories necessary to meet any demand we may experience. We may encounter difficulties in increasing the

Table of Contents

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 continuously subject to periodic inspections by the FDA, as well as various state agencies and foreign regulatory agencies. From time to time, we may expend significant resources in obtaining, maintaining and remedying 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. If we do not succeed in manufacturing 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, our business could be harmed.

Components used in our products are complex in design and any defects may not be discovered prior to shipment to customers. These defects could result in warranty obligations which would increase our cost and may negatively affect our operating results and our reputation.

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

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

loss of customer orders and delay in order fulfillment;

damage to our brand reputation;

increased cost of our warranty program due to product repair or replacement;

inability to attract new customers;

diversion of resources from our manufacturing and research and development departments into our service department; and

legal action.

The occurrence of any one or more of the foregoing could materially harm our business.

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, there is no 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 may cause our business to suffer.

Table of Contents

Our suppliers may not supply us with a sufficient amount of materials and components or materials and components of adequate quality.

We frequently do not use written supply contracts with our key suppliers; instead, we purchase certain materials and components included in our products from a limited group of suppliers using purchase orders. Our business depends, in part, on our ability to obtain timely deliveries of materials and components in acceptable quality and quantities from our suppliers. Certain components of our products, particularly specialized components used in our lasers, 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 one or more of our single-source suppliers cease to provide us with sufficient quantities of our components in a timely manner or on terms acceptable to us, or cease to manufacture components of acceptable quality, we would have to seek alternative sources of manufacturing. We could incur delays while we locate and engage alternative qualified suppliers and we might be unable to engage acceptable alternative suppliers on favorable terms. Any such disruption or increased expenses could harm our business efforts and adversely affect our ability to generate sales. Our reliance on these outside manufacturers and suppliers also subjects us to other risks that could harm our business, including:

we may not be able to obtain adequate supply in a timely manner or on commercially reasonable terms;

we may have difficulty locating and qualifying alternative suppliers for the various components in our laser systems;

switching components may require product redesign and submission to the FDA of a 510(k) application, which could significantly delay production;

our suppliers manufacture products for a range of customers, and fluctuations in demand for the products those suppliers manufacture for others may affect their ability to deliver components for us in a timely manner; and

our suppliers may encounter financial hardships, be acquired, or experience other business events unrelated to our demand for components, which could inhibit or prevent their ability to fulfill our orders and meet our requirements.

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 currently 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.

Rapidly changing standards and competing technologies could harm demand for our products or result in significant additional costs.

The markets in which our products compete are subject to rapid technological change, evolving industry standards, changes in the regulatory environment, and frequent introductions of new devices and evolving dental and surgical techniques. Competing products may emerge which could render our products uncompetitive or obsolete. The process of developing new medical devices is inherently complex and requires regulatory approvals or clearances that can be expensive, time consuming and uncertain. We cannot guarantee that we will successfully identify new product opportunities, identify new and innovative applications of our technology, or be financially or otherwise capable of completing the research and development required to bring new products to market in a timely manner. An inability to expand our product offerings or the application of our technology could limit our growth. In addition, we may incur higher manufacturing costs if manufacturing processes or standards change, and we may need to replace, modify, design or build and install equipment, all of which would require additional capital expenditures.

Table of Contents

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, 2012, 2011, and 2010, international sales accounted for approximately 29%, 33%, 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, 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, although we may consider doing so in the future.

Fluctuations in our revenue and operating results on a quarterly and annual basis could cause the market price of our common stock to decline.

Edgar Filing: BIOLASE, INC - Form 10-K

Our revenue and operating results fluctuate from quarter to quarter due to a number of factors, many of which are beyond our control. Historically, we have experienced fluctuations in revenue from quarter to quarter due to seasonality. Revenue in the first quarter typically is lower than average and revenue in the fourth quarter typically is stronger than average due to the buying patterns of dental professionals. 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. If our quarterly revenue or operating results fall below the expectations of investors, analysts or our previously stated financial guidance, the price of our common stock could decline substantially. Other factors that might cause quarterly fluctuations in our revenue and operating results include the following:

variation in demand for our products, including seasonality;

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;

Table of Contents

regulatory actions that impact our manufacturing processes;

the size, timing, rescheduling, or cancellation of orders from distributors;

the introduction of new products by competitors;

the length of and fluctuations in sales cycles;

the availability and reliability of components used to manufacture our products;

changes in our pricing policies or those of our suppliers and competitors, as well as increased price competition in general;

legal expenses, particularly related to litigation matters;

general economic conditions including the availability of credit for our existing and potential customer base to finance purchases;

the mix of our domestic and international sales and the risks and uncertainties associated with international business;

costs associated with any future acquisitions of technologies and businesses;

limitations on our ability to use net operating loss carry-forwards under the provisions of IRC Section 382 and similar state laws;

developments concerning the protection of our intellectual property rights;

catastrophic events such as hurricanes, floods, and earthquakes, which can affect our ability to advertise, sell, and distribute our products, including through national conferences held in regions in which these disasters strike; and

global economic, political, and social events, including international conflicts and acts of terrorism.

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

The continued financial crisis and general slowdown of the economy may adversely affect the credit availability and liquidity of our customers and suppliers.

The credit availability and liquidity of our customers and suppliers may be materially affected by the current financial crisis. If our suppliers experience credit or liquidity problems, important sources of raw materials or manufactured goods may be affected. We currently sell our products primarily to dentists in general practice. These dentists often purchase our products with funds they secure through various financing arrangements with third party financial institutions, including credit facilities and short-term loans. If interest rates increase or the availability of

Edgar Filing: BIOLASE, INC - Form 10-K

credit is otherwise negatively impacted by market conditions, these financing arrangements will be more expensive to our dental customers, which would effectively increase the overall cost of owning our products for our customers and, thereby, may decrease demand for our products. The recent recession made, and may continue to make, such funding less readily available. Any reduction in the sales of our products would cause our business to suffer.

We are subject to a variety of litigation in the course of our business that could adversely affect our results of operations and financial condition.

We are subject to a variety of litigation 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 and sales and trading practices, environmental matters, personal injury, and

Table of Contents

insurance coverage. Some of these lawsuits include claims for punitive as well as compensatory damages. The defense of these lawsuits may divert our management's attention, we may incur significant expenses in defending these lawsuits and we may be required to pay damage awards or settlements or become subject to equitable remedies that could adversely affect our financial condition, operations and results of operations. Moreover, any insurance or indemnification rights that we may have may be insufficient or unavailable to protect us against potential loss exposures. In addition, developments in legal proceedings in any given period may require us to record loss contingency estimates in our financial statements, which could adversely affect our results of operations in any period.

Our operations are consolidated primarily in one facility. A disruption at this facility could result in a prolonged interruption of our business and adversely affect our results of operation and financial condition.

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

If we lose the services of our key personnel, or if we are unable to attract other key personnel, we may not be able to manage our operations or meet our growth objectives.

We are highly dependent on our senior management, especially Federico Pignatelli, our Chief Executive Officer, Fred Furry, our Chief Financial Officer and Chief Operating Officer, and other key officers. We are also heavily dependent on our engineers and sales and marketing personnel and other highly skilled technical personnel. Our success will depend on our ability to retain our current management, engineers and marketing and sales team and other technical 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. The loss of the services of members of our key personnel could prevent the implementation and completion of our objectives, including the development and introduction of our products. In general, our officers may terminate their employment at any time without notice for any reason.

Existing or future acquisitions of businesses could negatively affect our business, financial condition and results of operations if we fail to integrate the acquired businesses successfully into our existing operations or if we discover previously undisclosed liabilities.

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

difficulties in integrating any acquired companies, personnel, products, and other assets into our existing business;

delays in realizing the benefits of the acquired company, product, or other assets;

diversion of our management's time and attention from other business concerns;

limited or no direct prior experience in new markets or countries we may enter;

higher costs of integration than we anticipated; and

Difficulties in retaining key employees of the acquired business who are necessary to manage these acquisitions.

Table of Contents

In addition, an acquisition could materially impair our operating results by causing us to incur debt or requiring us to amortize expenses and acquired assets. We may also discover deficiencies in internal controls, data adequacy and integrity, product quality, regulatory compliance, and product liabilities that we did not uncover prior to our acquisition of such businesses, which could result in us becoming subject to penalties or other liabilities. Any difficulties in the integration of acquired businesses or unexpected penalties or liabilities in connection with such businesses could have a material adverse effect on our business, financial condition, and result of operations.

If we fail to comply with the reporting obligations of the Securities Exchange Act of 1934 and Section 404 of the Sarbanes Oxley Act of 2002, or if we fail to maintain adequate internal control over financial reporting, our business, results of operations and financial condition and investors' confidence in us could be materially and adversely affected.

As a public company, we are required to comply with the periodic reporting obligations of the Securities Exchange Act of 1934, as amended, or the Exchange Act, including preparing annual reports, quarterly reports, and current reports. Our failure to prepare and disclose this information in a timely manner and meet our reporting obligations in their entirety could subject us to penalties under federal securities laws and regulations of The Nasdaq Stock Market LLC expose us to lawsuits and restrict our ability to access financing on favorable terms, or at all.

Section 1502 of the Dodd-Frank Wall Street Reform and Consumer Protection Act added Section 13(p) to the Securities Exchange Act of 1934 which requires us to disclose annually whether any conflict minerals, including tantalum, tin, gold and tungsten, that are necessary to the functionality or production of a product manufactured by us originated in the Democratic Republic of the Congo or an adjoining country. Components of our products containing these minerals are sourced through various vendors who may have complex supply chains which may change from time to time due to the influence of availability, pricing or other factors in their purchasing decisions. We are required to conduct a good faith and reasonable effort to determine the source of these materials; however, there can be no assurance that members in the supply chain will be willing or able to provide this information or further identify their sources of supply or notify us timely of changes. We must comply with the final rule for the calendar year beginning January 1, 2013 with the first reports due May 31, 2014.

In addition, pursuant to Section 404 of the Sarbanes Oxley Act of 2002, as amended (the Sarbanes Oxley Act), we are required to evaluate and provide a management report of our systems of internal control over financial reporting. During the course of the evaluation of our internal control over financial reporting, we may identify areas requiring improvement and may be required to design enhanced processes and controls to address issues identified through this review. This could result in significant delays and costs to us and require us to divert substantial resources, including management time from other activities. In addition, if we fail to maintain the adequacy of our internal controls 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 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 harm our business, negatively impact the trading price of our stock, and adversely affect investors' confidence in our company and our ability to access capital markets for financing.

Climate change initiatives may materially and adversely affect our business.

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

Table of Contents

greenhouse gas emissions. If our suppliers are unable to obtain energy at a reasonable cost in the future, the cost of our raw materials may be negatively impacted which could result in increased manufacturing costs.

Risks Related to Our Stock

Our stock price may be volatile, and your investment in our stock could suffer a decline in value.

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

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 of Directors, or certain institutional stockholders; and

Edgar Filing: BIOLASE, INC - Form 10-K

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 convertible securities or the future grant of equity by us.

You could experience substantial dilution of your investment as a result of subsequent exercises of outstanding options and warrants issued as incentive compensation for services performed by employees, directors, consultants and others or the grant of future equity awarded by us. As of December 31, 2012, an aggregate of 6,950,000 shares of common stock were reserved for future issuance under our equity incentive plan, 3,860,000 of which were subject to options outstanding as of that date at a weighted average exercise price of \$3.48 per share. In addition, as of December 31, 2012, 852,974 shares of our common stock were subject to warrants at a weighted average exercise price of \$5.84 per share. Of the 3,860,000 outstanding stock options at December 31, 2012, 2,314,000 stock options were exercisable. To the extent that outstanding options are exercised, our existing stockholders may incur dilution. We rely heavily on equity awards to motivate current employees and to attract new employees. The grant of future equity awards by us to our employees and other service providers may further dilute our stockholders. We also expect to issue additional shares of our equity securities to raise capital. During 2011, we sold approximately 2.5 million shares of common stock through a controlled equity offering for gross proceeds totaling approximately \$9.3 million. We also sold an aggregate of 1.6 million shares in a private placement for gross proceeds totaling approximately \$9 million. Our Board of

Table of Contents

Directors declared a 0.5% stock dividend and a 1% stock dividend in each of the four quarters in 2012 and 2011, respectively, which resulted in the issuance of 634,162 shares and 1,165,715 shares, respectively.

Our corporate documents and Delaware law contain provisions that could discourage, delay or prevent a change in control of our company and reduce the market price of our stock.

Provisions in our restated certificate of incorporation and amended and restated bylaws may discourage, delay, or prevent a merger or acquisition involving us that our stockholders may consider favorable. For example, our restated certificate of incorporation authorizes our Board of Directors to issue up to 500,000 shares of blank check preferred stock. As a result, without further stockholder approval, the Board of Directors has the authority to attach special rights, including voting and dividend rights, to this preferred stock. With these rights, preferred stockholders could make it more difficult for a third party to acquire us.

We are also subject to the anti-takeover provisions of the Delaware General Corporation Law. Under these provisions, if anyone becomes an interested stockholder, we may not enter into a business combination with that person for three years without special approval, which could discourage a third party from making a takeover offer and could delay or prevent a change in control of us. An interested stockholder generally means (subject to certain exceptions as described in the Delaware General Corporation Law) someone owning 15% or more of our outstanding voting stock or an affiliate of ours that owned 15% or more of our outstanding voting stock during the past three years.

In addition, we have adopted a stockholder rights plan. Under the stockholder rights plan, if any party acquires 15% or more of our outstanding common stock while the stockholder rights plan remains in place, subject to a number of exceptions set forth in the plan, the holders of these rights, other than the party acquiring the 15% position, will be able to purchase shares of our common stock, or other securities or assets, at a discounted price, causing substantial dilution to the party acquiring the 15% position. Following the acquisition of 15% or more of our stock by any person, without a redemption of the rights or a termination of the stockholder rights plan by the Board of Directors, if we are acquired by or merged with any other entity, holders of these rights, other than the party acquiring the 15% position, will also be able to purchase shares of common stock of the acquiring or surviving entity if the stockholder rights plan continues to remain in place. Our stockholder rights plan could discourage a takeover attempt and make an unsolicited takeover of our company more difficult. As a result, without the approval of our Board of Directors, you may not have the opportunity to sell your shares to a potential acquirer of us at a premium over prevailing market prices. This could reduce the market price of our stock.

We may elect to not declare cash dividends on our stock, or may elect to only pay dividends on an infrequent or irregular basis, and any return on your investment may be limited to the value of our stock.

Our Board of Directors may from time to time declare, and we may pay, cash dividends on our outstanding shares of common stock in the manner and upon the terms and conditions provided by law. However, we may elect to retain all future earnings for the operation and expansion of our business, rather than paying cash dividends on our stock. Any payment of cash dividends on our stock will be at the discretion of our Board of Directors and will depend upon our results of operations, earnings, capital requirements, financial condition, business prospects, contractual restrictions and other factors deemed relevant by our Board of Directors. In the event our Board of Directors declares any cash dividends, there is no assurance with respect to the amount, timing, or frequency of any such dividends.

Risks Related to Our Revolving Credit Facilities

The terms of our revolving credit facilities impose financial and operating restrictions on us and failure to comply may have an adverse effect on our business, liquidity and financial position.

Our revolving credit facilities contain a number of negative covenants that limit our ability to engage in activities. These covenants limit or restrict, among other things, our ability to:

incur additional indebtedness and grant liens on assets;

Table of Contents

make certain investments and restricted payments (including the ability to pay cash dividends and repurchase stock);

undertake certain acquisitions or sell certain assets;

enter into certain transactions with our affiliates; and

replace our Chief Executive Officer or Chief Financial Officer, unless our Board of Directors determines, in good faith, exigent circumstances require their prompt replacement.

These limitations and restrictions may adversely affect our ability to finance our future operations or capital needs or engage in other business activities that may be in our best interests. Further, the revolving credit facilities subject us to various reporting covenants and financial covenants which require us to maintain certain levels of debt ratios and minimum earnings before income taxes, depreciation, and amortization (EBITDA).

The lockbox arrangements under the revolving bank facilities provide that substantially all of the income generated is deposited directly into lockbox accounts and then swept into cash management accounts for the benefit of the bank. Cash is disbursed to us only after payment of the applicable debt service and principal.

Our ability to borrow under the revolving bank facilities is subject to compliance with the negative and financial covenants. If we breach any of the covenants in our revolving credit facilities, we may be in default under our revolving credit facilities. If we default, our borrowings under the revolving credit facilities could be declared due and payable, including accrued interest and other fees.

Item 1B. *Unresolved Staff Comments*

None.

Item 2. *Properties*

As of December 31, 2012, we owned or leased a total of approximately 73,000 square feet of space worldwide. We lease our corporate headquarters and manufacturing facility which consists of approximately 57,000 square feet in Irvine, California. Our lease expires on April 20, 2015. We also own a 12,000 square foot manufacturing and administrative facility in Floss, Germany. See Note 3 to the Notes to the Consolidated Financial Statements Property, Plant, and Equipment, Net.

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

Item 3. *Legal Proceedings*

We disclose material loss contingencies deemed to be reasonably possible and accrue for loss contingencies when, in consultation with our legal advisors, we conclude 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.

In the normal course of business, we are subject to legal proceedings, lawsuits and other claims. Although the ultimate aggregate amount of probable monetary liability or financial impact with respect to these matters is subject to many uncertainties and is therefore not predictable with assurance, management believes that any monetary liability or financial impact to us from these matters, individually and in the aggregate, would not be material to our financial condition, results of operations or cash flows. However, there can be no assurance with respect to such results, and monetary liability or financial impact to us from these other matters could differ materially from those projected.

Table of Contents

On April 24, 2012, CAO Group, Inc. (CAO) filed a lawsuit against us in the United States District Court for the District of Utah, Central Division, alleging patent infringement of U.S. Patent No. 7,485,116 involving our ezLase diode laser. On September 12, 2012, CAO filed a First Amended Complaint, which added claims for (1) business disparagement/injurious falsehood and (2) unfair competition. The new claims are based on a press release that we issued on or about April 30, 2012, which CAO alleges contain statements that are factually inaccurate and falsities that are disparaging to CAO and its diode product. The First Amended Complaint seeks unspecified damages, punitive damages, injunctive relief, treble damages, costs, interest, and attorneys' fees. On September 14, 2012, we filed an inter partes reexamination request with respect to the asserted patent with the United States Patent and Trademark Office. The Court then entered a stay of the lawsuit pending the request for reexamination, which reexamination request was subsequently granted. We plan to vigorously defend against the allegations.

Item 4. Mine Safety Disclosures

Not applicable.

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

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

The following table sets forth the high and low sale prices for our common stock for the periods indicated:

	Price Range	
	High	Low
Fiscal 2012:		
First Quarter	\$ 3.43	\$ 2.44
Second Quarter	\$ 2.99	\$ 1.72
Third Quarter	\$ 2.00	\$ 1.50
Fourth Quarter	\$ 2.37	\$ 1.65
Fiscal 2011:		
First Quarter	\$ 5.39	\$ 1.45
Second Quarter	\$ 6.92	\$ 3.97
Third Quarter	\$ 5.65	\$ 2.14
Fourth Quarter	\$ 3.90	\$ 2.27

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

As of March 8, 2013, the closing price of our common stock on the NASDAQ Capital Market was \$4.23 per share, and the number of stockholders of record was 165. 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 currently intend to retain our available funds from earnings for future growth and, therefore, do not anticipate paying any cash dividends in the foreseeable future. Stock dividends are discussed quarterly by our Board of Directors and management. The actual declaration of future stock dividends, and the establishment of record and payment dates, is subject to final determination by our Board of Directors after its review of our financial performance, expected future operations and earnings and any other factors as our Board of Directors may deem relevant. Our dividend policy may be changed at any time, and from time to time, by our board of directors.

