BIOLASE TECHNOLOGY INC
Form 10-K/A
December 16, 2003
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UNITED STATES

SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

FORM 10-K/A

(Amendment No. 2)

(Mark One)

[X] ANNUAL REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934

For the fiscal year ended December 31, 2002

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 TECHNOLOGY, INC.

(Exact Name of Registrant as Specified in Its Charter)

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

981 Calle Amanecer

San Clemente, California 92673

(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:

None.

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

Common Stock, par value $.001 per share

(Title of class)

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 x

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. x

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Indicate by check mark whether the Registrant is an accelerated filer (as defined in Rule 12b-2 of the Act).

Yes x No ¨

State the aggregate market value of the voting and non-voting common equity held by non-affiliates computed by reference to the price at which the common equity was last sold, or the average bid and asked price of such common equity, as of the last business day of the Registrant s most recently completed second fiscal quarter:

As of June 30, 2002, the aggregate market value of the voting and non-voting common equity held by non-affiliates was $102,142,534, based on the closing price per share of $5.79 for the Registrant s common stock as reported on the Nasdaq National Market on such date multiplied by 20,027,948 shares of the Registrant s common stock which were outstanding and held by non-affiliates on such date.

Indicate the number of shares outstanding of each of the Registrant s classes of common stock, as of the latest practicable date: As of August 31, 2003, there were 21,539,571 shares of the Registrant s common stock, par value $0.001 per share, outstanding.

DOCUMENTS INCORPORATED BY REFERENCE

Certain information required in Part III of the Registrant s Annual Report on Form 10-K for December 31, 2002, was incorporated therein by reference to portions of the Registrant s definitive proxy statement for the Registrant s 2003 Annual Meeting of Stockholders, which was filed with the Securities and Exchange Commission on March 27, 2003.

[Cover page 2 of 2 pages]

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BIOLASE TECHNOLOGY, INC. AND SUBSIDIARIES

AMENDMENT NO. 2 TO ANNUAL REPORT ON FORM 10-K/A

FOR THE YEAR ENDED DECEMBER 31, 2002

EXPLANATORY NOTE

The purpose of this Amendment No. 2 on Form 10-K/A is to re-file new certifications required under the Sarbanes-Oxley Act of 2002. The attached certifications in Exhibits 31.1, 31.2, 32.1 and 32.2 replace those filed on September 17, 2003 in Amendment No. 1 on Form 10-K/A for the year ended December 31, 2002. The contents of Amendment No. 1 are repeated in this filing because that is required when filing the new certifications. Except as noted below, the contents of Amendment No. 1, including the Introductory Note, numbers, text and all other information are repeated verbatim in this filing and have not changed from Amendment No. 1 filed on September 17, 2003. The only changes are the new certifications required under Section 302 of the Sarbanes-Oxley Act of 2002 (Exhibits 31.1 and 31.2) and corresponding changes to Item 9A of Part II, new certifications under Section 906 of that Act (Exhibits 32.1 and 32.2), an updated consent of independent accountants (Exhibit 23.1) and newly added Note 10 to the consolidated financial statements which was added to reflect a significant subsequent event that occurred after the filing date of Amendment No. 1.

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* This Form 10-K/A amends only items identified in the Table of Contents, and no other information included in the Company s Annual Report on Form 10-K is amended hereby. Information previously required under Item 14 of the Company s Annual Report on Form 10-K is set forth under Item 9A of this Form 10-K/A, pursuant to new rules adopted after the original filing of the Form 10-K.

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INTRODUCTORY NOTE

As reported in the press release in the report of BioLase Technology, Inc. (the Company) on Form 8-K filed August 14, 2003, the Company decided to seek guidance from the Securities and Exchange Commission (SEC) regarding the accounting effect of certain language in the Company s purchase order forms. To protect the Company s right to payment, the forms stated that title to goods transferred to the customer upon receipt of full payment. Legally, this language only provided the Company a lien to secure payment.

One of the revenue recognition criteria of Staff Accounting Bulletin No. 101 (SAB 101), Revenue Recognition in Financial Statements, requires the transfer of title and the risks and rewards of ownership to the customer. Historically, the Company recognized revenue when it received a purchase order, goods were shipped and the other criteria for revenue recognition were met. As reported in the press release in the Company s report on Form 8-K filed August 29, 2003, the Company is amending previously filed financial statements for all periods subsequent to the effective date of SAB 101 to recognize revenue with respect to domestic customers upon receipt of full payment. It was determined that under an interpretation of SAB 101 the language in the Company s purchase order regarding title prevents revenue from being recognized until full payment is received. In addition, the Company is amending its previously filed financial statements to recognize revenue with respect to direct European customers upon installation of the equipment, which is when the customer is obligated to pay, and not upon shipment.