Table of Contents

The following table sets forth certain information relating to our stock dividends declared during 2012 and 2011:

	Declaration Date	Record Date	Payment Date	Dividend per Share	Number of Shares Outstanding	Total Stock Dividends Declared
	(in thousands, except per share data)					
Calendar year 2012	Nov. 8, 2012	Dec. 14, 2012	Dec. 28, 2012	0.5%	31,283,974	159,490
	Aug. 22, 2012	Sept. 14, 2012	Sept. 28, 2012	0.5%	31,124,484	158,561
	May 10, 2012	Jun. 8, 2012	Jun. 25, 2012	0.5%	31,062,608	158,318
	Mar. 2, 2012	Mar. 15, 2012	Mar. 30, 2012	0.5%	30,805,300	157,793
Calendar year 2011	Nov. 11, 2011	Nov. 25, 2011	Dec. 5, 2011	1%	30,635,756	306,782
	Aug. 18, 2011	Aug. 29, 2011	Sept. 15, 2011	1%	30,283,112	303,866
	May 31, 2011	Jun. 10, 2011	Jun. 30, 2011	1%	29,845,323	283,656
	Mar. 10, 2011	Mar. 15, 2011	Mar. 31, 2011	1%	27,778,313	271,411

In February 2013, the Board of Directors announced a 2% annual stock dividend policy for 2013 and declared a one-half percent stock dividend (the March Stock Dividend) payable March 29, 2013 to stockholders of record on March 15, 2013. Although the Board expressed its desire to continue to declare stock dividends in each quarter, the March Stock Dividend was deemed to be a special dividend and there is no assurance, with respect to the amount or frequency, that any stock dividend will be declared in the future.

Stock Repurchase Program

On August 10, 2011, we announced that our Board of Directors had authorized a stock repurchase program, pursuant to which we may repurchase up to an aggregate of 2,000,000 shares of our outstanding common stock. The stock repurchase program became effective on August 12, 2011. We expect to fund the stock repurchase program with existing cash and cash equivalents on hand. Any shares repurchased will be retired and shall resume the status of authorized and unissued shares. Repurchases of our common stock may be made from time to time through a variety of methods, including open market purchases, privately negotiated transactions or block transactions. We have no obligation to repurchase shares under the stock repurchase program, and the timing, actual number and value of the shares that are repurchased will be at the discretion of our management and will depend upon a number of considerations, including the trading price of our common stock, general market conditions, applicable legal requirements and other factors. The stock repurchase program will expire on August 12, 2013, unless the program is completed sooner, suspended, terminated, or otherwise extended. Pursuant to the stock repurchase program, we repurchased 133,365 shares and 100,500 shares of our common stock at a weighted average price of \$1.73 and \$2.68 during the years ended December 31, 2012 and 2011, respectively.

Stock repurchase activities under the program are as follows:

	Total number of shares purchased	Average price paid per share	Total number of shares purchased as part of publicly announced plans or programs	Maximum number of shares that may yet be purchased under the plans or programs(1)
10/1/2011 12/31/2011	100,500	\$ 2.68	100,500	1,899,500
7/1/2012 7/31/2012	102,306	1.74	102,306	1,797,194
8/1/2012 8/31/2012	31,059	1.69	31,059	1,766,135
Total	233,865	\$ 2.14	233,865	1,766,135

- (1) All share repurchases were completed pursuant to the share repurchase plan approved by the Board of Directors on August 10, 2011, which such plan permits management to repurchase, subject to the terms of the plan, up to an aggregate of 2,000,000 shares of the Company's outstanding common stock prior to the plan's expiration on August 12, 2013.

Table of Contents**Stock Performance Graph**

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

The following stock performance graph below compares the cumulative total stockholder return for Biolase, Inc. on \$100 invested, assuming the reinvestment of all dividends, on December 31, 2007, the last trading day before our 2008 fiscal year, through the end of fiscal 2012 with the cumulative total return on \$100 invested for the same period in the NASDAQ Composite Index and the NASDAQ Medical Equipment Index. The historical stock performance shown on the graph below is not necessarily indicative of future price performance.

	Years Ended December 31,					
	2007	2008	2009	2010	2011	2012
Biolase, Inc.	\$ 100.00	\$ 63.14	\$ 80.93	\$ 74.15	\$ 113.32	\$ 83.22
NASDAQ Composite Index	100.00	59.10	82.19	97.23	98.85	110.91
NASDAQ Medical Equipment	100.00	53.91	75.19	78.88	89.14	97.76

Table of Contents**Item 6. Selected Financial Data**

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

	2012(1)	Years Ended December 31,			2008
		2011	2010	2009	
		(in thousands, except per share data)			
Consolidated Statements of Operations Data:					
Net revenue	\$ 57,356	\$ 48,858	\$ 26,225	\$ 43,347	\$ 64,625
Net cost of revenue(2)	30,878	27,540	17,400	23,285	31,963
Gross profit	26,478	21,318	8,825	20,062	32,662
Operating expenses:					
Sales and marketing(2)	16,250	13,075	9,938	11,041	22,040
General and administrative(2)	8,075	7,936	6,557	7,835	12,006
Engineering and development(2)	4,684	4,311	3,790	4,146	5,580
Patent infringement legal settlement(3)					1,232
Impairment of intangible asset(4)					232
Impairment of property, plant and equipment(5)			35		355
Total operating expenses	29,009	25,322	20,320	23,022	41,445
Loss from operations	(2,531)	(4,004)	(11,495)	(2,960)	(8,783)
Non-operating (loss) income	(414)	(393)	(468)	123	(225)
Loss before income taxes	(2,945)	(4,397)	(11,963)	(2,837)	(9,008)
Income tax provision	111	89	58	119	121
Net loss as reported	\$ (3,056)	\$ (4,486)	\$ (12,021)	\$ (2,956)	\$ (9,129)
Net loss from operations per share:					
Basic	\$ (0.08)	\$ (0.13)	\$ (0.44)	\$ (0.11)	\$ (0.34)
Diluted	\$ (0.08)	\$ (0.13)	\$ (0.44)	\$ (0.11)	\$ (0.34)
Net loss per share:					
Basic	\$ (0.10)	\$ (0.15)	\$ (0.46)	\$ (0.11)	\$ (0.35)
Diluted	\$ (0.10)	\$ (0.15)	\$ (0.46)	\$ (0.11)	\$ (0.35)
Shares used in computing net loss from operations per share and net loss per share(6):					
Basic	31,308	29,907	26,250	26,082	25,977
Diluted	31,308	29,907	26,250	26,082	25,977
Consolidated Balance Sheet Data*:					
Working capital (deficit)	\$ 7,542	\$ 9,044	\$ (5,717)	\$ 5,250	\$ 5,023
Total assets	\$ 31,973	\$ 29,807	\$ 18,147	\$ 22,177	\$ 35,708
Long-term liabilities	\$ 804	\$ 956	\$ 1,534	\$ 3,086	\$ 2,547
Stockholders' equity (deficit)	\$ 11,794	\$ 12,569	\$ (3,047)	\$ 7,929	\$ 9,390

(1) Net revenue and net cost of revenue for 2012 includes the non-recurring event of approximately \$1.1 million, which if excluded would result in net revenue of \$58.5 million and net cost of revenue of \$32.0 million.

Edgar Filing: BIOLASE, INC - Form 10-K

- (2) 2012, 2011, and 2010 include \$1.6 million, \$1.5 million, and \$727,000, respectively, in total compensation cost related to stock options classified in cost of revenue, sales and marketing, general and administrative, and engineering and development expenses.

Table of Contents

- (3) Relates to cash payment made in connection with the intellectual property portfolio of Diodem, LLC, (Diodem), which was acquired in January 2005 as part of a litigation settlement with the owners of Diodem.
- (4) Relates to the write-off of the Diolase trade name during the year ended December 31, 2008.
- (5) In December 2008, we wrote down the value of our land and building in Germany by \$355,000 to reflect the market value of the asset. In 2010, the land and building was written down by an additional \$35,000.
- (6) Shares used in computing net loss from operations per share and net loss per share have been adjusted to reflect the effects of stock dividends.

* Certain amounts have been reclassified to conform to current year presentation.

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

You should read the following discussion and analysis in conjunction with our Consolidated Financial Statements and related Notes thereto included in Part II, Item 8 of this Report and the Risk Factors included in Part I, Item 1A of this Report, as well as other cautionary statements and risks described elsewhere in this Report, before deciding to purchase, hold or sell our common stock.

Overview

We are a biomedical company that develops, manufactures, and markets lasers in dentistry and medicine and also markets and distributes dental imaging equipment, including cone beam digital x-rays and CAD/CAM intra-oral scanners. Our dental laser systems that allow dentists, periodontists, endodontists, oral surgeons, and other specialists to perform a broad range of dental procedures, including cosmetic and complex surgical applications. Our systems are designed to provide clinically superior performance for many types of dental procedures with less pain and faster recovery times than are generally achieved with drills, scalpels, and other dental instruments. We have clearance from the FDA to market our laser systems in the United States and also have the necessary approvals to sell our laser systems in Canada, the European Union and various other international markets. Our licensed dental imaging equipment and other related products are designed to improve applications and procedures in dentistry and medicine.

We offer two categories of laser system products: Waterlase systems and Diode systems. Our flagship product category, the Waterlase system, uses a patented combination of water and laser energy to perform most procedures currently performed using dental 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 currently have approximately 160 issued and 150 pending U.S. and international patents, the majority of which are related to our core Waterlase technology and dental and medical lasers. Since 1998, we have sold over 9,500 Waterlase systems, including more than 5,500 Waterlase MD and iPlus systems, and more than 21,600 laser systems in over 60 countries.

We have suffered recurring losses from operations and have not generated cash from operations for the three years ended December 31, 2012. In order for us to continue operations and discharge our liabilities and commitments in the normal course of business, we must sell our products directly to end-users and through multiple distributors; establish profitable operations through increased sales and reduced operating expenses; and potentially raise additional funds, principally through the additional sales of our securities or debt financings to meet our working capital needs.

We intend to increase sales by increasing our product offerings, by expanding our direct sales force and our distributor relationships both domestically and internationally. Accordingly, we have taken steps during Fiscal 2012, which we believe will improve our financial condition and ultimately improve our financial results, including increasing our product offerings with the launch of the new Epic diode laser system, for which we received the CE Mark in late September 2012 and FDA clearance in October 2012, executing a definitive five-

Table of Contents

year agreement with Copenhagen-based 3Shape Corporation (3Shape), making the Company a distributor of 3Shape s TRIOS intra-oral scanning technologies for digital impression-taking solutions in the U.S. and Canada, expanding our direct sales force and certain distributor relationships, and establishing two revolving credit facilities to meet our quarterly working capital needs.

Credit Facilities Established

On May 24, 2012, we entered into two revolving credit facility agreements with Comerica Bank (the Credit Agreements), as amended on August 6, 2012, (Amendment No. 1), which provide for borrowings against certain domestic accounts receivable and inventory, as set forth in the \$4.0 million revolving credit facility agreement (the Domestic Revolver), and borrowings against certain export related accounts receivable and inventory, as set forth in the \$4.0 million revolving credit facility agreement (the Ex-Im Revolver), for a combined aggregate commitment of borrowings up to \$8.0 million. The Credit Agreements mature on May 1, 2014 and are secured by substantially all assets now owned or hereinafter acquired. The Credit Agreements require compliance with certain financial and non-financial covenants, as defined therein. If a default occurs, Comerica Bank may declare the amounts outstanding under the Credit Agreements immediately due and payable. As of December 31, 2012, we were in compliance with these covenants.

As additional consideration for the lines of credit, we also issued warrants to Comerica Bank (the Comerica Warrants) to purchase up to 80,000 shares of our common stock at an exercise price of \$2.83 per share. The Comerica Warrants vest in four equal quarterly tranches beginning on May 24, 2012 and are exercisable once vested. The Comerica Warrants may be exercised with a cash payment from Comerica Bank, or, in lieu of a cash payment, Comerica Bank may convert the warrants into a number of shares, in whole or in part. In February 2013, Comerica Bank exercised 60,000 of the 80,000 warrants pursuant to the Notice of Exercise resulting in a net issuance of 30,515 shares of common stock. The remaining warrants to purchase 20,000 shares of common stock have an expiration date of May 24, 2017. The \$135,000 estimated fair value of the warrants was recorded as equity, resulting in a discount to the credit facilities at issuance. The discount is being amortized to interest expense over the term of the lines of credit. In connection with Amendment No. 1, we reduced the exercise price of the Comerica Warrants from \$2.83 to \$2.00 per share. The modification to the Comerica Warrants resulted in an incremental expense of \$7,000 which was added to the discount and is being amortized on a straight-line basis over the remaining term of the Credit Agreements.

Termination of Master Distribution Agreement

In August 2006, we entered into a License and Distribution Agreement with HSIC, a large distributor of healthcare products to office-based practitioners, pursuant to which we granted HSIC the exclusive right to distribute our complete line of dental laser systems, accessories and services in the United States and Canada.

On September 23, 2010, we entered into a Distribution and Supply Agreement with HSIC, effective August 30, 2010, (the D&S Agreement), which terminated all prior agreements with HSIC. Under the D&S Agreement, we granted HSIC certain non-exclusive distribution rights in North America and several international markets with respect to our dental laser systems, accessories, and related support and services in certain circumstances. In addition, we granted HSIC exclusivity in selected international markets subject to review of certain performance criteria. In connection with the D&S Agreement, HSIC placed two irrevocable purchase orders totaling \$9 million for our products. The first purchase order, totaling \$6 million, was for the purchase of iLase systems and was fully satisfied during the first quarter of 2011. The second purchase order, totaling \$3 million, was for the purchase of a combination of laser systems and was fully satisfied during the third quarter of 2011. The D&S Agreement granted HSIC a security interest in our inventory and assets, including our intellectual property.

On April 12, 2012, we completed a transaction with HSIC (the 2012 Termination Agreement) whereby we purchased HSIC s inventory of Waterlase MD Turbo laser systems for approximately \$1.1 million and HSIC

Table of Contents

released its liens on our assets. The arrangement enabled us to remove lien restrictions on our assets, including our inventory and intellectual property, and enabled us to reacquire 153 MD Turbo laser systems at a cost well below market. Pursuant to the terms of the transaction, the entire purchase price was paid by offsetting certain accounts receivable currently due from HSIC from sales made in the normal course of business. None of the funds used to offset the purchase price were related to the original sales of the MD Turbo laser systems that were purchased. As a result of the transaction, we are no longer required to fulfill certain future service obligations and, accordingly, derecognized approximately \$155,000 of accounts receivable due from HSIC related to support services previously provided and approximately \$142,000 of accrued warranties during the quarter ended March 31, 2012. During the quarter ended June 30, 2012, the Company reversed accrued sales and marketing service liabilities of approximately \$350,000 because the liability was extinguished with the closing of the 2012 Termination Agreement. During the year ended December 31, 2012, we sold all laser systems purchased under this arrangement at margins consistent with our comparable laser products.

License Agreement

In May 2010, we entered into a License Agreement (the 2010 P&G Agreement) with Procter & Gamble Company (P&G), which replaced an existing license agreement between us and P&G (the 2006 P&G Agreement). Pursuant to the 2010 P&G Agreement, we agreed to continue granting P&G an exclusive license to certain of our patents to enable P&G to develop products aimed at the consumer market and P&G agreed to pay royalties based on sales of products developed with such intellectual property. The prepaid royalty payments previously paid by P&G were applied to the new exclusive license period from January 1, 2009 through December 31, 2010. At this time, we had deferred royalty revenue totaling \$1.9 million from the 2006 P&G Agreement. The 2010 P&G Agreement permitted us to recognize \$1.5 million in royalty revenue for the year ended December 31, 2010 related to the 2009 and 2010 exclusivity period. As of December 31, 2010, \$375,000 remained in long term deferred revenue. On June 28, 2011, we entered into an amendment to the 2010 P&G Agreement (the 2011 P&G Amendment) which extended the effective period for the 2010 P&G Agreement from December 31, 2010 through June 30, 2011, and resulted in us recognizing the previously deferred \$375,000 of revenue as royalty revenue during the quarter ended June 30, 2011.

The 2011 P&G Amendment also provided that effective January 1, 2011, P&G's exclusive license to our patents converted to a non-exclusive license unless P&G paid us a license payment in the amount of \$187,500 by the end of the third quarter of 2011, and at the end of each quarter thereafter, throughout the term of the 2010 P&G Agreement. As a result of P&G not making any payments to us in the third or fourth quarters of the year ended December 31, 2011, their license converted to a non-exclusive license. We are currently engaged in an active collaboration with P&G to commercialize a consumer product utilizing our patents.

Critical Accounting Policies

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

Revenue Recognition. From September 2006 through August 2010, we sold our products in North America through an exclusive distribution relationship with HSIC. Effective August 30, 2010, we began selling our products in North America directly to customers through our direct sales force and through non-exclusive distributors, including HSIC. We sell our products internationally through exclusive and non-exclusive distributors as well as direct to customers in certain countries. Sales are recorded upon shipment from our facility and payment of our invoices is generally due within 90 days or less. Internationally, we sell products through independent distributors, including HSIC in certain countries. We record revenue based on four basic criteria that must be met before revenue can be recognized: (i) persuasive evidence of an arrangement exists; (ii) delivery has occurred and title and the risks and rewards of ownership have been transferred to our customer, or services have been rendered; (iii) the price is fixed or determinable; and (iv) collectability is reasonably assured.

Table of Contents

Sales of our laser systems include separate deliverables consisting of the product, disposables used with the laser systems, installation, and training. For these sales, effective January 1, 2011, we apply the relative selling price method, which requires that arrangement consideration be allocated at the inception of the arrangement to all deliverables using the relative selling price method. This requires us to use estimated selling prices of each of the deliverables in the total arrangement. The sum of those prices is then compared to the arrangement, and any difference is applied to the separate deliverable ratably. This method also establishes a selling price hierarchy for determining the selling price of a deliverable, which includes: (i) vendor-specific objective evidence (VSOE), if available, (ii) third-party evidence if vendor-specific objective evidence is not available, and (iii) estimated selling price if neither vendor-specific nor third-party evidence is available. VSOE is determined based on the value we sell the undelivered element to a customer as a stand-alone product. Revenue attributable to the undelivered elements is included in deferred revenue when the product is shipped and is recognized when the related service is performed. Disposables not shipped at time of sale and installation services are typically shipped or installed within 30 days. Training is included in deferred revenue when the product is shipped and is recognized when the related service is performed or upon expiration of time offered under the agreement, typically within six months from date of sale. The adoption of the relative selling price method does not significantly change the value of revenue recognized.

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

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

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

For sales transactions involving used laser trade-ins, we record the purchased trade-ins as inventory at the fair value of the asset surrendered with the offset to accounts receivable. In determining the estimated fair value of used laser trade-ins, we make an assessment of usable parts, key components, and consider the ultimate resale value of the certified pre-owned (or CPO) laser with applicable margins. We sell these CPO laser trade-ins as refurbished lasers following our laser system revenue recognition policy. Trade-in rights are not established nor negotiated with customers during the initial sales transaction of the original lasers. Trade-in rights are promotional events used at our discretion to encourage existing laser customers to purchase new lasers by offering perceived discounts in exchange for customers trading in original lasers. A customer is not required to trade-in a laser nor are we required to accept a trade-in, however, the promotional value offered in exchange for the trade-in laser is not offered without a laser trade-in. The transaction is treated as a monetary transaction as each sale transaction involving a customer trade-in includes significant boot of greater than 25% of the fair value of the exchange. As a monetary transaction, the sale is recognized following our laser system revenue recognition policy. There have been no sales transactions in which the cash consideration was less than 25% of the total transaction value.

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

Table of Contents

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

Accounting for Stock-Based Payments. We recognize compensation cost related to all stock-based payments based on the grant-date fair value.

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

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

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

Valuation of Goodwill and Other Intangible Assets. Goodwill and other intangible assets with indefinite lives are not amortized but are evaluated for impairment annually or whenever events or changes in circumstances indicate that the asset might be impaired. We conducted our annual impairment analysis of our goodwill as of June 30, 2012 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. Waterlase systems sold domestically are covered by our warranty for a period of one year while our Diode systems warranty period is for two years from date of sale by us or the distributor to the end-user. Waterlase systems sold internationally are generally covered by our warranty for a period of sixteen months while our Diode systems warranty period is up to twenty eight months from 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

Table of Contents

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 do not offer warranties on imaging products which are 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 will assess whether such information warrants the recording of expense relating to contingencies. To be recorded as expense, a loss contingency must be both probable and reasonably estimable. If a loss contingency is material but is not both probable and estimable, we will disclose the matter in the notes to the consolidated financial statements.

Income Taxes. Based upon our operating losses during 2012 and 2011 and the available evidence, management has determined that it is more likely than not that the deferred tax assets as of December 31, 2012 will not be realized in the near term, excluding a portion of the foreign deferred tax assets totaling approximately \$16,000. Consequently, we have established a valuation allowance against our net deferred tax asset totaling approximately \$33.3 and \$33.8 million as of December 31, 2012 and 2011, respectively. In this determination, we considered factors such as our earnings history, future projected earnings and tax planning strategies. If sufficient evidence of our ability to generate sufficient future taxable income tax benefits becomes apparent, we may reduce our valuation allowance, resulting in tax benefits in our statement of operations and in additional paid-in-capital. Management evaluates the potential realization of our deferred tax assets and assesses the need for reducing the valuation allowance periodically.

Fair Value of Financial Instruments

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

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

Money market securities. Money market securities are cash equivalents, which are included in cash and cash equivalents, and consist of highly liquid investments with original maturities of three months or less. We use quoted active market prices for identical assets to measure fair value. We had money market securities of approximately \$1.3 million and \$0 at December 31, 2012 and 2011, respectively.

Table of Contents**Results of Operations**

The following table sets forth certain data from our operating results for each of the years ended December 31, 2012, 2011, and 2010, expressed as percentages of revenue:

	Years Ended December 31,		
	2012	2011	2010
Net revenue			
Products and services	101.7%	99.1%	93.7%
Non-recurring event	(2.0)		
License fees and royalty	0.3	0.9	6.3
Total net revenue	100.0	100.0	100.0
Net cost of revenue			
Products and services	55.8	56.4	66.3
Non-recurring event	(2.0)		
Total net cost of revenue	53.8	56.4	66.3
Gross profit	46.2	43.6	33.7
Operating expenses:			
Sales and marketing	28.3	26.8	37.9
General and administrative	14.1	16.2	25.0
Engineering and development	8.2	8.8	14.5
Impairment of property, plant and equipment			0.1
Total operating expenses	50.6	51.8	77.5
Loss from operations	(4.4)	(8.2)	(43.8)
Non-operating (loss) income, net	(0.7)	(0.8)	(1.8)
Loss before income taxes	(5.1)	(9.0)	(45.6)
Income tax provision	0.2	0.2	0.2
Net loss	(5.3)%	(9.2)%	(45.8)%

The following table summarizes our net revenues by category for the years ended December 31, 2012, 2011, and 2010 (dollars in thousands):

	Years Ended December 31,					
	2012(1)		2011(2)		2010(2)	
Waterlase systems	\$ 36,041	63%	\$ 29,288	60%	\$ 8,241	32%
Diode systems	6,307	11%	9,172	19%	7,907	30%
Total Laser systems	42,348	74%	38,460	79%	16,148	62%
Imaging systems	3,365	6%	238	0%		0%
Consumables and other	5,954	10%	5,236	11%	4,234	16%
Services	5,524	10%	4,485	9%	4,198	16%
Total Products and services	57,191	100%	48,419	99%	24,580	94%

Edgar Filing: BIOLASE, INC - Form 10-K

License fees and royalties	165	0%	439	1%	1,645	6%
Net revenue	\$ 57,356	100%	\$ 48,858	100%	\$ 26,225	100%

- (1) The summary of net revenue includes the non-recurring event of approximately \$1.1 million, which if excluded would result in Waterlase systems revenue of \$37.2M and 64%, total laser systems revenue of \$43.5M and 74%, and net revenue of \$58.5M and 100% for the year ended December 31, 2012, and the remaining categorical percentages would decrease correspondingly.

- (2) Certain amounts have been reclassified to conform to the current year presentation.

Table of Contents***Year Ended December 31, 2012 Compared With Year Ended December 31, 2011***

Net Revenue. Net revenue for the year ended December 31, 2012 (Fiscal 2012) was \$57.4 million, an increase of \$8.5 million, or 17%, as compared with net revenue of \$48.9 million for the year ended December 31, 2011 (Fiscal 2011). Excluding the non-recurring event resulting from the 2012 Termination Agreement with HSIC, net revenue for Fiscal 2012 was \$58.5 million, an increase of \$9.6 million, or 20%, as compared to net revenue of \$48.9 million for Fiscal 2011. The increase in net revenue, excluding the non-recurring event, was primarily attributed to continued demand for our all-tissue Waterlase systems and increased sales of imaging systems. These increases, fueled by increased sales and marketing efforts, were offset by decreased sales of diode laser systems and lower royalty revenues. Domestic revenues were \$40.6 million, or 71% of net revenue, for Fiscal 2012 compared to \$32.8 million, or 67% of net revenue, for Fiscal 2011. International revenues for Fiscal 2012 were \$16.8 million, or 29% of net revenue compared to \$16.1 million, or 33% of net revenue for Fiscal 2011.

Laser system net revenues (Waterlase and Diode systems combined) increased by approximately \$3.9 million, or 10%, in Fiscal 2012 compared to Fiscal 2011. Net revenues from the sales of our Waterlase systems increased \$6.8 million, or 23%, in Fiscal 2012 compared to Fiscal 2011. Excluding the non-recurring event, laser system net revenue increased by approximately \$5.0 million, or 13%, for Fiscal 2012, compared to Fiscal 2011. Sales of our Waterlase systems, excluding the non-recurring event, increased \$7.9 million, or 27%, for Fiscal 2012, compared to Fiscal 2011. The increase, excluding the non-recurring event, was primarily due to increased sales and marketing efforts. Sales of our Diode systems decreased \$2.9 million, or 31%, in Fiscal 2012 compared to Fiscal 2011. The decrease was primarily attributed to lower sales of the iLase and ezlase lasers due to market anticipation of the new Epic laser which was launched at the end of September 2012, after unexpected delays in obtaining regulatory clearances. The fourth quarter 2012 compared with fourth quarter 2011 resulted in an overall increase in diode laser sales of \$1.3 million or 80%, from \$1.5 million to \$2.8 million, due primarily to a strong market acceptance of the new Epic laser offset by lower sales of the iLase and ezlase lasers. We expect that diode laser sales as a percentage of total laser sales will continue to increase as a result of the successful launch of our Epic laser and the planned expansion of diode lasers, including the launch of our Epic V-Series for the veterinary market during the first half of 2013.

Imaging system net revenue was \$3.4 million in Fiscal 2012 compared to \$238,000 in Fiscal 2011. Imaging systems were included in our product offerings beginning in late 2011. The 2012 addition of the intra-oral CAD/CAM scanning technology to our imaging system product offerings is expected to further enhance revenue growth in future periods.

Consumables and other net revenue, which includes consumable products, such as disposable tips, and shipping revenue increased approximately \$718,000, or 14%, for Fiscal 2012, as compared to Fiscal 2011. This increase in consumables and other net revenue is primarily a result of a larger customer base using our lasers.

Services net revenue, which consists of extended warranty service contracts, advanced training programs, and other services, increased by approximately \$1.0 million, or 23%, for Fiscal 2012, as compared to Fiscal 2011. The increased revenues were due to increased follow on sales related to a larger customer base using our lasers and increased sales and marketing efforts in this part of our business.

License fees and royalty revenue decreased approximately \$274,000 to approximately \$165,000 in Fiscal 2012 compared to \$439,000 in Fiscal 2011. The decrease resulted primarily as a result of recognition of deferred royalty revenue from P&G of \$375,000 during Fiscal 2011. We are currently engaged in an active collaboration with P&G to commercialize a consumer product utilizing our patents.

Net Cost of Revenue. Net cost of revenue in Fiscal 2012 increased by \$3.4 million, or 12%, to \$30.9 million, compared with net cost of revenue of \$27.5 million in Fiscal 2011. Excluding the non-recurring event, cost of revenue for Fiscal 2012 increased by \$4.5 million, or approximately 16%, to \$32.0 million, compared with net cost of revenue of \$27.5 million for Fiscal 2011. This increase, excluding the non-recurring event, was primarily attributed to increased sales.

Table of Contents

Gross Profit. Gross profit for Fiscal 2012 was \$26.5 million, or 46% of net revenue, an increase of \$5.2 million, as compared with gross profit of \$21.3 million, or 44% of net revenue, for Fiscal 2011. Excluding the non-recurring event, gross profit for Fiscal 2012 represented 45% of revenue. The increase was primarily due to increased sales, continued quality improvements, and efficiencies gained through improvements in the manufacturing process.

Operating Expenses. Operating expenses for Fiscal 2012 were \$29.0 million, or 51% of net revenue, a \$3.7 million increase as compared with \$25.3 million, or 52% of net revenue, for Fiscal 2011. Excluding the non-recurring event, operating expenses for Fiscal 2012 represented 50% of revenue. The year-over-year increase in expense is explained in the following expense categories:

Sales and Marketing Expense. Sales and marketing expenses for Fiscal 2012 increased by \$3.2 million, or 24%, to \$16.3 million, or 28% of net revenue, as compared with \$13.1 million, or 27% of net revenue, for Fiscal 2011. The increase was primarily a result of increased commission expenses of \$1.0 million related to higher sales, increased convention costs of \$988,000 related to the launch and integration of the Cefla NewTom and Biolase DaVinci 3-D Imaging product lines, higher payroll and consulting related expenses of \$645,000, and increased media and advertising expenses of \$533,000, offset by a net reduction in support services of \$252,000 related to the non-recurring event.

General and Administrative Expense. General and administrative expenses for Fiscal 2012 increased by \$139,000, or 2%, to \$8.1 million, or 14% of net revenue, as compared with \$7.9 million, or 16% of net revenue, for Fiscal 2011. The increase in general and administrative expenses resulted primarily from increased bank fees of \$206,000 and increased allowance for doubtful accounts of \$143,000, offset by decreased patent and legal costs of \$135,000 and decreased payroll and consulting related expenses of \$103,000.

Engineering and Development Expense. Engineering and development expenses for Fiscal 2012 increased by \$373,000, or 9%, to \$4.7 million, or 8% of net revenue, as compared with \$4.3 million, or 9% of net revenue, for Fiscal 2011. The increase was primarily related to increased payroll and consulting related expenses of \$266,000 and increased supplies expenses of \$196,000, offset by lower depreciation expenses of \$87,000. We expect to maintain our investment in engineering and development as we continue our efforts in new product development in the future.

The Affordable Care Act imposes a 2.3% medical device excise tax on certain U.S. revenues generated after December 31, 2012. This tax is assessed whether or not we earn a profit. A significant portion of our product sales to customers located in the U.S. will be subject to this tax which may negatively impact our operating expenses. We are evaluating our pricing strategy and operational initiatives to identify areas of cost savings that may help to offset the negative impact of this tax.

Non-Operating Income (Loss)

(Loss) Gain on Foreign Currency Transactions. We recognized an \$175,000 loss on foreign currency transactions for Fiscal 2012 compared to an \$88,000 loss for Fiscal 2011 due to exchange rate fluctuations between the U.S. dollar and other currencies.

Interest Expense. Interest expense consists primarily of interest on our revolving credit facilities, amortization of debt issuance costs and debt discount, the financing of our business insurance premiums, and interest on our term loan payable which was repaid in full in February 2011. Interest expense totaled approximately \$239,000 and \$305,000 for Fiscal 2012 and 2011, respectively. Interest expense for Fiscal 2011 included \$225,000 of unamortized debt-related costs that were expensed in conjunction with the repayment of our outstanding balances under the Loan and Security Agreement during February 2011.

Provision for Income Taxes. Our provision for income taxes was \$111,000 for Fiscal 2012, compared to \$89,000 in Fiscal 2011.

Table of Contents

Net Loss. For the reasons stated above, our net loss was \$3.1 million for Fiscal 2012 compared to a net loss of \$4.5 million for Fiscal 2011.

Year Ended December 31, 2011 Compared With Year Ended December 31, 2010

Net Revenue. Net revenue for Fiscal 2011 was \$48.9 million, an increase of \$22.7 million, or 87%, as compared with net revenue of \$26.2 million for the year ended December 31, 2010 (Fiscal 2010). Domestic revenues were \$32.8 million, or 67% of net revenue, for Fiscal 2011 compared to \$16.9 million, or 64% of net revenue, for Fiscal 2010. International revenues for Fiscal 2011 were \$16.1 million, or 33% of net revenue compared to \$9.3 million, or 36% of net revenue for Fiscal 2010.

Laser system net revenues increased by approximately \$22.3 million, or 138%, in Fiscal 2011 compared to Fiscal 2010. Sales of our Waterlase systems increased \$21.0 million, or 255%, in Fiscal 2011 compared to Fiscal 2010 primarily due to the Company's return to a direct and multi-distributor sales model in North America and sales of the Waterlase iPlus system after its introduction in early 2011. Sales of our Diode systems increased \$1.3 million, or 16%, in Fiscal 2011 compared to Fiscal 2010. The increase resulted primarily from volume sales of the iLase system and increased direct sales of our ezlase system.

Imaging system net revenue was \$238,000 in Fiscal 2011. We did not sell any Imaging Systems prior to Fiscal 2011.

Consumables and other net revenue, which includes consumable products, such as disposable tips, and shipping revenue increased approximately \$1.0 million, or 24%, for Fiscal 2011, as compared to Fiscal 2010. This increase in consumables net revenue is primarily a result of selling our products in North America directly to consumers and through non-exclusive distributor arrangements (rather than exclusively through a single distributor) and the launch of our Biolase Store in late 2010.

Services net revenue, which consists of extended warranty service contracts, advanced training programs, and other services, increased by approximately \$287,000, or 7%, for Fiscal 2011, as compared to Fiscal 2010. The increased revenues were due to increased follow on sales related to a larger customer base using our lasers and increased sales and marketing efforts in this part of our business, including selling in North America directly to consumers and through non-exclusive distributor arrangements (rather than exclusively through a single distributor).

License fees and royalty revenue decreased approximately \$1.2 million to approximately \$439,000 in Fiscal 2011 compared to \$1.6 million in Fiscal 2010. The decrease resulted primarily from the recognition of \$1.5 million of deferred P&G royalties in Fiscal 2010 as compared to the recognition of \$375,000 of deferred P&G royalties in Fiscal 2011. We are currently engaged in an active collaboration with P&G to commercialize a consumer product utilizing our patents.

Net Cost of Revenue. Cost of revenue in Fiscal 2011 increased by \$10.1 million, or 58%, to \$27.5 million, compared with cost of revenue of \$17.4 million in Fiscal 2010. This increase is primarily attributable to increases in sales. Although cost of revenue increased in Fiscal 2011 on an absolute basis as compared to Fiscal 2010, cost of revenue actually decreased when expressed as a percentage of net revenues, from 66% of net revenues for Fiscal 2010 to 56% of net revenues for Fiscal 2011, due to improved overhead absorption on increased sales volumes.

Gross Profit. Gross profit for Fiscal 2011 was \$21.3 million, or 44% of net revenue, an increase of \$12.5 million, as compared with gross profit of \$8.8 million, or 34% of net revenue, for Fiscal 2010. The increase was primarily due to higher sales volumes, better utilization of fixed costs, and reduced expenses. These factors were partially offset by strategic price concessions to luminaries and key opinion leaders in the dental field, increased costs related to the launch of the Waterlase iPlus system, the decline in P&G royalties, and reduced margins from international revenue.

Table of Contents

Operating Expenses. Operating expenses for Fiscal 2011 were \$25.3 million, or 52% of net revenue, a \$5.0 million increase as compared with \$20.3 million, or 77% of net revenue, for Fiscal 2010, as explained in the following expense categories:

Sales and Marketing Expense. Sales and marketing expenses for Fiscal 2011 increased by \$3.2 million, or 32%, to \$13.1 million, or 27% of net revenue, as compared with \$9.9 million, or 38% of net revenue, for Fiscal 2010. The increase in expenses resulted primarily from increased payroll and consulting related expenses of \$559,000, increased commissions of \$1.2 million, increased travel expenses of \$281,000, increased convention related expenses of \$622,000, and increased sales consumables and supplies expense of approximately \$356,000.

General and Administrative Expense. General and administrative expenses for Fiscal 2011 increased by \$1.3 million, or 20%, to \$7.9 million, or 16% of net revenue, as compared with \$6.6 million, or 25% of net revenue, for Fiscal 2010. The increase in general and administrative expenses resulted primarily from increased payroll and consulting expenses of \$473,000, increased professional service fees of \$457,000, increased investor relation expenses of \$122,000, and increased bank fees of \$186,000.

Engineering and Development Expense. Engineering and development expenses for Fiscal 2011 increased by \$521,000, or 14%, to \$4.3 million, or 9% of net revenue, as compared with \$3.8 million, or 14% of net revenue, for Fiscal 2010. The increase was primarily related to increased payroll and consulting expenses of \$557,000 in Fiscal 2011 compared with Fiscal 2010. We expect to continue to invest in engineering and development in the future for new product development in dentistry and other areas of medicine and, as such, these expenses may increase during the year ending December 31, 2012.

Non-Operating Income (Loss)

(Loss) Gain on Foreign Currency Transactions. We recognized an \$88,000 loss on foreign currency transactions for Fiscal 2011 compared to an \$110,000 loss for Fiscal 2010 due to exchange rate fluctuations between the U.S. dollar and other currencies.

Interest Expense. Interest expense consists primarily of interest on the financing of our business insurance premiums and interest on our term loan payable which was funded in May 2010 and repaid in full in February 2011. Interest expense, excluding the amortization of debt related costs, totaled approximately \$305,000 and \$361,000 for Fiscal 2011 and Fiscal 2010, respectively. Interest expense for Fiscal 2011 included \$225,000 of unamortized debt-related costs that were expensed in conjunction with the repayment of our outstanding balances under the Loan and Security Agreement during February 2011.

Provision for Income Taxes. Our provision for income taxes was \$89,000 for Fiscal 2011, compared to \$58,000 in Fiscal 2010.

Net Loss. For the reasons stated above, our net loss was \$4.5 million for Fiscal 2011 compared to a net loss of \$12.0 million for Fiscal 2010.