The purpose of this Amendment No. 1 on Form 10-K/A to the Company s Annual Report is to:

(i) restate the Company s consolidated financial statements as of December 31, 2002 and 2001, and for each of the three years ended December 31, 2002; and

(ii) modify certain disclosures in response to comments from the SEC in connection with the Company s registration statement on Form S-3 filed on June 19, 2003 for the Company s proposed stock offering.

In addition to this report on Form 10-K/A, the Company is filing amended Quarterly Reports on Form 10-Q/A to restate the Company s financial statements for the periods ended March 31, 2002 through March 31, 2003. The Company is also filing its Quarterly Report on Form 10-Q for the period ended June 30, 2003, which was delayed while the Company sought SEC guidance on the revenue recognition issue. The Company will also file an amendment to its Current Report on Form 8-K/A relating to its acquisition of the American Dental Laser product line of American Medical Technologies, which was initially filed on June 4, 2003, and subsequently amended on June 23, 2003 and August 1, 2003.

The Company did not amend its annual reports on Form 10-K for years prior to 2002 because financial statements for 2001 and 2000 are contained in this Form 10-K/A. Similarly, the Company did not amend its Quarterly Reports on Form 10-Q for the quarterly periods in 2001 because financial statements for those periods are contained in the Forms 10-Q/A the Company is filing for 2002. You should not rely on the financial statements and other financial information contained in the Company s Forms 10-K and 10-Q for periods prior to 2002. You should also not rely on any financial statements or financial information contained in the Company s Forms 8-K that were filed before this Form 10-K/A.

Except where this report indicates that information is as of December 31, 2002 or another specific date, the information in this Form 10-K/A speaks as of the filing date of this Form 10-K/A. This report should be read in conjunction with Amendment No. 1 to the Company s Quarterly Report on Form 10-Q/A for the quarter ended March 31, 2003 and the Quarterly Report on Form 10-Q for the quarter ended June 30, 2003, as well as the Company s subsequent filings.

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CAUTIONARY STATEMENT

This report contains forward-looking statements, which include, but are not limited to, statements concerning projected operational plans, results of operations and financial condition, potential market applications and the market acceptance of our products, the competitive nature of and anticipated growth in our markets and the need for additional capital. These forward-looking statements are based on our current expectations, estimates, assumptions and projections about our industry and reflect management s beliefs based on information available to us at the time of this report. Words such as anticipates, expects, plans, believes, seeks, estimates, may, will, and variations of these words or similar are intended to identify forward-looking statements. These forward-looking statements are not guarantees of future performance and are subject to risks, uncertainties and assumptions that are difficult to predict, including those set forth under Risk Factors in Item 7. These risks and uncertainties, some of which are more fully discussed below and in our other filings with the Securities and Exchange Commission include but are not limited to the following:

Uncertainties relating to worldwide political stability, general economic conditions and trade policies;

Uncertainties relating to government and regulatory policies;

Unforeseen technological developments by competitors;

The entry of new, well-capitalized competitors;

The availability and pricing of materials used in the manufacture of our products;

Uncertainties relating to the development, ownership and enforcement of intellectual property rights;

Adverse changes in the financing and coverage of commercial health and dental plans;

Adverse changes in the financial markets affecting the availability and cost of capital;

The impact of natural disasters, including a major earthquake, on our operations; or

The ability to attract and retain qualified personnel to grow and compete effectively.

Due to the foregoing risks and uncertainties, among others, our actual results could differ materially and adversely from those expressed in any forward-looking statements as a result of various factors. We undertake no obligation to revise or update publicly any forward-looking statements for any reason.

The information contained in this report 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 the report and in our other reports filed with the

Securities and Exchange Commission.

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PART 1

Item 1. Business

We design, manufacture and market proprietary dental laser systems that allow dentists, oral surgeons and other specialists to perform a broad range of common dental procedures, including cosmetic applications. Our systems provide clinically superior performance for many types of dental procedures, with less pain and faster recovery times than are generally achieved with drills and other dental instruments. We have clearance from the U.S. Food and Drug Administration to market our laser systems in the United States. We also have the approvals necessary to sell our laser systems in Canada, the European Union and other international markets.

Our primary product, the Waterlase system, uses a patented combination of water and laser to perform most procedures currently performed using dental drills, scalpels and other traditional dental instruments. We refer to our patented interaction of water with laser as YSGG Laser Hydrokinetics. YSGG is a shortened abbreviation referring to the unique crystal (Er, Cr: YSGG) laser used in the Waterlase, which contains the elements erbium, chromium, yttrium, scandium, gallium and garnet. This unique crystal laser produces energy with specific absorption and tissue interaction characteristics optimized for dental applications. Hydrokinetics refers to the interaction of laser with water to produce energy to cut tissue. Through YSGG Laser Hydrokinetics, the Waterlase system can precisely cut hard tissue, such as bone and teeth, and soft tissue, such as gums, with minimal or no damage to surrounding tissue. The Waterlase is the best selling dental laser system and we estimate it currently accounts for a majority of all dental lasers sold worldwide.