Table of Contents**Selected Quarterly Financial Data**

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

	(in thousands, except per share data)			
	March 31,	June 30	September 30,	December 31,
2012				
Net revenue	\$ 12,320	\$ 12,175(1)	\$ 13,781	\$ 19,080
Gross profit	\$ 5,807	\$ 5,500	\$ 6,281	\$ 8,890
(Loss) income from operations(2)	\$ (1,622)	\$ (1,713)	\$ (388)	\$ 1,192
Net (loss) income(2)	\$ (1,672)	\$ (1,877)	\$ (548)	\$ 1,041
Net (loss) income per share(4):				
Basic	\$ (0.05)	\$ (0.06)	\$ (0.02)	\$ 0.03
Diluted	\$ (0.05)	\$ (0.06)	\$ (0.02)	\$ 0.03
2011				
Net revenue	\$ 10,561	\$ 12,079	\$ 13,061	\$ 13,157
Gross profit	\$ 4,839	\$ 5,613	\$ 5,318	\$ 5,548
Loss from operations(3)	\$ (406)	\$ (717)	\$ (938)	\$ (1,943)
Net loss(3)	\$ (750)	\$ (753)	\$ (953)	\$ (2,030)
Net loss per share(4):				
Basic	\$ (0.03)	\$ (0.03)	\$ (0.03)	\$ (0.06)
Diluted	\$ (0.03)	\$ (0.03)	\$ (0.03)	\$ (0.06)

- (1) Net revenue for the quarter ended June 30, 2012 includes the non-recurring event of approximately \$1.1 million, which if excluded would result in net revenue of \$13.3 million.
- (2) Loss from operations and net loss includes \$583,000, \$340,000, \$357,000, and \$320,000 in compensation cost related to stock options for the quarters ended March 31, June 30, September 30, and December 31, 2012, respectively.
- (3) Loss from operations and net loss includes \$266,000, \$456,000, \$324,000, and \$482,000 in compensation cost related to stock options for the quarters ended March 31, June 30, September 30, and December 31, 2011, respectively.
- (4) Net (loss) income per share calculations for each of the quarters were based upon the weighted average number of shares outstanding for each period, adjusted to reflect the effects of stock dividends, and the sum of the quarters may not necessarily be equal to the full year net (loss) income per common share amount.

Liquidity and Capital Resources

At December 31, 2012, we had approximately \$2.5 million in cash and cash equivalents. Management defines cash and cash equivalents as highly liquid deposits with original maturities of 90 days or less when purchased. The decrease in our cash and cash equivalents by \$764,000 was primarily due to net cash used in operating and investing activities of \$1.7 million and \$698,000, respectively, offset by cash provided by financing activities of \$1.6 million.

At December 31, 2012, we had approximately \$7.5 million in working capital. Our principal sources of liquidity at December 31, 2012, consisted of approximately \$2.5 million in cash and cash equivalents, \$11.7 million of net accounts receivable, and \$6.4 million of available borrowings under two revolving credit facility agreements.

Table of Contents

Our ability to meet our obligations in the ordinary course of business is dependent upon our ability to sell our products directly to end-users and through distributors, establish profitable operations through increased sales, decrease expenses, and to generate cash from operations or obtain additional funds when needed. We intend to continue to increase sales by increasing our product offerings, expanding our direct sales force, and expanding our distributor relationships both domestically and internationally.

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 would be available on acceptable terms, if at all, or that any such financing activity would not be dilutive to our stockholders.

We anticipate that the cash generated from operations and the borrowings available under the lines of credit with Comerica Bank will be sufficient to fund our working capital requirements for 2013.

Credit Facilities Established

On May 24, 2012, we entered into two revolving credit facility agreements with Comerica Bank (the *Credit Agreements*), as amended on August 6, 2012, (*Amendment No. 1*), which provide for borrowings against certain domestic accounts receivable and inventory, as set forth in the \$4.0 million revolving credit facility agreement (the *Domestic Revolver*), and borrowings against certain export related accounts receivable and inventory, as set forth in the \$4.0 million revolving credit facility agreement (the *Ex-Im Revolver*), for a combined aggregate commitment of borrowings up to \$8.0 million. The *Credit Agreements* mature on May 1, 2014 and are secured by substantially all assets now owned or hereinafter acquired. The *Credit Agreements* require compliance with certain financial and non-financial covenants, as defined therein. If a default occurs, Comerica Bank may declare the amounts outstanding under the *Credit Agreements* immediately due and payable. As of December 31, 2012, we were in compliance with these covenants.

Lockbox arrangements under the revolving bank facilities provide that substantially all of the income generated is deposited directly into lockbox accounts and then swept into cash management accounts for the benefit of Comerica Bank. Cash is disbursed from Comerica Bank to us only after payment of the applicable debt service and principal. At December 31, 2012, there were no restricted cash amounts. Our obligations are generally secured by substantially all of our assets now owned or hereinafter acquired.

As additional consideration for the lines of credit, we also issued warrants to Comerica Bank (the *Comerica Warrants*) to purchase up to 80,000 shares of our common stock at an exercise price of \$2.83 per share. The *Comerica Warrants* vest in four equal quarterly tranches beginning on May 24, 2012 and are exercisable once vested. The *Comerica Warrants* may be exercised with a cash payment from Comerica Bank, or, in lieu of a cash payment, Comerica Bank may convert the warrants into a number of shares, in whole or in part. In February 2013, Comerica Bank exercised 60,000 of the 80,000 warrants pursuant to the Notice of Exercise resulting in a net issuance of 30,515 shares of common stock. These remaining warrants to purchase 20,000 shares of common stock have an expiration date of May 24, 2017.

Repayment of Loan and Security Agreement

On February 8, 2011, we repaid all outstanding balances under the Loan and Security Agreement with MidCap Funding III, LLC and Silicon Valley Bank, which included approximately \$2.6 million in principal, \$30,000 of accrued interest and \$169,000 of loan related expenses. In connection therewith, the banks released their security interest in all of our assets. Unamortized costs totaling approximately \$240,000 associated with the term loan payable were expensed in February 2011.

Table of Contents**Equity Financings**

During the year ended December 31, 2011, the Company raised approximately \$17.2 million in net proceeds through public and private equity financings which it utilized for working capital purposes.

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 invest 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 their customers which allow us to monitor current changes in business operations so we can respond as needed. We do not, generally, require customers to provide collateral before we sell them our products; however we have required certain distributors to make prepayments for significant purchases of our products. For the years ended December 31, 2012, 2011, and 2010, sales to HSIC worldwide accounted for approximately 3%, 19%, and 38%, respectively, of our net sales.

Receivables and Allowance for Doubtful Accounts

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

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

Consolidated Cash Flows

The following table summarizes our statements of cash flows for Fiscal 2012, Fiscal 2011, and Fiscal 2010 (in thousands):

	Years Ended December 31,		
	2012	2011	2010
Net cash provided by (used in):			
Operating activities	\$ (1,664)	\$ (13,320)	\$ (3,812)
Investing activities	(698)	(428)	(237)
Financing activities	1,559	15,387	2,814
Effect of exchange rates on cash	39	(26)	(46)
Net change in cash and cash equivalents	\$ (764)	\$ 1,613	\$ (1,281)

Fiscal 2012 Compared to Fiscal 2011

Net cash used in operating activities consists of our net loss, adjusted for our non-cash charges, plus or minus working capital changes. Cash used in operating activities for Fiscal 2012 totaled \$1.7 million and was primarily comprised of a net loss of \$3.1 million plus increases in accounts receivable of \$3.2 million offset by non-cash charges of \$3.2 million plus increases in deferred revenue of \$1.1 million.

The \$11.7 million decrease in net cash used in operating activities for Fiscal 2012 compared to Fiscal 2011 was primarily due to our decreased net loss, lower spending on inventory and prepaid expenses and other current assets kept on hand, and increased deferred revenue and customer deposits, offset by increased accounts receivable.

Table of Contents

Net cash used in investing activities for Fiscal 2012 was \$270,000 higher than for Fiscal 2011 due to increased capital asset expenditures offset slightly by proceeds from the sale of long-lived real estate assets in Germany. For fiscal 2013, we expect capital expenditures to total approximately \$750,000, and we expect depreciation and amortization to total approximately \$600,000.

The \$13.8 million decrease in net cash provided by financing activities for Fiscal 2012 compared to Fiscal 2011 was primarily due to non-recurring net proceeds from the issuance of stock in 2011 in the amount of \$17.2 million offset by the 2011 payoff of our term loan of \$2.7 million and the 2012 net borrowing under lines of credit of \$1.6 million.

Fiscal 2011 Compared to Fiscal 2010

Net cash used in operating activities represents our net loss adjusted for changes in working capital and non-cash charges. Cash used in operating activities for Fiscal 2011 totaled \$13.3 million and was primarily comprised of a net loss of \$4.5 million plus increases in accounts receivable and inventory of \$5.6 million and \$4.7 million, respectively, offset by a decrease in customer deposits of \$5.7 million.

The \$9.5 million increase in net cash used in operating activities for Fiscal 2011 compared to Fiscal 2010 was primarily due to our decreased net loss offset by increased accounts receivable and inventory.

Net cash used in investing activities for Fiscal 2011 was \$191,000 higher than for Fiscal 2010 due to increased capital asset expenditures.

The \$12.6 million increase in net cash provided by financing activities for Fiscal 2011 compared to Fiscal 2010 was primarily due to net proceeds from issuance of stock in the amount of \$17.2 million and the exercise of warrants and stock options of \$1.3 million, partially offset by the payoff of our term loan of \$2.7 million and the repurchase of stock and warrants in amount of \$398,000.

Contractual Obligations

We lease our facility under a non-cancellable operating lease that expires in April 2015. In January 2011, we amended the lease to defer a portion of the basic rent to future periods. In December 2012, we financed approximately \$379,000 of insurance premiums payable in nine equal monthly installments of approximately \$43,000 each, including a finance charge of 3.0%. These amounts are included in the outstanding obligations as of December 31, 2012 listed below.

The following table presents our expected cash requirements for contractual obligations outstanding as of December 31, 2012, for the years ending as indicated below (in thousands):

	Less Than 1 Year	1 to 3 Years	3 to 5 Years	More Than 5 years	Total
Operating lease obligations	\$ 683	\$ 810	\$	\$	\$ 1,493
Purchase obligations	9,660				9,660
Lines of credit	1,637				1,637
Other liabilities	409				409
Total	\$ 12,389	\$ 810	\$	\$	\$ 13,199

The purchase obligations relate to purchase orders with suppliers that we expect to complete during the year ending December 31, 2013. In conformity with accounting principles generally accepted in the United States of America (GAAP), purchase obligations and operating lease obligations are not reported in the consolidated balance sheet as of December 31, 2012.

Table of Contents

In addition to the amounts shown in the table above, \$91,000 of unrecognized tax benefits have been recorded as liabilities, and we are uncertain as to if or when such amounts may be settled. Related to these unrecognized tax benefits, we have also recorded a liability for potential penalties and interest of \$18,000 and \$29,000, respectively, at December 31, 2012.

Seasonality

Historically, we have experienced fluctuations in revenue from quarter to quarter due to seasonality. Revenue in the first quarter typically is lower than average and revenue in the fourth quarter typically is stronger than average due to the buying patterns of dental professionals. 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.

Recent Accounting Pronouncements

See Note 2 to the *Notes to the Consolidated Financial Statements - Summary of Significant Accounting Policies* included in this report for a discussion on recent accounting pronouncements.

Off-Balance Sheet Arrangements

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

Item 7A. *Quantitative and Qualitative Disclosures About Market Risk*

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

Our primary objective in managing our cash balances has been preservation of principal and maintenance of liquidity to meet our operating needs. Most of our excess cash balances are invested in money market accounts in which there is minimal interest rate risk. An increase in the LIBOR rate associated with our lines of credit would increase the interest expense we must pay. Our risk associated with fluctuation in interest expense is limited to our outstanding lines of credit balances. Under our current policies, we do not use interest rate derivative instruments to manage exposure to interest rate changes.

Item 8. *Financial Statements and Supplementary Data*

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

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

None.

Table of Contents

Item 9A. Controls and Procedures

Disclosure Controls and Procedures

Our management, with the participation of our CEO and CFO, evaluated the effectiveness of our disclosure controls and procedures (as defined in Rules 13a-15(e) and 15d-15(e) under the Exchange Act) as of December 31, 2012. Based on this evaluation, our CEO and CFO concluded that our disclosure controls and procedures were effective as of December 31, 2012.

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 Securities Exchange Act of 1934. A company's internal control over financial reporting is a process designed by, or under the supervision of, our principal executive and financial officers, and effected by our board of directors, management, and other personnel, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles. A company's internal control over financial reporting includes those policies and procedures that (i) pertain to the maintenance of records that, in reasonable detail, accurately and fairly reflect the transactions and dispositions of our assets; (ii) provide reasonable assurance that transactions are recorded as necessary to permit preparation of financial statements in accordance with generally accepted accounting principles, and that our receipts and expenditures are being made only in accordance with authorizations of our management and directors; and (iii) provide reasonable assurance regarding prevention or timely detection of unauthorized acquisition, use, or disposition of our assets that could have a material effect on our financial statements.

Under the supervision and with the participation of management, including our CEO and CFO, management conducted an assessment 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* (the COSO Framework). Based on our evaluation under the COSO Framework, management has concluded that our internal control over financial reporting was effective at a reasonable assurance level as of December 31, 2012.

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

BDO USA, LLP, our independent registered public accounting firm that audited the consolidated financial statements included in this Annual Report on Form 10-K, issued an attestation report on our internal control over financial reporting as of December 31, 2012; their report is included herein.

Changes in Internal Control over Financial Reporting

There have been no changes in our internal control over financial reporting (as defined in Rules 13a-15(f) and 15d-15(f) under the Securities Exchange Act of 1934) that occurred during the fourth quarter of 2012 that have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

Report of Independent Registered Public Accounting Firm

Board of Directors and Stockholders

BIOLASE, Inc.

Irvine, California

We have audited BIOLASE, Inc.'s (the Company's) internal control over financial reporting as of December 31, 2012, based on criteria established in Internal Control Integrated Framework issued by the

Table of Contents

Committee of Sponsoring Organizations of the Treadway Commission (the COSO criteria). The Company's management is responsible for maintaining effective internal control over financial reporting and for its assessment of the effectiveness of internal control over financial reporting, included in the accompanying Item 9A, Management's Report on Internal Control Over Financial Reporting. Our responsibility is to express an opinion on the Company's internal control over financial reporting based on our audit.

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

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

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

In our opinion, BIOLASE, Inc. maintained, in all material respects, effective internal control over financial reporting as of December 31, 2012, based on the COSO criteria.

We also have audited, in accordance with the standards of the Public Company Accounting Oversight Board (United States), the consolidated balance sheets of BIOLASE, Inc. as of December 31, 2012 and 2011, and the related consolidated statements of operations and comprehensive loss, stockholders' equity (deficit), and cash flows for each of the three years in the period ended December 31, 2012 and our report dated March 15, 2013 expressed an unqualified opinion thereon.

/s/ BDO USA, LLP

Costa Mesa, California

March 15, 2013

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

Table of Contents

Election of Directors and Security Ownership of Certain Beneficial Owners and Management Section 16(a) Beneficial Ownership Reporting Compliance in the definitive proxy statement (the Proxy Statement) to be filed in connection with our 2013 Annual Meeting of Stockholders, which Proxy Statement will be filed with the SEC within 120 days of December 31, 2012, is incorporated by reference herein.

We have adopted the Biolase, Inc. Code of Business Conduct and Ethics which applies to all our employees, officers and directors, including our Chief Executive Officer and Chief Financial Officer, and is filed as an exhibit to this Annual Report on Form 10-K.

Item 11. *Executive Compensation*

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

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

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

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

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

Item 14. *Principal Accountant Fees and Services*

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

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:*

<u>Report of Independent Registered Public Accounting Firm</u>	Page
<u>Consolidated Balance Sheets as of December 31, 2012 and 2011</u>	F-2
<u>Consolidated Statements of Operations and Comprehensive Loss for the years ended December 31, 2012, 2011, and 2010</u>	F-3
<u>Consolidated Statements of Stockholders' Equity (Deficit) for the years ended December 31, 2012, 2011, and 2010</u>	F-4
<u>Consolidated Statements of Cash Flows for the years ended December 31, 2012, 2011, and 2010</u>	F-5
<u>Notes to Consolidated Financial Statements</u>	F-6
	F-7

(2) *Financial Statement Schedule:*

<u>Schedule II Consolidated Valuation and Qualifying Accounts and Reserves for the years ended December 31, 2012, 2011, and 2010</u>	S-1
--	-----

Table of Contents

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 following exhibits are filed with this Annual Report on Form 10-K or are incorporated by reference herein in accordance with the designated footnote references.