We also offer the LaserSmile system, which uses a laser to perform soft tissue and cosmetic procedures, including tooth whitening. The LaserSmile serves the growing markets for cosmetic and hygiene procedures. In May 2003, we acquired the American Dental Laser product line of American Medical Technologies, Inc., including the Diolase and Pulsemaster systems, which can be used for common soft tissue procedures. The Diolase and Pulsemaster, together with our Waterlase and LaserSmile systems, offer practitioners a broad product line with a range of features and price points. We also manufacture and sell accessories and disposables for our laser systems, such as handpieces, laser tips and tooth whitening gel.

We believe there is a large market for our products in the United States and abroad. According to the American Dental Association, there are over 160,000 practicing dentists in the United States. According to the World Federation of Dentistry, an international dental organization, there are at least 700,000 dentists worldwide, and we believe that a substantial percentage of them practice in major international markets outside the United States. The use of lasers in dentistry is growing. However, we believe only a small percentage of dentists currently use laser systems, and that there is a significant opportunity to increase sales of our products worldwide.

Our goal is to establish our laser systems as essential tools in dentistry and to continue our leading position in the dental laser market. Our sales and marketing efforts focus on educating dental professionals and patients on the benefits of our laser systems, particularly our Waterlase system. In 2002, we founded the World Clinical Laser Institute, an association that includes prominent dental industry leaders, to formalize our efforts to educate and train dentists and oral surgeons in laser dentistry. We participate in numerous other symposia and dental industry events to stimulate demand for our products. We have also developed numerous relationships with dental schools, research facilities and dental institutions, in the United States and abroad, which use our products for education and training. More than 20 institutions use our products, including St. Barnabas Hospital and the dental schools of Columbia University, Loma Linda University, Tufts University, University of Barcelona and University of Vienna. We believe this will expand awareness of our products among new generations of dental professionals.

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Company Background and Recent Events

From inception in 1987 until 1998, we were engaged primarily in the research and development of the use of water and laser technology. Our company was originally formed as Societe Endo Technic, SA, or SET, in 1984 in Marseilles, France, to develop and market various endodontic and laser products developed by Dr. Guy Levy, then chairman of the Endodontics Department at the University of Marseilles. In 1987, SET was moved to the United States and was merged with a public holding company, Pamplona Capital Corp. In 1994, we changed our name to BioLase Technology, Inc. Through the end of fiscal 2000, we were financed by approximately $42 million in stockholder investments through a series of private placements of stock and the exercise of warrants and stock options.

Since 1998, our objective has been to become the leading designer, manufacturer and marketer of laser systems for the dental industry. We have focused our efforts on receiving governmental clearances with the U.S. Food and Drug Administration as well as furthering the commercial success and viability of our water and laser technology via our direct sales campaign initiatives and intellectual property advancements. In 1998, we began the commercialization of our systems based on water and laser technology.

The selective pursuit of acquisitions represents an important component of our business strategy. We focus primarily on those candidates that will enable us to consolidate positions of leadership in our existing markets, further develop our portfolio of intellectual property, expand our strategic partnerships with leading companies and increase our capability and capacity to derive value for our customers and stockholders.

In December 2001, we formed BIOLASE Europe, GmbH, a wholly owned subsidiary based in Germany. In February 2002, BIOLASE Europe acquired a laser manufacturing facility in Germany and commenced manufacturing operations at that location. This acquisition has enabled us to initiate an expansion of our sales in Europe and neighboring regions. We purchased the facility for cash consideration of approximately Euros 1.2 million payable in installments through 2003, subject to reduction if we were unable to conclude a patent license arrangement with the seller and another company. We did not conclude that arrangement and the consideration was reduced in September 2003 to Euros 989,000 per the agreement. We are in discussions with the seller regarding a further reduction based on our belief that the seller failed to fulfill its responsibilities under the purchase agreement.

On May 21, 2003, we acquired the American Dental Laser product line and other dental laser assets of American Medical Technologies, Inc., or AMT, for approximately $5.8 million, consisting of $1.8 million in cash, 307,500 shares of our common stock and $134,000 in costs directly attributable to the acquisition. As a part of the purchase transaction, we and AMT agreed to dismiss with prejudice the lawsuit we had filed in October 2002 against AMT which alleged infringement of certain of our patents. In the dismissal, AMT acknowledged that it had infringed our intellectual property rights as identified in our complaint and recognized that the patents we had asserted in the legal action are valid and enforceable. The acquired assets included dental laser patents, customer lists, brand names and other intellectual property as well as laser systems, including the Diolase and Pulsemaster systems. The purchase price will be allocated to the assets based on their fair value. We intend to sell the Diolase and Pulsemaster systems both domestically and internationally under the American Dental Laser brand name, commencing in the second half of 2003. We expect sales of the new systems to begin in the second half of 2003.