Exhibit	Description	Filed Herewith	Form	Incorporated by Reference		
				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	Fifth Amended and Restated Bylaws of The Registrant, adopted on July 1, 2010.		8-K	07/02/2010	3.1	07/07/2010
4.1	Rights Agreement, dated as of December 31, 1998, between the Registrant and U.S. Stock Transfer Corporation.		8-A	12/31/1998	1	12/29/1998
4.2	Amendment to Rights Agreement, dated December 19, 2008, between the Registrant and Computershare Trust Company, N.A.		8-K	12/19/2008	4.1	12/22/2008
4.3	Specimen of common stock certificate.		S-3	06/03/2002	4.1	06/03/2002
10.1*	2002 Stock Incentive Plan.		Proxy	10/17/2005	E	10/17/2005
10.2*	Form of Stock Option Agreement under the 2002 Stock Option Plan.		10-K	12/31/04	10.26	07/19/2005
10.3	2002 Stock Incentive Plan.		Proxy	05/16/2007	A	04/10/2007
10.4	Form of Securities Purchase Agreement, dated April 7, 2011, by and between the Registrant and the investors signatory thereto.		8-K	04/07/2011	10.1	04/12/2011

Table of Contents

Exhibit	Description	Filed Herewith	Form	Incorporated by Reference		
				Period Ending/Date of Report	Exhibit	Filing Date
10.5	Form of Securities Purchase Agreement, dated June 24, 2011, by and between the Registrant and the investors signatory thereto.		8-K	06/24/2011	10.3	06/29/2011
10.6	Form of Common Stock Purchase Warrant, dated June 29, 2011, by and between the Registrant and the investors signatory thereto.		8-K	06/24/2011	10.4	06/29/2011
10.7	Form of Registration Rights Agreement, dated June 24, 2011, by and between the Registrant and the investors signatory thereto.		8-K	06/24/2011	10.5	06/29/2011
10.8	Engagement Agreement, dated June 22, 2011, by and between Registrant and Rodman & Renshaw, LLC.		8-K	06/24/2011	10.6	06/29/2011
10.9	Engagement Agreement Amendment, dated June 23, 2011, by and between Registrant and Rodman & Renshaw, LLC.		8-K	06/24/2011	10.7	06/29/2011
10.10	License Agreement between SurgiLight, Inc. and the Registrant dated February 3, 2005.		8-K	02/03/2005	2.1	03/18/2005
10.11*	Form of Indemnification Agreement between Registrant and its officers and directors.		10-Q	09/30/2005	10.1	11/09/2005
10.12	Lease, dated January 10, 2006 between Registrant and The Irvine Company LLC.		8-K	01/10/06	10.1	01/17/2006
10.13	Letter Agreement, dated June 28, 2006, by and between The Procter & Gamble Company and the Registrant.		10-Q	06/30/2006	10.1	08/09/2006
10.14	License Agreement, dated January 24, 2007, by and between The Procter & Gamble Company and the Registrant.		10-Q	03/31/2007	10.1	05/10/2007
10.15	Letter Agreement, dated June 28, 2011, by and between the Registrant and The Procter & Gamble Company.		10-Q	06/30/2011	10.2	08/11/2011
10.16	Loan and Security Agreement, dated May 27, 2010, by and among the Registrant, MidCap Financial, LLC, and Silicon Valley Bank.		10-Q	06/30/2010	10.2	08/16/2010
10.17	Secured Promissory Note, dated May 27, 2010, in favor of MidCap Financial, LLC.		10-Q	06/30/2010	10.3	08/16/2010

Table of Contents

Exhibit	Description	Filed Herewith	Form	Incorporated by Reference		
				Period Ending/Date of Report	Exhibit	Filing Date
10.18	Secured Promissory Note, dated May 27, 2010, in favor of Silicon Valley Bank.		10-Q	06/30/2010	10.4	08/16/2010
10.19	Intellectual Property Security Agreement, dated May 27, 2010, by and between the Registrant and MidCap Financial.		10-Q	06/30/2010	10.7	08/16/2010
10.20	Warrant to Purchase 71,186 shares of Common Stock of the Registrant issued to MidCap Financial, LLC, dated May 27, 2010.		10-Q	06/30/2010	10.5	08/16/2010
10.21	Warrant to Purchase 30,508 shares of Common Stock of the Registrant issued to Silicon Valley Bank, dated May 27, 2010.		10-Q	06/30/2010	10.6	08/16/2010
10.22	Amendment No. 1 to Warrant, dated September 23, 2010, in favor of MidCap Financial, LLC.		10-Q	09/30/2010	10.8	11/03/2010
10.23	Amendment No. 1 to Warrant, dated September 23, 2010, in favor of SVB Financial Group.		10-Q	09/30/2010	10.9	11/03/2010
10.24	Settlement Agreement, dated July 1, 2010, by and among Federico Pignatelli and the directors and officers named therein.		8-K	07/02/2010	10.1	07/07/2010
10.25	Settlement Agreement, dated July 6, 2010, by and between the Registrant and Brett Scott.		10-Q	09/30/2010	10.1	11/03/2010
10.26	Separation and General Release Agreement, dated August 24, 2010, by and between the Registrant and David M. Mulder.		10-Q	09/30/2010	10.4	11/03/2010
10.27	Distribution and Supply Agreement, dated September 23, 2010, by and between the Registrant and Henry Schein, Inc.		10-Q	09/30/2010	10.5	11/03/2010
10.28	Amended and Restated Security Agreement, dated September 23, 2010, by and between Biolase Technology, Inc. and Henry Schein, Inc.		10-Q	09/30/2010	10.6	11/03/2010
10.29	Forbearance Agreement, dated August 16, 2010, by and among Biolase Technology, Inc., MidCap Financial LLC, and Silicon Valley Bank.		10-Q	09/30/2010	10.3	11/03/2010

Table of Contents

Exhibit	Description	Filed Herewith	Form	Incorporated by Reference		
				Period Ending/Date of Report	Exhibit	Filing Date
10.30	Waiver and Amendment No. 1 to Loan and Security Agreement, dated September 23, 2010, by and among Biolase Technology, Inc., MidCap Funding III, LLC, and Silicon Valley Bank.		10-Q	09/30/2010	10.7	11/03/2010
10.31	Controlled Equity Offering Agreement, dated December 23, 2010, by and between Biolase Technology, Inc. and Ascendant Securities, LLC		8-K	12/23/2010	99.1	12/23/2010
10.32	Settlement Agreement, dated February 22, 2012, by and between Biolase Technology, Inc. and Henry Schein, Inc.		10-K	12/31/2011	10.32	3/13/2012
10.33	Loan and Security Agreement, dated May 24, 2012, by and between Biolase, Inc. and Comerica Bank.		10-Q	6/30/2012	10.1	8/9/2012
10.34	Borrower Agreement, dated May 24, 2012, by and between Biolase, Inc. and Comerica Bank, in favor of the Export-Import Bank of the United States.		10-Q	6/30/2012	10.2	8/9/2012
10.35	Warrant to purchase 80,000 shares of Common Stock of Biolase Inc., dated May 24, 2012.		10-Q	6/30/2012	4.1	8/9/2012
10.36	Amendment No. 1 to Warrant to purchase 80,000 shares of Common Stock of Biolase Inc., dated August 6, 2012.		10-Q	6/30/2012	4.2	8/9/2012
10.37	Master Revolving Note, dated May 24, 2012, in favor of Comerica Bank.		10-Q	6/30/2012	10.3	8/9/2012
14.1	Biolase Technology, Inc. Code of Business Conduct and Ethics. (Filed with the Registrant's Definitive Proxy Statement for its 2004 Annual Meeting of Stockholders filed May 10, 2004 and incorporated herein by reference.)		Proxy	05/10/2001	D	05/10/2004
21.1	Subsidiaries of the Registrant.	X				
23.1	Consent of Independent Registered Public Accounting Firm, BDO USA, LLP	X				
24.1	Power of Attorney (included in Signature page).					
31.1	Certification of Chief Executive Officer pursuant to Rule 13a-14 and Rule 15d-14(a) of the Securities Exchange Act of 1934, as amended	X				

Table of Contents

Exhibit	Description	Filed Herewith	Form	Incorporated by Reference		Filing Date
				Period Ending/Date of Report	Exhibit	
31.2	Certification of Chief Financial Officer pursuant to Rule 13a-14 and Rule 15d-14(a) of the Securities Exchange Act of 1934, as amended	X				
32.1	Certification of Chief Executive Officer pursuant to 18 U.S.C. 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002	X				
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	X				
101#	The following financial information from the Company's Annual Report on Form 10-K, for the year ended December 31, 2012, formatted in eXtensible Business Reporting Language: (i) Consolidated Balance Sheets, (ii) Consolidated Statements of Operations and Comprehensive Loss, (iii) Consolidated Statements of Stockholders Equity (Deficit) (iv) Consolidated Statements of Cash Flows, (v) Notes to Consolidated Financial Statements	X				

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

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

* Management contract or compensatory plan or arrangement.

Pursuant to Rule 406T of Regulation S-T, this interactive data file is deemed not filed or part of a registration statement or prospectus for purposes of Sections 11 or 12 of the Securities Act of 1933, is deemed not filed for purposes of section 18 of the Securities Exchange Act of 1934, and otherwise is not subject to liability under these sections.

Table of Contents

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 15, 2013

By: /s/ FEDERICO PIGNATELLI
Federico Pignatelli
Chief Executive Officer

Dated: March 15, 2013

By: /s/ FREDERICK D. FURRY
Frederick D. Furry
Chief Financial Officer and
Chief Operating 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/ FEDERICO PIGNATELLI Federico Pignatelli	Chairman of the Board and Chief Executive Officer, (Principal Executive Officer)	March 15, 2013
/s/ FREDERICK D. FURRY Frederick D. Furry	Chief Financial Officer and Chief Operating Officer (Principal Financial Officer and Principal Accounting Officer)	March 15, 2013
/s/ DR. ALEXANDER K. ARROW Dr. Alexander K. Arrow	Director	March 15, 2013
/s/ DR. NORMAN J. NEMOY Dr. Norman J. Nemoy	Director	March 15, 2013
/s/ GREGORY E. LICHTWARDT Gregory E. Lichtwardt	Director	March 15, 2013

Table of Contents

BIOLASE, INC.

Index to Consolidated Financial Statements and Schedule

	Page
<u>Report of Independent Registered Public Accounting Firm</u>	F-2
<u>Consolidated Balance Sheets as of December 31, 2012, and 2011</u>	F-3
<u>Consolidated Statements of Operations and Comprehensive Loss for the years ended December 31, 2012, 2011, and 2010</u>	F-4
<u>Consolidated Statements of Stockholders' Equity (Deficit) for the years ended December 31, 2012, 2011, and 2010</u>	F-5
<u>Consolidated Statements of Cash Flows for the years ended December 31, 2012, 2011, and 2010</u>	F-6
<u>Notes to Consolidated Financial Statements</u>	F-7
SCHEDULE	
Schedule numbered in accordance with Rule 5.04 of Regulation S-X:	
<u>II. Consolidated Valuation and Qualifying Accounts and Reserves</u>	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.	

Table of Contents

Report of Independent Registered Public Accounting Firm

Board of Directors and Stockholders

BIOLASE, Inc.

Irvine, California

We have audited the accompanying consolidated balance sheets of BIOLASE, Inc. (the Company's) as of December 31, 2012 and 2011 and the related consolidated statements of operations and comprehensive loss, stockholders' equity (deficit), and cash flows for each of the three years in the period ended December 31, 2012. In connection with our audits of the consolidated financial statements, we have also audited the consolidated financial statement schedule listed in the accompanying index as of and for the years ended December 31, 2012, 2011, and 2010. These consolidated financial statements and schedule are the responsibility of the Company's management. Our responsibility is to express an opinion on these consolidated financial statements and schedule based on our audits.

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

In our opinion, the consolidated financial statements referred to above present fairly, in all material respects, the financial position of BIOLASE, Inc. at December 31, 2012 and 2011, and the results of its operations and its cash flows for each of the three years in the period ended December 31, 2012, in conformity with accounting principles generally accepted in the United States of America.

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

We have also audited, in accordance with the standards of the Public Company Accounting Oversight Board (United States), the Company's internal control over financial reporting as of December 31, 2012, based on criteria established in *Internal Control - Integrated Framework* issued by the Committee of Sponsoring Organizations of the Treadway Commission (COSO) and our report dated March 15, 2013 expressed an unqualified opinion thereon.

/s/ BDO USA, LLP

Costa Mesa, California

March 15, 2013

Table of Contents**BIOLASE, INC.****CONSOLIDATED BALANCE SHEETS**

(in thousands, except per share data)

	December 31,	
	2012	2011
ASSETS		
Current assets:		
Cash and cash equivalents	\$ 2,543	\$ 3,307
Accounts receivable, less allowance of \$304 and \$289 in 2012 and 2011, respectively	11,680	8,899
Inventory, net	11,142	11,312
Prepaid expenses and other current assets	1,552	1,808
Total current assets	26,917	25,326
Property, plant and equipment, net	1,509	1,148
Intangible assets, net	300	212
Goodwill	2,926	2,926
Deferred tax asset	16	8
Other assets	305	187
Total assets	\$ 31,973	\$ 29,807
LIABILITIES AND STOCKHOLDERS EQUITY (DEFICIT)		
Current liabilities:		
Lines of credit	\$ 1,637	\$
Accounts payable	7,663	7,804
Accrued liabilities	6,267	6,177
Customer deposits	582	165
Deferred revenue, current portion	3,226	2,136
Total current liabilities	19,375	16,282
Deferred tax liabilities	663	594
Deferred revenue, long-term	3	25
Other liabilities, long-term	138	337
Total liabilities	20,179	17,238
Commitments and contingencies (Notes 5 and 7)		
Stockholders equity (deficit):		
Preferred stock, par value \$0.001; 1,000 shares authorized, no shares issued and outstanding		
Common stock, par value \$0.001; 50,000 shares authorized, 33,248 and 32,502 shares issued in 2012 and 2011, respectively; 31,284 shares and 30,538 shares outstanding in 2012 and 2011, respectively	34	33
Additional paid-in capital	140,747	138,507
Accumulated other comprehensive loss	(320)	(360)
Accumulated deficit	(112,268)	(109,212)
	28,193	28,968
Treasury stock (cost of 1,964 shares repurchased)	(16,399)	(16,399)
Total stockholders equity	11,794	12,569

Total liabilities and stockholders equity	\$ 31,973	\$ 29,807
--	-----------	-----------

See accompanying notes to consolidated financial statements.

F-3

Table of Contents**BIOLASE, INC.****CONSOLIDATED STATEMENTS OF OPERATIONS AND COMPREHENSIVE LOSS**

(in thousands, except per share data)

	Years Ended December 31,		
	2012	2011	2010
Products and services revenue	\$ 58,332	\$ 48,419	\$ 24,580
Non-recurring event (Note 11)	(1,141)		
License fees and royalty revenue	165	439	1,645
Net revenue	57,356	48,858	26,225
Cost of revenue	32,019	27,540	17,400
Non-recurring event (Note 11)	(1,141)		
Net cost of revenue	30,878	27,540	17,400
Gross profit	26,478	21,318	8,825
Operating expenses:			
Sales and marketing	16,250	13,075	9,938
General and administrative	8,075	7,936	6,557
Engineering and development	4,684	4,311	3,790
Impairment of property, plant and equipment			35
Total operating expenses	29,009	25,322	20,320
Loss from operations	(2,531)	(4,004)	(11,495)
Loss on foreign currency transactions	(175)	(88)	(110)
Interest income			3
Interest expense	(239)	(305)	(361)
Non-operating loss, net	(414)	(393)	(468)
Loss before income tax provision	(2,945)	(4,397)	(11,963)
Income tax provision	111	89	58
Net loss	(3,056)	(4,486)	(12,021)
Other comprehensive income (loss) items:			
Foreign currency translation adjustments	40	(36)	(102)
Comprehensive loss	\$ (3,016)	\$ (4,522)	\$ (12,123)
Net loss per share:			
Basic	\$ (0.10)	\$ (0.15)	\$ (0.46)
Diluted	\$ (0.10)	\$ (0.15)	\$ (0.46)
Shares used in the calculation of net loss per share:			

Edgar Filing: BIOLASE, INC - Form 10-K

Basic	31,308	29,907	26,250
Diluted	31,308	29,907	26,250

See accompanying notes to consolidated financial statements.

F-4

Table of Contents**BIOLASE, INC.****CONSOLIDATED STATEMENTS OF STOCKHOLDERS EQUITY (DEFICIT)**

(in thousands)

	Common Stock and Additional Paid-in Capital		Treasury Stock		Accumulated Other Comprehensive	Accumulated	Total
	Shares	Amount	Shares	Amount	(Loss)	Deficit	Stockholders Equity (Deficit)
Balances, January 1, 2010	26,340	\$ 117,255	(1,964)	\$ (16,399)	\$ (222)	\$ (92,705)	\$ 7,929
Exercise of stock options, net	225	199					199
Stock-based compensation		727					727
Non-employee equity instruments		19					19
Other compensation		87					87
Warrants issued in connection with loan payable		115					115
Net loss						(12,021)	(12,021)
Foreign currency translation adjustment					(102)		(102)
Balances, December 31, 2010	26,565	\$ 118,402	(1,964)	\$ (16,399)	\$ (324)	\$ (104,726)	\$ (3,047)
Exercise of stock options, net	628	1,244					1,244
Stock-based compensation		1,528					1,528
Non-employee equity instruments		273					273
Other compensation		250					250
Issuance of stock, net	4,117	17,223					17,223
Stock repurchase	(100)	(268)					(268)
Warrant repurchase		(130)					(130)
Exercise of warrants	126	18					18
Stock dividends	1,166						
Net loss						(4,486)	(4,486)
Foreign currency translation adjustment					(36)		(36)
Balances, December 31, 2011	32,502	\$ 138,540	(1,964)	\$ (16,399)	\$ (360)	\$ (109,212)	\$ 12,569
Exercise of stock options, net	214	455					455
Stock-based compensation		1,600					1,600
Non-employee equity instruments		23					23
Other compensation		250					250
Stock repurchase	(133)	(235)					(235)
Warrant issued in connection with lines of credit		142					142
Exercise of warrants	31	6					6
Stock dividends	634						
Net loss						(3,056)	(3,056)
Foreign currency translation adjustment					40		40
Balances, December 31, 2012	33,248	\$ 140,781	(1,964)	\$ (16,399)	\$ (320)	\$ (112,268)	\$ 11,794

See accompanying notes to consolidated financial statements.

Table of Contents**BIOLASE, INC.****CONSOLIDATED STATEMENTS OF CASH FLOWS**

(in thousands)

	Years Ended December 31,		
	2012	2011	2010
Cash Flows From Operating Activities:			
Net loss	\$ (3,056)	\$ (4,486)	\$ (12,021)
Adjustments to reconcile net loss to net cash and cash equivalents used in operating activities:			
Depreciation and amortization	513	695	1,070
Loss on disposal of assets, net	15	36	55
Impairment of property, plant and equipment			35
Provision for (recovery of) bad debts	241	74	(80)
Provision for inventory excess and obsolescence	330	392	
Amortization of discount on lines of credit	43		
Amortization of discounts on term loan payable		78	37
Amortization of debt issuance costs	91	99	70
Stock-based compensation	1,600	1,528	727
Other equity instruments compensation	23	273	19
Other non-cash compensation	250	250	87
Deferred income taxes	61	53	76
Incurred and unpaid interest expense	19		
Changes in operating assets and liabilities:			
Accounts receivable	(3,222)	(5,642)	978
Inventory	(160)	(4,716)	874
Prepaid expenses and other current assets	450	(552)	173
Customer deposits	417	(5,711)	5,877
Accounts payable and accrued liabilities	(347)	4,230	(773)
Deferred revenue	1,068	79	(1,016)
Net cash and cash equivalents used in operating activities	(1,664)	(13,320)	(3,812)
Cash Flows From Investing Activities:			
Additions to property, plant and equipment	(808)	(428)	(237)
Proceeds from disposal of long-lived assets	124		
Purchased other intangible assets	(14)		
Net cash and cash equivalents used in investing activities	(698)	(428)	(237)
Cash Flows From Financing Activities:			
Borrowings under lines of credit	16,600		
Payments under lines of credit	(14,963)		
Proceeds from term loan payable			3,000
Payments under term loan payable		(2,700)	(300)
Payment of debt issuance costs	(304)		(85)
Proceeds from exercise of warrants	6	18	
Payment to repurchase equity warrants		(130)	
Proceeds from equity offering, net of expenses		17,223	
Stock repurchase	(235)	(268)	
Proceeds from exercise of stock options	455	1,244	199
Net cash and cash equivalents provided by financing activities	1,559	15,387	2,814

Edgar Filing: BIOLASE, INC - Form 10-K

Effect of exchange rate changes	39	(26)	(46)
Increase (decrease) in cash and cash equivalents	(764)	1,613	(1,281)
Cash and cash equivalents, beginning of year	3,307	1,694	2,975
Cash and cash equivalents, end of year	\$ 2,543	\$ 3,307	\$ 1,694
Supplemental cash flow disclosure:			
Interest paid	\$ 88	\$ 80	\$ 236
Income taxes paid (refunded)	\$ 62	\$ 44	\$ (96)
Supplemental disclosure of non-cash transactions:			
Intangible assets acquired for accounts receivable reduction	\$ 200	\$	\$
	See accompanying notes to consolidated financial statements.		

F-6

Table of Contents

BIOLASE, INC.

NOTES TO CONSOLIDATED FINANCIAL STATEMENT

NOTE 1 BASIS OF PRESENTATION

The Company

BIOLASE, Inc., (the Company) incorporated in Delaware in 1987, is a biomedical company operating in one business segment that develops, manufactures, and markets lasers in dentistry and medicine and also markets and distributes dental imaging equipment, including cone beam digital x-rays and CAD/CAM intra-oral scanners.

Basis of Presentation

The consolidated financial statements include the accounts of BIOLASE, Inc. and its wholly-owned subsidiaries. The Company has eliminated all material intercompany transactions and balances in the accompanying consolidated financial statements. Certain amounts for prior years have been reclassified to conform to the current year presentation.

Use of Estimates

The preparation of these consolidated financial statements in conformity with accounting principles generally accepted 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, indefinite-lived intangible assets and the ability of goodwill to be realized, revenue deferrals for multiple element arrangements, 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.

Fair Value of Financial Instruments

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

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

Concentration of credit risk, interest rate risk and foreign currency exchange rate risk

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 invests 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 which allow management to monitor current changes in business operations respond as needed. The Company does not, generally, require customers to provide collateral before it sells them products; however is has required certain distributors to make prepayments for significant purchases of products. For the years ended December 31, 2012, 2011, and 2010, sales to Henry Schein, Inc. (HSIC) worldwide accounted for approximately 3%, 19%, and 38%, respectively, of our net sales.

Table of Contents

BIOLASE, INC.

NOTES TO CONSOLIDATED FINANCIAL STATEMENT (Continued)

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, including the facilities, consulting services and employee-related costs. To date, the Company has not entered into any hedging contracts. Future fluctuations in the value of the U.S. dollar may, however, affect the price competitiveness of the Company's products outside the United States.

Management's primary objective in managing the Company's cash balances has been preservation of principal and maintenance of liquidity to meet the Company's operating needs. Most of the Company's excess cash balances are invested in money market accounts in which there is minimal interest rate risk. An increase in the LIBOR rate associated with the Company's lines of credit would increase the interest expense the Company must pay. The Company's risk associated with fluctuation in interest expense is limited to its outstanding lines of credit balances. The Company does not use interest rate derivative instruments to manage exposure to interest rate changes.

Liquidity and Management's Plans

Although the Company generated \$1.9 million of cash from operations during the quarter ended December 31, 2012, the Company has suffered recurring losses from operations and has not generated cash from operations for the three years ended December 31, 2012. In order for the Company to continue operations and discharge its liabilities and commitments in the normal course of business, the Company must sell its products directly to end-users and through distributors; establish profitable operations through increased sales and reduced operating expenses; and potentially raise additional funds, principally through the additional sales of securities or debt financings to meet its working capital needs.

The Company intends to increase sales by increasing its product offerings, expanding its direct sales force and its distributor relationships both domestically and internationally. Accordingly, the Company has taken steps during Fiscal 2012 to improve its financial condition and ultimately improve its financial results, including increasing its product offerings with the launch of the new Epic diode laser system, for which the Company received the CE Mark in late September 2012 and FDA clearance in October 2012, executing a definitive five-year agreement with Copenhagen-based 3Shape Corporation (3Shape), making the Company a distributor of 3Shape's TRIOS intra-oral CAD/CAM scanning technologies for digital impression-taking solutions in the U.S. and Canada, expanding our direct sales force and certain distributor relationships, and establishing two revolving credit facilities to meet quarterly working capital needs.

Management anticipates that the cash generated from operations and the borrowings available under the lines of credit with Comerica Bank will be sufficient to fund the working capital requirements of the Company for 2013.

At December 31, 2012, the Company had approximately \$7.5 million in working capital. The Company's principal sources of liquidity at December 31, 2012 consisted of approximately \$2.5 million in cash and cash equivalents, \$11.7 million of net accounts receivable, and \$6.4 million of available borrowings under two revolving credit facility agreements.

On May 24, 2012, the Company entered into two revolving credit facility agreements with Comerica Bank which provide for borrowings of up to \$8.0 million. The Company had approximately \$1.6 million of borrowings outstanding under these lines of credit as of December 31, 2012. See Note 5 *Lines of Credit and Other Borrowings* for additional information.

Table of Contents

BIOLASE, INC.

NOTES TO CONSOLIDATED FINANCIAL STATEMENT (Continued)

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. Generally, any excess cash is invested in money market funds. Cash equivalents are carried at cost, which approximates fair market value.

Restricted Cash

The Company maintains bank accounts under deposit account control agreements with Comerica Bank, to be held for repayment of lines of credit and accrued interest expense or disbursement to its operating bank account, pursuant to the terms of two revolving credit facility agreements with Comerica Bank. At December 31, 2012, there were no restricted cash amounts.

Accounts Receivable

Trade accounts receivable are recorded at the invoiced amount and do not bear interest. The allowance for doubtful accounts is the Company's best estimate of the amount of probable credit losses in its existing accounts receivable. The Company evaluates its allowance for doubtful accounts based upon its knowledge of customers and their compliance with credit terms. The evaluation process includes a review of customers accounts on a regular basis which incorporates input from sales, service, and finance personnel. The review process evaluates all account balances with amounts outstanding more than 90 days and other specific amounts for which information obtained indicates that the balance may be uncollectible. The allowance for doubtful accounts is adjusted based on such evaluation, with a corresponding provision included in general and administrative expenses. Account balances are charged off against the allowance when it is probable the receivable will not be recovered. The Company does not have any off-balance-sheet credit exposure related to its customers.

Inventory

The Company values inventory at the lower of cost, determined using the first-in, first-out method, or market. 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 our allocation of fixed production overhead is based on the normal capacity of our 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.

Table of Contents**BIOLASE, INC.****NOTES TO CONSOLIDATED FINANCIAL STATEMENT (Continued)**

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, 2012, 2011, and 2010 totaled approximately \$377,000, \$565,000, and \$940,000, respectively.

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. The Company operates in one operating segment and has one 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. If goodwill is considered impaired, the impairment loss to be recognized is measured by the amount by which the carrying amount of the goodwill exceeds the implied fair value of that goodwill. 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 regards 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 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 (deficit) but

Table of Contents**BIOLASE, INC.****NOTES TO CONSOLIDATED FINANCIAL STATEMENT (Continued)**

is excluded from net (loss) income. Accumulated other comprehensive gain (loss) consists of the effects of foreign currency translation adjustments and unrealized gains or losses on marketable securities classified as available for sale.

Foreign Currency Translation and Transactions

Transactions of the Company's German, Spanish, Australian, and Indian subsidiaries are denominated in their local 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 gain (loss) in stockholders' equity (deficit). Gains 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

The Company's products were sold exclusively through HSIC in North America from September 2006 through August 2010. Effective August 30, 2010, the Company's products were sold domestically both directly to customers through its direct sales force and through non-exclusive distributors. Sales are recorded upon shipment and payment is generally due within 90 days or less. Internationally, the Company sells products through independent distributors, including HSIC. Revenue is recorded based on four basic criteria that must be met before revenue can be recognized: (1) persuasive evidence of an arrangement exists; (2) delivery has occurred and title and the risks and rewards of ownership have been transferred to the customer or services have been rendered; (3) the price is fixed or determinable; and (4) collectability is reasonably assured. Revenue is recorded for all sales upon shipment assuming all other revenue recognition criteria are met.

Sales of the Company's laser systems include separate deliverables consisting of the product, disposables used with the laser systems, installation, and training. For these sales, effective January 1, 2011, the Company applies the relative selling price method, which requires that arrangement consideration be allocated at the inception of an arrangement to all deliverables using the relative selling price method. This requires the Company to use (estimated) selling prices of each of the deliverables in the total arrangement. The sum of those prices is then compared to the arrangement, and any difference is applied to the separate deliverable ratably. This method also establishes a selling price hierarchy for determining the selling price of a deliverable, which includes: (1) vendor-specific objective evidence (VSOE) if available, (2) third-party evidence if vendor-specific objective evidence is not available, and (3) estimated selling price if neither vendor-specific nor third-party evidence is available. VSOE is determined based on the value the Company sells the undelivered element to a customer as a stand-alone product. Revenue attributable to the undelivered elements is included in deferred revenue when the product is shipped and is recognized when the related service is performed. Disposables not shipped at time of sale and installation services are typically shipped or installed within 30 days. Training is included in deferred revenue when the product is shipped and is recognized when the related service is performed or upon expiration of time offered under the agreement, typically within six months from date of sale. The adoption of the relative selling price method does not significantly change the value of revenue recognized. Deferred revenue attributable to undelivered elements, which primarily consists of training, totaled \$1.7 million and \$1.1 million as of December 31, 2012 and 2011, respectively.

Key judgments of the Company's revenue recognition include the collectability of payment from the customer, the satisfaction of all elements of the arrangement having been delivered, and that no additional customer credits and discounts are needed. The Company evaluates the customer's credit worthiness prior to the shipment of the product. Based on the assessment of the credit information available, the Company may determine the credit risk is

Table of Contents

BIOLASE, INC.

NOTES TO CONSOLIDATED FINANCIAL STATEMENT (Continued)

higher than normally acceptable, and will either decline the purchase or defer the revenue until payment is reasonably assured. Future obligations required at the time of sale may also cause the Company to defer the revenue until the obligation is satisfied.

Although all sales are final, the Company accepts returns of products in certain, limited circumstances and records a provision for sales returns based on historical experience concurrent with the recognition of revenue. The sales returns allowance is recorded as a reduction of accounts receivable and revenue. As of December 31, 2012 and 2011, \$110,000 and \$110,000, respectively, was recorded as a reduction of accounts receivable for sales returns.

Extended warranty contracts, which are sold to non-distributor customers, are recorded as revenue on a straight-line basis over the period of the contracts, which is typically one year. Included in deferred revenue for each of the years ended December 31, 2012 and 2011, was \$1.5 million and \$1.1 million, respectively, for extended warranty contracts. This is inclusive of an extended service contract commitment assumed as part of a settlement, of which \$3,000 will not be recognized as revenue until 2014 and beyond.

For sales transactions involving used laser trade-ins, the Company records the purchased trade-ins as inventory at the fair value of the asset surrendered with the offset to accounts receivable. In determining the estimated fair value of used laser trade-ins, Management makes an assessment of usable parts, key components, and consider the ultimate resale value of the certified pre-owned (or CPO) laser with applicable margins. The Company sells these CPO laser trade-ins as refurbished lasers following its laser system revenue recognition policy. Trade-in rights are not established nor negotiated with customers during the initial sales transaction of the original lasers. Trade-in rights are promotional events used at Management s discretion to encourage existing laser customers to purchase new lasers by offering perceived discounts in exchange for customers trading in original lasers. A customer is not required to trade-in a laser nor is the Company required to accept a trade-in, however, the promotional value offered in exchange for the trade-in laser is not offered without a laser trade-in. The transaction is treated as a monetary transaction as each sale transaction involving a customer trade-in includes significant boot of greater than 25% of the fair value of the exchange. As a monetary transaction, the sale is recognized following the Company s laser system revenue recognition policy. There have been no sales transactions in which the cash consideration was less than 25% of the total transaction value.

The Company recognizes revenue for royalties under licensing agreements for our patented technology when the product using our technology is sold. The Company estimates and recognizes the amount earned based on historical performance and current knowledge about the business operations of our licensees. Historically, the Company s estimates have generally been consistent with amounts reported by the licensees. Licensing revenue related to exclusive licensing arrangements is recognized concurrent with the related exclusivity period and totaled \$0, \$64,000, and \$145,000 for the years ended December 31, 2012, 2011, and 2010, respectively.

From time to time, the Company may offer sales incentives and promotions on its products. The cost of sales incentives are recorded at the date at which the related revenue is recognized as a reduction in revenue, increase in cost of goods sold or as a selling expense, as applicable, or later, in the case of incentives offered after the initial sale has occurred.

Provision for Warranty Expense

The Company provides warranties against defects in materials and workmanship of its laser systems for specified periods of time. Waterlase systems sold domestically are covered by the Company s warranty for a period of one year while the Company s Diode systems warranty period is for two years from date of sale by the Company or the distributor to the end-user. Waterlase systems sold internationally are generally covered by the

Table of Contents**BIOLASE, INC.****NOTES TO CONSOLIDATED FINANCIAL STATEMENT (Continued)**

Company's warranty for a period of sixteen months while its Diode systems warranty period is up to twenty eight months from 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. The Company does not offer warranties on imaging products which are covered by the manufacturer's warranties.

Changes in the initial product warranty accrual and the expenses incurred under our initial and extended warranties for the years ended December 31 were as follows (in thousands):

	Years Ended December 31,		
	2012	2011	2010
Initial warranty accrual, beginning balance	\$ 2,218	\$ 2,725	\$ 2,235
Provision for estimated warranty cost	1,705	1,586	3,126
Warranty expenditures	(2,224)	(2,093)	(2,636)
Initial warranty accrual, ending balance	1,699	2,218	2,725
Total warranty accrual, long term			424
Total warranty accrual, current portion	\$ 1,699	\$ 2,218	\$ 2,301

Shipping and Handling Costs and Revenues

Shipping and handling costs are expensed as incurred and are recorded as a component of cost of revenue. Charges to customers for shipping and handling are included as a component of revenue.

Advertising Costs

Advertising costs are expensed as incurred and totaled approximately \$907,000, \$444,000, and \$610,000 for the years ended December 31, 2012, 2011, and 2010, 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.

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.

Table of Contents**BIOLASE, INC.****NOTES TO CONSOLIDATED FINANCIAL STATEMENT (Continued)**

On January 1, 2007, the Company adopted the interpretations issued by the Financial Accounting Standards Board (FASB) which establishes a single model to address accounting for uncertain tax positions. The interpretations clarify the accounting for income taxes by prescribing a minimum recognition threshold a tax position is required to meet before being recognized in the financial statements and also provides guidance on de-recognition, measurement, classification, interest and penalties, accounting in interim periods, disclosure and transition.

Stock-Based Compensation

During the years ended December 31, 2012, 2011, and 2010, the Company recognized compensation cost related to stock options of \$1.6 million, \$1.5 million, and \$727,000, respectively, based on the grant date fair value. The net impact to earnings for the years ended December 31, 2012, 2011, and 2010, was \$(0.05), \$(0.05) and \$(0.03) per diluted share, respectively. The following table summarizes the income statement classification of compensation expense associated with share-based payments (in thousands):

	Years Ended December 31,		
	2012	2011	2010
Cost of revenue	\$ 245	\$ 175	\$ 41
Sales and marketing	514	463	193
General and administrative	668	751	407
Engineering and development	173	139	86
	\$ 1,600	\$ 1,528	\$ 727

As of December 31, 2012 and 2011, the Company had \$1.9 million and \$2.6 million, respectively, of total unrecognized compensation cost, net of estimated forfeitures, related to unvested share-based compensation arrangements granted under our existing plans. The cost is expected to be recognized over a weighted average period of 1.2 years.

The Black-Scholes option valuation model is used in estimating the fair value of traded options. 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 dates of grant. 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 assumption used in calculating the fair value of stock options is the expected volatility of the Company's common stock. 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 period of time is used in approximating the estimated volatility of new stock options. The expected term is estimated by analyzing the Company's historical share option exercise experience over a five year period. Compensation expense is recognized using the straight-line method for all stock-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 as necessary in subsequent periods if actual forfeitures differ from those estimates.

Table of Contents**BIOLASE, INC.****NOTES TO CONSOLIDATED FINANCIAL STATEMENT (Continued)**

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

	2012	2011	2010
Expected term (years)	3.70	4.15	4.54
Volatility	97%	105%	91%
Annual dividend per share	\$ 0.00	\$ 0.00	\$ 0.00
Risk-free interest rate	0.77%	1.53%	1.94%

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. Common shares outstanding, as included in the calculation of basic and diluted loss per share, includes retroactive adjustments to reflect increases resulting from stock dividends that have been paid through the date that these financial statements are issued.

Outstanding stock options and warrants to purchase approximately 4,713,000, 4,626,000, and 4,282,000 shares were not included in the calculation of diluted loss per share amounts for the years ended December 31, 2012, 2011, and 2010, respectively, as their effect would have been anti-dilutive.

Stock Dividends

The Board declared special one-half percent stock dividends during each of the quarters of 2012. The stock dividend declared during the quarter ended December 31, 2012 was payable December 28, 2012 to shareholders of record on December 14, 2012, the stock dividend declared during the quarter ended September 30, 2012 was payable September 28, 2012 to shareholders of record on September 14, 2012, the stock dividend declared during the quarter ended June 30, 2012 was payable June 25, 2012 to shareholders of record on June 8, 2012, and the stock dividend declared during the quarter ended March 31, 2012 was payable March 30, 2012 to shareholders of record on March 15, 2012. The Board deems these four stock dividends to be special dividends and there is no assurance, with respect to amount or frequency, that any stock dividend will be declared again in the future. All stock information presented, other than that related to stock options and warrants, has been adjusted to reflect the effects of these stock dividends. The number of shares issued as part of these quarterly stock dividends totaled 634,162 shares. During the year ended December 31, 2011, the Company declared and paid 1% stock dividends in each of the four quarters resulting in the issuance of 1,165,715 shares. The Board of Directors deems these four dividends to be special dividends and there is no assurance, with respect to amount or frequency, that any stock dividend will be declared again in the future. All stock information presented, other than that related to stock options and warrants, has been adjusted to reflect the effects of the stock dividends.

In February 2013, the Board of Directors announced a 2% annual stock dividend policy for 2013 and declared a one-half percent stock dividend (the March Stock Dividend) payable March 29, 2013 to stockholders of record on March 15, 2013. The Company expects to record the effects of the March Stock Dividend in the first quarter ending March 31, 2013.

Stock Repurchase Program

On August 10, 2011, the Company announced that its Board of Directors authorized a stock repurchase program, pursuant to which the Company may repurchase up to an aggregate of 2,000,000 shares of the Company's

Table of Contents**BIOLASE, INC.****NOTES TO CONSOLIDATED FINANCIAL STATEMENT (Continued)**

outstanding common stock. The stock repurchase program became effective on August 12, 2011. The Company expects to fund the stock repurchase program with existing cash and cash equivalents on hand. Any shares repurchased will be retired and shall resume the status of authorized and unissued shares. Repurchases of the Company's common stock may be made from time to time through a variety of methods, including open market purchases, privately negotiated transactions or block transactions. The Company has no obligation to repurchase shares under the stock repurchase program, and the timing, actual number and value of the shares that are repurchased will be at the discretion of the Company's management and will depend upon a number of considerations, including the trading price of the Company's common stock, general market conditions, applicable legal requirements and other factors. The stock repurchase program will expire on August 12, 2013, unless the program is completed sooner, suspended, terminated, or otherwise extended. Pursuant to the stock repurchase program, the Company repurchased 133,365 shares and 100,500 shares of our common stock at a weighted average price of \$1.73 and \$2.68 during the years ended December 31, 2012 and 2011, respectively.

Recent Accounting Pronouncements

Changes to U.S. GAAP are established by the FASB in the form of accounting standards updates (ASU's) to the FASB's Accounting Standards Codification (ASC).

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

Newly Adopted Accounting Standards

In September 2011, the FASB issued guidance for the impairment testing of goodwill. The guidance permits an entity to first assess qualitative factors to determine whether it is more-likely-than-not that the fair value of a reporting unit is less than its carrying amount as a basis for determining whether it is necessary to perform the two-step goodwill impairment test. This guidance is effective for annual and interim goodwill impairment tests performed for fiscal years beginning after December 15, 2011. The Company adopted this guidance effective January 1, 2012. The adoption did not have a material impact on the Company's consolidated financial statements.

In June 2011, the FASB updated the accounting guidance relating to presentation of comprehensive income. This guidance requires companies to present total comprehensive income, the components of net income, and the components of other comprehensive income (OCI) either in a single continuous statement of comprehensive income or in two, but consecutive, statements. Additionally, companies are required to present on the face of the consolidated financial statements the reclassification adjustments that are reclassified from OCI to net income, where the components of net income and the components of OCI are presented. This guidance is effective for fiscal years and interim periods within those years beginning after December 15, 2011, and requires retrospective application to all periods presented. The Company adopted this guidance effective January 1, 2012 and elected to present a single continuous statement of comprehensive loss. The adoption did not have a material impact on the Company's consolidated financial statements.

Accounting Standards not yet Adopted

In July 2012, the FASB simplified the guidance for testing for impairment of indefinite-lived intangible assets other than goodwill. The changes are intended to reduce compliance costs. The revised guidance allows a qualitative approach for testing indefinite-lived intangible assets for impairment, similar to the recently issued impairment testing guidance for goodwill and allows the option to first assess qualitative factors (events and

Table of Contents**BIOLASE, INC.****NOTES TO CONSOLIDATED FINANCIAL STATEMENT (Continued)**

circumstances) that could have affected the significant inputs used in determining the fair value of the indefinite-lived intangible asset to determine whether it is more likely than not (meaning a likelihood of more than 50 percent) that the indefinite-lived intangible asset is impaired. An organization may choose to bypass the qualitative assessment for any indefinite-lived intangible asset in any period and proceed directly to calculating its fair value. The amendments are effective for annual and interim impairment tests performed for fiscal years beginning after September 15, 2012. Early adoption is permitted. Management believes that the adoption of this guidance will not have a material impact on the Company's consolidated financial statements.

NOTE 3 SUPPLEMENTARY BALANCE SHEET INFORMATION

ACCOUNTS RECEIVABLE (in thousands):	December 31,	
	2012	2011
Components of accounts receivable, net of allowances, are as follows:		
Trade	\$ 11,456	\$ 8,583
Royalties	45	29
Other	179	287
Total receivables, net	\$ 11,680	\$ 8,899

Accounts receivable is net of allowances for doubtful accounts and sales returns totaling approximately \$414,000 and \$399,000 at December 31, 2012 and 2011, respectively.

INVENTORY, NET (in thousands):	December 31,	
	2012	2011
Components of inventory, net of allowances, are as follows:		
Raw materials	\$ 4,017	\$ 4,280
Work-in-process	1,949	2,538
Finished goods	5,176	4,494
Inventory, net	\$ 11,142	\$ 11,312

Inventory is net of a provision for excess and obsolete inventory totaling approximately \$1.9 million and \$2.3 million at December 31, 2012 and 2011, respectively.

PROPERTY, PLANT AND EQUIPMENT, NET (in thousands):	December 31,	
	2012	2011
Components of property, plant and equipment, net of depreciation, are as follows:		
Land	\$ 191	\$ 247
Building	246	317
Leasehold improvements	1,193	957
Equipment and computers	5,219	5,729
Furniture and fixtures	1,046	1,036
Construction in progress	132	26

Edgar Filing: BIOLASE, INC - Form 10-K

Accumulated depreciation and amortization	8,027 (6,518)	8,312 (7,164)
Property, plant and equipment, net	\$ 1,509	\$ 1,148

F-17

Table of Contents**BIOLASE, INC.****NOTES TO CONSOLIDATED FINANCIAL STATEMENT (Continued)**

On August 21, 2012, pursuant to a Sale and Purchase Agreement entered on June 12, 2012, the Company sold the smaller of two buildings and a portion of the land parcel of its two-building property in Floss, Germany. The purchase price of approximately \$136,000 was reduced by transaction costs, resulting in net proceeds of approximately \$124,000. As of December 31, 2012, the Company recorded a realized gain on the sale of these assets of approximately \$3,000. The Company also undertook an appraisal of the remaining land and building at the Floss property and determined that no impairment charge was necessary.

ACCRUED LIABILITIES (in thousands):	December 31,	
	2012	2011
Components of accrued liabilities are as follows:		
Payroll and benefits	\$ 2,326	\$ 1,928
Warranty accrual, current portion	1,699	2,218
Sales tax	763	526
Accrued professional services	502	669
Accrued insurance premium	751	433
Accrued support services		200
Other	226	203
Accrued liabilities	\$ 6,267	\$ 6,177

DEFERRED REVENUE (in thousands):	December 31,	
	2012	2011
Components of deferred revenue are as follows:		
Undelivered elements (training, installation, product and support services)	\$ 1,723	\$ 1,105
Extended warranty contracts	1,506	1,056
Total Deferred Revenue	3,229	2,161
Less Long-Term amounts:		
Extended warranty contracts	(3)	(25)
Total Deferred Revenue Long Term	(3)	(25)
Total Deferred Revenue Current	\$ 3,226	\$ 2,136

On May 20, 2010, the Company entered into a license agreement (the 2010 P&G Agreement), with Procter and Gamble Company (P&G), which replaced an existing license agreement between the Company and P&G (the 2006 P&G Agreement). Pursuant to the 2010 P&G Agreement, the Company agreed to continue granting P&G an exclusive license to certain of the Company's patents to enable P&G to develop products aimed at the consumer market and P&G agreed to pay royalties based on sales of products developed with such intellectual property. On June 28, 2011, the Company entered into an amendment to the 2010 P&G Agreement (the 2011 P&G Amendment) which extended the effective period for the 2010 P&G Agreement from December 31, 2010 through June 30, 2011, and resulted in the Company recognizing the previously deferred \$375,000 of revenue as royalty revenue during the quarter ended June 30, 2011.

The 2011 P&G Amendment also provided that effective January 1, 2011, P&G's exclusive license to the Company's patents converted to a non-exclusive license unless P&G paid the Company a license payment in the amount of \$187,500 by the end of the third quarter of 2011, and at the end of each quarter thereafter, throughout the term of the 2010 P&G Agreement. As a result of P&G not making any payments to the

Edgar Filing: BIOLASE, INC - Form 10-K

Company in the third and fourth quarters of the year ended December 31, 2011, their license converted to a non-exclusive license. The Company is currently engaged in an active collaboration with P&G to commercialize a consumer product utilizing its patents.

F-18

Table of Contents**BIOLASE, INC.****NOTES TO CONSOLIDATED FINANCIAL STATEMENT (Continued)****NOTE 4 INTANGIBLE ASSETS AND GOODWILL**

The Company conducted its annual two-step impairment test of intangible assets and goodwill as of June 30, 2012 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. No events have occurred that would trigger further impairment testing of the Company's intangible assets and goodwill during the years ended December 31, 2012 and 2011.

Amortization expense for the years ended December 31, 2012, 2011, and 2010, totaled \$136,000, \$130,000, and \$130,000, respectively. Estimated intangible asset amortization expense, based on existing intangible assets, for the years ending December 31, 2013, 2014, 2015, and 2016, is \$118,000, \$69,000, \$62,000, and \$51,000, respectively.

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

	As of December 31, 2012				As of December 31, 2011			
	Gross	Accumulated Amortization	Impairment	Net	Gross	Accumulated Amortization	Impairment	Net
Patents (4-10 years)	\$ 1,914	\$ (1,833)	\$	\$ 81	\$ 1,914	\$ (1,702)	\$	\$ 212
Trademarks (6 years)	69	(69)			69	(69)		
Other (4 to 6 years)	817	(598)		219	593	(593)		
Total	\$ 2,800	\$ (2,500)	\$	\$ 300	\$ 2,576	\$ (2,364)	\$	\$ 212
Goodwill (Indefinite life)	\$ 2,926			\$ 2,926	\$ 2,926			\$ 2,926

In December 2012, the Company capitalized approximately \$224,000 related to intangible assets acquired from its former distributor in India. These assets primarily include a non-compete agreement and customer and luminary lists. Of the total capitalized balance, \$200,000 was a noncash investment whereby the Company reduced the accounts receivable from its former distributor in exchange for these assets. The Company is amortizing these assets on a straight-line basis over the expected useful life of four years and has recognized amortization expense of approximately \$5,000 related to these intangible assets during the year ended December 31, 2012.

NOTE 5 LINES OF CREDIT AND OTHER BORROWINGS*Lines of Credit*

On May 24, 2012, the Company entered into two revolving credit facility agreements with Comerica Bank (the Credit Agreements), as amended on August 6, 2012 (Amendment No. 1), which provide for borrowings against certain domestic accounts receivable and inventory, as set forth in the \$4.0 million revolving credit facility agreement (the Domestic Revolver), and borrowings against certain export related accounts receivable and inventory, as set forth in the \$4.0 million revolving credit facility agreement (the Ex-Im Revolver), for a combined aggregate commitment of borrowings up to \$8.0 million. The lines of credit mature on May 1, 2014, at which date any remaining borrowings and accrued interest under the lines of credit become due and payable. As of December 31, 2012, the Company had outstanding borrowings totaling approximately \$1.6 million, which included \$0 under the Domestic Revolver and \$1.6 million under the Ex-Im Revolver.

Lockbox arrangements under the revolving bank facilities provide that substantially all of the income generated is deposited directly into lockbox accounts and then swept into cash management accounts for the

Table of Contents**BIOLASE, INC.****NOTES TO CONSOLIDATED FINANCIAL STATEMENT (Continued)**

benefit of Comerica Bank. Cash is disbursed from Comerica Bank to the Company only after payment of the applicable debt service and principal. At December 31, 2012, there were no restricted cash amounts. The Company's obligations are generally secured by substantially all of the Company's assets now owned or hereinafter acquired.

The Credit Agreements require the Company to maintain compliance with certain financial and non-financial covenants, as defined therein. If a default occurs, Comerica Bank may declare the amounts outstanding under the Credit Agreements immediately due and payable. As of December 31, 2012, the Company was in compliance with these covenants.

The interest rates on the outstanding principal balance of the credit facilities bear interest at annual percentage rates equal to the daily adjusting LIBOR rate, plus spreads of 5.25% for the Domestic Revolver and 4.25% for the Ex-Im Revolver. The daily adjusting LIBOR rate is subject to a floor of 1.00% per annum. The Company is also required to pay an unused commitment fee of 0.25% based on a portion of the undrawn lines of credit, payable quarterly in arrears. During the year ended December 31, 2012, the Company incurred \$232,000 of interest expense associated with the credit facilities, of which approximately \$19,000 was payable at December 31, 2012. Included in interest expense during the year ended December 31, 2012 is \$91,000 of amortization of deferred debt issuance costs and \$43,000 of amortization of the discount on lines of credit.

Pursuant to the Credit Agreements, the Company paid both the first and second annual \$120,000 commitment fees, each being one and one-half percent of the aggregate \$8.0 million commitment, totaling \$240,000. The commitment fees and the legal costs associated with acquiring the credit facilities were capitalized and are being amortized on a straight-line basis as interest expense over the term of the Credit Agreements.

As additional consideration for the lines of credit, the Company also issued warrants to Comerica Bank (the Comerica Warrants) to purchase up to 80,000 shares of the Company's common stock at an exercise price of \$2.83 per share. The Comerica Warrants vest in four equal quarterly tranches beginning on May 24, 2012 and are exercisable once vested. The Comerica Warrants may be exercised with a cash payment from Comerica Bank, or, in lieu of a cash payment, Comerica Bank may convert the warrants into a number of shares, in whole or in part. In February 2013, Comerica Bank exercised 60,000 of the 80,000 warrants pursuant to the Notice of Exercise resulting in a net issuance of 30,515 shares of common stock. These remaining warrants to purchase 20,000 shares of common stock have an expiration date of May 24, 2017. The fair value of the Comerica Warrants was estimated using the Black-Scholes option-pricing model with the following assumptions: expected term of 5.00 years; volatility of 99.55%; annual dividend per share of \$0.00; and risk-free interest rate of 0.77%; and resulted in an estimated fair value of \$135,000 which was recorded as equity and resulted in a discount to the credit facilities at issuance. The discount is being amortized on a straight-line basis to interest expense over the term of the Credit Agreements.

In connection with Amendment No. 1, the Company reduced the exercise price of the Comerica Warrants from \$2.83 to \$2.00 per share. The fair value of the re-priced Comerica Warrants was estimated using the Black-Scholes option-pricing model with the following assumptions: expected term of 4.80 years; volatility of 100.37%; annual dividend per share of \$0.00; and risk-free interest rate of 0.65%. The modification to the Comerica Warrants resulted in an incremental expense of \$7,000 which was added to the discount and is being amortized on a straight-line basis over the remaining term of the Credit Agreements.

Loan and Security Agreement

In May 2010, the Company entered into the Loan and Security Agreement with MidCap Financial, LLC (subsequently assigned to MidCap Funding III, LLC) and Silicon Valley Bank. In connection with the Loan and

Table of Contents**BIOLASE, INC.****NOTES TO CONSOLIDATED FINANCIAL STATEMENT (Continued)**

Security Agreement, the Company issued two secured promissory notes in an aggregate principal amount of \$3 million, at 14.25%, secured by the Company's assets, and warrants to purchase up to an aggregate of 101,694 shares of Common Stock at an exercise price of \$1.77 per share, which was subsequently reduced to \$0.84 per share, with an expiration date of May 26, 2015.

During February 2011, the Company repaid approximately \$2.6 million in principal and MidCap Funding III, LLC and Silicon Valley Bank performed a cashless exercise of all of their warrants, which resulted in the combined issuance of 78,172 shares of unregistered stock.

During the years ended December 31, 2011 and 2010, the Company incurred \$293,000 and \$345,000, respectively, of interest expense, including amortization of debt issuance costs and discounts, associated with the Loan and Security Agreement.

Other Borrowings

The Company finances a portion of its annual insurance premiums which it pays in installments over nine months. As of December 31, 2012 and 2011, \$379,000 at an annual interest rate of 3.0% and \$433,000 at an annual interest rate of 2.5%, respectively, were outstanding under this arrangement. The Company incurred interest expense associated with the financed insurance premiums of approximately \$5,000 during each of the years ended December 31, 2012, 2011, and 2010.

NOTE 6 INCOME TAXES

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

	2012	2011	2010
Current:			
Federal	\$	\$	\$(19)
State	18	16	4
Foreign	32	20	(3)
	50	36	(18)
Deferred:			
Federal	57	66	55
State	12	(16)	16
Foreign	(8)	3	5
	61	53	76
	\$ 111	\$ 89	\$ 58

Table of Contents**BIOLASE, INC.****NOTES TO CONSOLIDATED FINANCIAL STATEMENT (Continued)**

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:

	2012	2011	2010
Statutory regular federal income tax rate	(34.0)%	(34.0)%	(34.0)%
Change in valuation allowance	(13.0)%	(2.3)%	30.4%
Tax return to prior year provision adjustments	16.2%	2.0%	2.7%
Expiration of federal net operating losses	28.2%	20.2%	6.4%
Reduction of net operating loss attributes	(3.7)%	(2.3)%	(1.3)%
State tax benefit (net of federal benefit)	4.1%	18.1%	(6.9)%
Research credits		(3.0)%	(0.6)%
Foreign amounts with no tax benefit	(0.6)%	(0.2)%	0.1%
Non-deductible expenses	6.1%	3.8%	0.8%
Stock option expenses with no tax benefit			3.8%
Other	0.6%	(0.1)%	(0.9)%
Total	3.9%	2.2%	0.5%

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

	2012	2011
Capitalized intangible assets for tax purposes	\$ 405	\$ 576
Reserves not currently deductible	2,082	2,450
Deferred revenue	328	
Stock options	2,348	1,959
State Taxes	45	41
Income tax credits	1,167	1,322
Inventory	868	906
Property and equipment	240	357
Other comprehensive income	127	144
Unrealized gain on foreign currency	160	99
Net operating losses	25,746	26,075
Total deferred tax assets	33,516	33,929
Valuation allowance	(33,341)	(33,784)
Net deferred tax assets	175	145
Capitalized intangible assets	(703)	(630)
State tax		
Other	(119)	(101)
Total deferred tax liabilities	(822)	(731)
Net deferred tax liabilities	\$ (647)	\$ (586)

Edgar Filing: BIOLASE, INC - Form 10-K

Based upon the Company's operating losses incurred for the three years ended December 31, 2012, and the available evidence, the Company has established a valuation allowance against its net deferred tax assets in the amount of \$33.3 million as of December 31, 2012, excluding a portion of the foreign operations totaling \$16,000 and \$8,000 at December 31, 2012 and 2011, respectively. Management considered factors such as the Company's earnings history, future projected earnings and tax planning strategies. If sufficient evidence of the

F-22

Table of Contents**BIOLASE, INC.****NOTES TO CONSOLIDATED FINANCIAL STATEMENT (Continued)**

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.

As of December 31, 2012, the Company had net operating loss (NOL) carryforwards for federal and state purposes of approximately \$67.0 million and \$42.8 million, respectively, which begin to expire in 2013. 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. During the year ended December 31, 2006, the Company completed an analysis to determine the potential applicability of any annual limitations imposed by IRC Section 382. Based on the analysis, management determined that there was no significant IRC Section 382 limitation. As of December 31, 2012, the Company had research and development tax credit carryforwards for federal and state purposes of approximately \$786,000 and \$319,000, respectively, which will begin to expire in 2018 for federal purposes and will carryforward 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.

In addition to the NOL carryforwards included in the deferred tax asset and liability schedule are excess tax deductions relating to stock options that have not been realized. When the benefit of the NOLs containing these excess tax deductions are realized, the benefit will not affect earnings, but rather additional paid-in-capital. As of December 31, 2012, the cumulative unrealized excess tax deductions amounted to approximately \$6.4 million. These amounts have been excluded from the Company's NOL carryforwards. To the extent that such excess tax deductions are realized in the future by virtue of reducing income taxes payable, the Company would expect additional paid-in-capital to increase by approximately \$1.5 million. The Company follows the appropriate ordering rules to determine when such NOLs have been realized.

Recently enacted tax laws may also affect the tax provision on the Company's financial statements. The state of California passed a new law which mandates the use of a single sales factor apportionment formula for tax years beginning on or after January 1, 2013. As a result, the state deferred tax assets will be revalued during the year ending December 31, 2013 in order to account for the change in the tax law. As of December 31, 2012, there was a 100% valuation allowance against the state deferred tax asset.

The following table summarizes the activity related to the Company's unrecognized tax benefits during the year ended December 31, 2012 (in thousands):

Balance at January 1, 2012	\$ 1,066
Additions for tax positions related to the prior year	160
Lapse of statute of limitations	
Balance at December 31, 2012	\$ 1,226

Included in the payable at December 31, 2012, are \$91,000 of tax positions, which if recognized, would increase the Company's annual effective tax rate. As of December 31, 2012, the Company has recorded a liability for potential penalties and interest of \$18,000 and \$29,000, respectively. The Company does not expect its unrecognized tax benefits to change significantly over the next 12 months.

The federal and state NOL and credit carryforwards per the income tax returns filed in prior years included uncertain tax positions taken and are larger than the NOL and credit carryforwards recognized for financial statement purposes.

Table of Contents**BIOLASE, INC.****NOTES TO CONSOLIDATED FINANCIAL STATEMENT (Continued)**

The Company files U.S., state and foreign income tax returns in jurisdictions with varying statutes of limitations. The 2007 through 2011 tax years generally remain subject to examination by federal and most state tax authorities. In foreign jurisdictions, the 2005 through 2011 tax years remain subject to examination by their respective tax authorities.

U.S. income taxes or withholding taxes were provided for all the distributed earnings for the Company's foreign subsidiaries as of December 31, 2012. There were no undistributed earnings from foreign subsidiaries as of December 31, 2012. The Company intends to reinvest any earnings until such time a decision is made to liquidate the foreign operations.

NOTE 7 COMMITMENTS AND CONTINGENCIES***Leases***

In January 2006, the Company entered into a five-year lease for its 57,000 square foot corporate headquarters and manufacturing facility located at 4 Cromwell, Irvine, California, with initial monthly installments of \$38,692 and annual adjustments over the lease term. On September 24, 2009, the lease was amended to extend the term through April 20, 2015, adjust the basic rent, and modify provisions to the security deposit. On January 4, 2011, the lease was further amended to defer a portion of the basic rent to future periods. The Company is recognizing rent expense on a straight line basis with the difference between rent expense and the cash paid recorded to deferred rent. These amounts are reflected in the commitments as of December 31, 2011, listed below. The Company also leases certain office equipment and automobiles under various operating lease arrangements.

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

2013	\$ 683
2014	618
2015	192
2016	
Thereafter	
Total future minimum lease obligations	\$ 1,493

Rent expense totaled approximately \$789,000, \$1.0 million, and \$849,000 for the years ended December 31, 2012, 2011, and 2010, 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 \$714,000 at December 31, 2012. The Company also has agreements with certain employees to pay bonuses based on targeted performance criteria. No amount was required to be accrued at December 31, 2012.

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 \$9.7 million of purchase commitments as of

Table of Contents**BIOLASE, INC.****NOTES TO CONSOLIDATED FINANCIAL STATEMENT (Continued)**

December 31, 2012, for which the Company has not received the goods or services and which is expected to be purchased 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 the Company in the United States District Court for the District of Utah, Central Division, alleging patent infringement of U.S. Patent No. 7,485,116 involving the Company's ezLase diode laser. On September 12, 2012, CAO filed a First Amended Complaint, which added claims for (1) business disparagement/injurious falsehood and (2) unfair competition. The new claims are based on a press release that the Company issued on or about April 30, 2012, which CAO alleges contain statements that are factually inaccurate and falsities that are disparaging to CAO and its diode product. The First Amended Complaint seeks unspecified damages, punitive damages, injunctive relief, treble damages, costs, interest, and attorneys' fees. On September 14, 2012, the Company filed an inter partes reexamination request with respect to the asserted patent with the United States Patent and Trademark Office. The Court then entered a stay of the lawsuit pending the request for reexamination, which reexamination request was subsequently granted. Management plans to vigorously defend against the allegations.

Other Matters

In the normal course of business, the Company may be subject to other legal proceedings, lawsuits and other claims. Although the ultimate aggregate amount of probable monetary liability or financial impact with respect to these matters is subject to many uncertainties and is therefore not predictable with assurance, the Company's management believes that any monetary liability or financial impact to the Company from these other matters, individually and in the aggregate, would not be material to the Company's financial condition, results of operations or cash flows. However, there can be no assurance with respect to such result, and monetary liability or financial impact to the Company from these other matters could differ materially from those projected.

NOTE 8 STOCKHOLDERS' EQUITY***Preferred Stock***

The Board of Directors, 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, 2012 and 2011, none of the preferred stock was outstanding.

The Company has a stockholder rights plan under which one preferred stock purchase right was distributed on January 11, 1999 with respect to each share of common stock outstanding at the close of business on December 31, 1998. The rights provide, among other things, that in the event any person becomes the beneficial

Table of Contents

BIOLASE, INC.

NOTES TO CONSOLIDATED FINANCIAL STATEMENT (Continued)

owner of 15% or more of the Company's common stock while the rights are outstanding, each right will be exercisable to purchase shares of common stock having a market value equal to two times the then current exercise price of a right (initially \$30.00). The rights also provide that, if on or after the occurrence of such event, the Company merges with any other corporation or 50% or more of its assets or earning power are sold, each right will be exercisable to purchase common stock of the acquiring corporation having a market value equal to two times the then current exercise price of such stock. The rights are subject to redemption at \$0.001 per right at any time prior to the first date upon which they become exercisable to purchase common shares. The rights had an original expiration date of December 31, 2008, which was amended further extending the term to December 31, 2018.

Common Stock

At December 31, 2012, the Company had 33,248,000 shares of common stock issued with 31,284,000 shares outstanding. The Company currently has 50,000,000 shares of common stock authorized for issuance and 1,964,000 shares of common stock in its treasury.

Offering Agreement, Shelf Registration, and Securities Purchase Agreement

On December 23, 2010, the Company entered into a Controlled Equity Offering Agreement (the "Offering Agreement") with Ascendant, as sales agent. In accordance with the terms of the Offering Agreement, the Company was able to issue and sell up to 3,000,000 shares of its common stock under the 2010 Shelf Registration Statement with a fee of 3.75% of the gross proceeds in a series of transactions over time as the Company directed in privately negotiated transactions and/or any other method permitted by law, including sales deemed to be an "at the market" offering as defined in Rule 415 under the Securities Act of 1993. At the market sales include sales made directly on the NASDAQ Capital Market, the existing trading market for the Company's common stock, or sales made to or through a market maker other than on an exchange.

During the year ended December 31, 2011, the Company sold approximately 2.2 million shares of common stock with gross proceeds of approximately \$7.5 million and net proceeds of approximately \$7.2 million, net of commissions and direct costs, through the Offering Agreement with Ascendant.

On April 7, 2011, the Company entered into an agreement with Rodman & Renshaw, LLC ("Rodman & Renshaw"), pursuant to which Rodman & Renshaw arranged for the sale of shares of its common stock in a registered direct placement (the "April 2011 Registered Direct Placement") pursuant to the 2010 Shelf Registration Statement with a fee of 4.5% of the aggregate gross proceeds. In addition, on April 7, 2011, the Company and certain institutional investors entered into a securities purchase agreement arranged by Rodman & Renshaw, pursuant to which the Company sold in an aggregate of 320,000 shares of the Company's common stock in the April 2011 Registered Direct Placement with a purchase price of \$5.60 per share for gross proceeds of approximately \$1.8 million. The net proceeds to the Company from the April 2011 Registered Direct Placement totaled approximately \$1.7 million. The costs associated with the April 2011 Registered Direct Placement of approximately \$124,000 were paid in April 2011 upon the closing of the transaction. The shares of common stock sold in connection with the April 2011 Registered Direct Placement were issued pursuant to a prospectus supplement dated April 11, 2011 to the 2010 Shelf Registration Statement, which was filed with the SEC.

The transactions described above exhausted the securities available for sale under the Company's 2010 Shelf Registration Statement.

In June 2011, the Company entered into a securities purchase agreement (the "June 2011 Securities Purchase Agreement") with certain institutional investors (the "June 2011 Purchasers") under which the Company sold an

Table of Contents**BIOLASE, INC.****NOTES TO CONSOLIDATED FINANCIAL STATEMENT (Continued)**

aggregate of 1,625,947 shares of the Company's common stock at a price of \$5.55 per share, together with five-year warrants to purchase 812,974 shares of its common stock having an exercise price of \$6.50 per share (the June 2011 Warrants). The June 2011 Warrants were not exercisable for six months following their issuance. Gross proceeds from the offering totaled approximately \$9 million, and net proceeds to the Company, after commissions and other offering expenses of approximately \$622,000, totaled approximately \$8.4 million. The Company used the proceeds for working capital and general corporate purposes. In connection with the June 2011 Securities Purchase Agreement, the Company entered into an agreement with Rodman & Renshaw in which Rodman & Renshaw agreed to act as the Company's exclusive placement agent for the offering and the Company paid Rodman & Renshaw fees totaling approximately \$451,000, and reimbursed expenses of \$50,000. The commissions and expenses paid to Rodman and Renshaw were included in the offering expenses.

The common stock and the June 2011 Warrants were offered and sold, and the common stock issuable upon exercise of the June 2011 Warrants were offered, pursuant to exemptions from registration set forth in section 4(2) of the 1933 Act and Rule 506 of Regulation D promulgated under the 1933 Act. As such, the common stock, the June 2011 Warrants, and the common stock issuable upon exercise of the June 2011 Warrants was not permitted to be re-offered or resold absent either registration under the 1933 Act or the availability of an exemption from the registration requirements.

The June 2011 Securities Purchase Agreement was subject to a registration rights agreement whereby the Company would have incurred penalties of up to 3.0% of the offering proceeds if it was unable to file a registration statement by July 19, 2011. The Company filed a registration statement on Form S-3 with the SEC to register the Registerable Securities (File No. 333-175664) on July 19, 2011 which was declared effective by the SEC on August 25, 2011, thereby satisfying the registration rights agreement.

On August 2, 2011, the Company repurchased 90,000 of the June 2011 Warrants for \$99,900, or \$1.11 per underlying share, plus expenses of \$30,000.

Additional Warrants

On November 8, 2012, the Company issued warrants to purchase up to 50,000 shares of the Company's common stock to an investor relations consultant, at a price per share of \$2.50. The warrants vest and become exercisable only if the Company's common stock closing price on NASDAQ reaches or exceeds \$7.00 by November 7, 2013. The warrant expires November 7, 2015. As of December 31, 2012, no stock-based compensation has been recognized. The Company will reassess whether achievement of the contingent exercise provision is probable on a quarterly basis and recognize stock-based compensation when it is probable that the market performance requirement will be achieved.

In May 2012, the Company issued warrants to purchase up to 80,000 shares of the Company's common stock to Comerica Bank at a price per share of \$2.83, which was subsequently reduced to \$2.00. See *Note 5 - Lines of Credit and Other Borrowings* for further discussion.

During September 2010, the Company issued warrants (the IR Warrants) to purchase an aggregate of 50,000 shares of common stock at a price per share of \$0.74 to three service providers who provide investor relations services. Pursuant to the agreement, the service providers were also entitled to a second tranche of IR Warrants to purchase an aggregate of 50,000 shares of common stock at a price per share of \$0.74. The IR Warrants were fully exercised during the year ended December 31, 2012. In connection with the issuance of the IR Warrants, the Company recognized expenses of approximately \$23,000 and \$273,000 for the years ended December 31, 2012 and 2011, respectively.

Table of Contents**BIOLASE, INC.****NOTES TO CONSOLIDATED FINANCIAL STATEMENT (Continued)**

In May 2010, the Company granted warrants to purchase an aggregate of 101,694 shares of its common stock to MidCap Financial, LLC, and Silicon Valley Bank at a price per share of \$1.77, which was subsequently reduced to \$0.84. See *Note 5 Lines of Credit and Other Borrowings* for further discussion.

Stock Options

As of December 31, 2012, a total of 6,950,000 shares have been authorized for issuance under the Company's 2002 Stock Incentive Plan, of which 2,498,000 shares have been issued for options which have been exercised, 3,860,000 shares have been reserved for options that are outstanding, and 592,000 shares are available for the granting of additional options.

Stock options may be granted as incentive or nonqualified 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 three 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:

	Shares	Weighted Average Exercise Price Per Share	Weighted Average Remaining Contractual Term (Years)	Aggregate Intrinsic Value(1)
Options outstanding, January 1, 2010	3,650,000	\$ 4.50		
Granted at fair market value	434,000	\$ 1.77		
Granted at above fair market value	1,657,000	\$ 2.00		
Exercised	(225,000)	\$ 0.89		
Forfeited, cancelled, or expired	(1,386,000)	\$ 3.91		
Options outstanding, December 31, 2010	4,130,000	\$ 3.60		
Granted at fair market value	1,151,000	\$ 4.11		
Granted at above fair market value		\$		
Exercised	(657,000)	\$ 2.08		
Forfeited, cancelled, or expired	(766,000)	\$ 4.92		
Options outstanding, December 31, 2011	3,858,000	\$ 3.75		
Granted at fair market value	614,000	\$ 1.80		
Granted at above fair market value	568,000	\$ 0.95		
Exercised	(214,000)	\$ 2.12		
Forfeited, cancelled, or expired	(966,000)	\$ 3.63		
Options outstanding, December 31, 2012	3,860,000	\$ 3.48	3.96	\$ 199,000
Options exercisable, December 31, 2012	2,314,000	\$ 4.02	3.86	\$ 195,000
Vested options				
Vested options expired during the twelve months ended December 31, 2012	208,000	\$ 4.84		\$

Edgar Filing: BIOLASE, INC - Form 10-K

- (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.

F-28

Table of Contents**BIOLASE, INC.****NOTES TO CONSOLIDATED FINANCIAL STATEMENT (Continued)**

The following table summarizes additional information for those options that are outstanding and exercisable as of December 31, 2012:

Range of Exercise Prices	Options Outstanding			Exercisable	
	Number of Shares	Weighted Average Exercise Price	Weighted Average Remaining Life (Years)	Number of Shares	Weighted Average Exercise Price
\$ 0.72 \$1.99	456,000	\$ 1.43	5.50	379,000	\$ 1.35
\$ 2.00 \$2.99	2,175,000	\$ 2.28	3.91	917,000	\$ 2.08
\$ 3.00 \$3.99	159,000	\$ 3.20	3.50	75,000	\$ 3.20
\$ 4.00 \$4.99	268,000	\$ 4.25	4.50	232,000	\$ 4.15
\$ 5.00 \$5.99	373,000	\$ 5.44	4.22	288,000	\$ 5.45
\$ 6.00 \$9.99	225,000	\$ 7.49	3.12	219,000	\$ 7.53
\$ 10.00 \$13.99	150,000	\$ 11.34	1.31	150,000	\$ 11.34
\$ 14.00 \$18.99	54,000	\$ 14.14	1.43	54,000	\$ 14.14
Total	3,860,000	\$ 3.48	3.96	2,314,000	\$ 4.02

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):

	Twelve Months Ended		
	December 31,		
	2012	2011	2010
Proceeds from stock options exercised	\$ 455	\$ 1,244	\$ 199
Tax benefit related to stock options exercised(1)	N/A	N/A	N/A
Intrinsic value of stock options exercised(2)	\$ 91	\$ 1,328	\$ 111
Weighted-average fair value of options granted	\$ 1.39	\$ 2.97	\$ 1.09
Total fair value of shares vested during the year	\$ 1,737	\$ 1,259	\$ 713

- (1) Excess tax benefits received related to stock option exercises are presented as financing cash inflows. Currently the Company does 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.

On May 7, 2012, the Board granted a non-qualified stock option to purchase 65,000 shares of the Company's common stock to a consultant, at a price per share of \$2.55, the closing market price of the Company's common stock on the grant date. The option fully vests and becomes exercisable upon the achievement of certain specified performance conditions, as defined in the consulting agreement with this consultant, and the option expires five years from the grant date. As of December 31, 2012, no stock-based compensation has been recognized. The Company will reassess whether achievement of the performance conditions is probable on a quarterly basis and recognize stock-based compensation when it is probable that the performance conditions will be achieved.

On March 2, 2012, the Company's Board of Directors (the "Board") accelerated the vesting period for options to purchase 95,833 shares of common stock held by Federico Pignatelli, the Company's Chief Executive Officer ("CEO"). The options were originally granted in December 2011 at \$2.58 per share with monthly vesting over four years. The Board accelerated the vesting period to March 2, 2012, in part due to the CEO's continued

Table of Contents**BIOLASE, INC.****NOTES TO CONSOLIDATED FINANCIAL STATEMENT (Continued)**

commitment to maintain his annual salary of one dollar for the year ending December 31, 2012. Accelerating the vesting period of the common stock options resulted in the Company recognizing unamortized compensation cost of approximately \$183,000 in March 2012. The transaction did not result in any additional compensation cost primarily as the effects of the decrease in the expected term and volatility offset the effects of the difference between the stock price and the option price on the date the vesting of the common stock options were modified.

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. For the year ended December 31, 2012, sales in the United States accounted for approximately 71% of net revenue and international sales accounted for approximately 29% of net revenue. For the years ended December 31, 2011 and 2010, sales in the United States accounted for approximately 67% and 64% of net revenue and international sales accounted for approximately 33% and 36% of net revenue, respectively.

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

	Years Ended December 31,		
	2012	2011	2010
United States	\$ 40,524	\$ 32,782	\$ 16,900
International	16,832	16,076	9,325
	\$ 57,356	\$ 48,858	\$ 26,225

No individual international country represented more than 10% of net revenue during the years ended December 31, 2012, 2011, and 2010.

Long-lived assets located outside of the United States at our foreign subsidiaries, totaled approximately \$412,000 and \$542,000 as of December 31, 2012 and 2011, respectively.

NOTE 10 CONCENTRATIONS

Revenue from Waterlase systems, the Company's principal product line, which includes the iPlus and the MD Turbo, comprised 63%, 60%, and 32% of total net revenues for the years ended December 31, 2012, 2011, and 2010, respectively. Revenue from Diode systems comprised 11%, 19%, and 30% of total revenue for the same periods. Revenue from consumables and other comprised 10%, 11%, and 16% of total revenue for the same periods. Revenue from imaging systems comprised 6%, 0%, and 0% of total net revenue for the same periods. Revenue from services comprised 10%, 9%, and 16% of total net revenue for the same periods. Revenue from license fees and royalties comprised 0%, 1%, and 6% of total net revenue for the same periods.

Approximately 3%, 19%, and 38% of the Company's revenue in 2012, 2011, and 2010, respectively, was generated through sales to HSIC worldwide.

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.

No individual customer represented more than 10% of the Company's accounts receivable at December 31, 2012 and 2011.

Table of Contents

BIOLASE, INC.

NOTES TO CONSOLIDATED FINANCIAL STATEMENT (Continued)

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 results of operations.

NOTE 11 NON-RECURRING EVENT

On April 12, 2012, the Company completed the 2012 Termination Agreement with HSIC whereby the Company purchased HSIC's inventory of Waterlase MD Turbo laser systems for approximately \$1.1 million and HSIC released its liens on the Company's assets. Pursuant to the terms of the 2012 Termination Agreement, the Company paid the entire purchase price by offsetting accounts receivable currently due from HSIC from sales made in the normal course of business. None of the funds used to offset the purchase price were related to the original sales of the MD Turbo laser systems that were purchased. During the year ended December 31, 2012, the Company sold all laser systems purchased under this arrangement at margins consistent with the Company's comparable laser products.

As a result of the transaction, the Company recorded a decrease to accounts receivable of approximately \$1.1 million with a corresponding decrease to revenue to pay for the purchase of the Waterlase MD Turbo laser systems. The Company also recorded an increase to inventory for the same amount with a corresponding decrease to cost of revenue to record the inventory acquired. As such, while the Company's revenues and cost of revenues were both reduced by \$1.1 million to record the effects of the transaction, there was no effect on the Company's gross profit during the year ended December 31, 2012. Additionally, as a result of the transaction, during the year ended December 31, 2012, the Company de-recognized approximately \$155,000 of accounts receivable due from HSIC related to support services previously provided to HSIC and approximately \$142,000 of accrued warranties previously provided to HSIC and reversed accrued sales and marketing service liabilities of approximately \$350,000.

NOTE 12 SUBSEQUENT EVENT

Stock Dividend

In February 2013, the Board of Directors announced a 2% annual stock dividend policy for 2013 and declared a one-half percent stock dividend (the March Stock Dividend) payable March 29, 2013 to stockholders of record on March 15, 2013. The Company expects to record the effects of the March Stock Dividend in the first quarter ending March 31, 2013.

Table of Contents**BIOLASE, INC.****Schedule II Consolidated Valuation and Qualifying Accounts and Reserves****For the Years Ended December 31, 2012, 2011, and 2010****(in thousands)**

	Balance at Beginning of Year	Charges (Reversals) to Cost or Expenses	Deductions	Balance at End of Year
Year Ended December 31, 2012:				
Allowance for doubtful accounts	\$ 289	\$ 241	\$ (226)	\$ 304
Allowance for sales returns	110			110
Allowance for tax valuation	33,784	(443)		33,341
Year Ended December 31, 2011:				
Allowance for doubtful accounts	\$ 311	\$ 74	\$ (96)	\$ 289
Allowance for sales returns	110			110
Allowance for tax valuation	34,250	(466)		33,784
Year Ended December 31, 2010:				
Allowance for doubtful accounts	\$ 421	\$ (80)	\$ (30)	\$ 311
Allowance for sales returns	110			110
Allowance for tax valuation	30,177	4,073		34,250

S-1