Products

We have two principal product lines. Our BioLase product line includes the Waterlase and LaserSmile systems, which we developed through our own research and development. In May 2003, we acquired the American Dental Laser product line, which includes the Diolase and Pulsemaster systems.

We currently sell our products in over 20 countries. All of our laser systems have been cleared by the U.S. Food and Drug Administration for the applications listed below, which enables us to market the systems in the United States. Our systems have the CE Mark and may be sold in the European Union. Additionally, we have approval to sell our Waterlase system in Canada, Australia, New Zealand and other Pacific Rim countries.

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PRODUCT	SELECTED APPLICATIONS	TECHNOLOGY
BioLase Product Line		
Waterlase System	*Hard Tissue:* Cavity preparation, caries removal, roughening or etching, root canal and other hard tissue surgical applications. *Bone:* Cutting, shaping, contouring, resection, crown lengthening (restorative), apicoectomy or amputation of root end, and other oral osseous or bone procedures. *Soft Tissue:* Incision, excision and biopsy of soft tissue, frenectomy, troughing, fibroma removal, hemostasis, aphthous oral ulcers, operculectomy and other soft tissue surgical applications. *Cosmetic:* Gingivectomy, gingivoplasty and crown lengthening.	Solid State Crystal, Erbium, Chromium: Yttrium, Scandium, Gallium, Garnet (Er, Cr: YSGG), Laser with Air-Water Spray
LaserSmile System	*Soft Tissue:* Incision, excision and biopsy of soft tissue, frenectomy, troughing, gingivoplasty and other soft tissue surgical applications. *Cosmetic:* Gingivectomy, gingivoplasty and tooth whitening.	Semiconductor Diode Laser
American Dental Laser Product Line		
Diolase System	*Soft Tissue:* Incision, excision and biopsy of soft tissue, frenectomy, troughing and other soft tissue surgical applications. *Cosmetic:* Gingivectomy and gingivoplasty.	Semiconductor Diode Laser
Pulsemaster System	*Soft Tissue:* Incision, excision and biopsy of soft tissue, frenectomy, troughing, gingivectomy, gingivoplasty and other soft tissue surgical applications. *Cosmetic:* Gingivectomy and gingivoplasty.	Neodymium: Yttrium, Aluminum, Garnet (Nd:YAG), Crystal Laser
BioLase Product Line		

The following are the two laser systems developed by our in-house team of engineers.

Waterlase System. The Waterlase laser uses an Er, Cr: YSGG crystal, which produces a unique wavelength optimized for dental applications. Using YSGG Laser Hydrokinetics, the Waterlase enables highly

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controlled cutting of bone and tooth with minimal to no damage to surrounding tissue, resulting in less trauma and pain than is achieved with dental drills or other dental instruments. The Waterlase can cut teeth or bone in narrow spaces with limited access for conventional instruments. By reducing or eliminating the water spray level, the Waterlase can also be used to perform a number of soft tissue procedures. Our Waterlase cuts soft tissue efficiently and provides effective coagulation in many types of soft tissue procedures. The approximate list price of the Waterlase system is $50,000.

LaserSmile System. The LaserSmile system uses a semiconductor diode laser primarily for use in soft tissue and cosmetic procedures, particularly tooth whitening. For tooth whitening, the LaserSmile is used with our proprietary gel to whiten teeth faster than competitive non-laser whitening systems. In addition, the high power of the LaserSmile makes it particularly effective in soft tissue procedures where deeper penetration and faster coagulation is desired. The approximate list price of the LaserSmile system is $23,000.

American Dental Laser Product Line

In May 2003, we acquired the American Dental Laser product line, including the Diolase and Pulsemaster systems. We believe that the Diolase system complements our Waterlase and LaserSmile systems and will enable us to increase market penetration by offering a broad line of laser systems with a range of features and price points.

Diolase System. Our recently acquired Diolase system uses a semiconductor diode laser for a range of dental soft tissue, cosmetic and hygiene procedures. The Diolase has simpler features than our other systems, and is positioned as an entry level laser system. The approximate list price of the Diolase system is $14,000.

Pulsemaster System. Our recently acquired Pulsemaster system uses the popular Nd:YAG crystal that is broadly accepted for a variety of soft tissue procedures. The Pulsemaster system is well established and has been adopted by many dental practitioners, especially for periodontal procedures. The Pulsemaster system performs many of the same functions as our existing LaserSmile system. As a result, we plan to make the Pulsemaster available only in limited quantities, on a made-for-order basis, to dental practitioners who express a strong preference for that system. The approximate list price of the Pulsemaster system is $27,500.

Related Accessories and Disposable Products

We also manufacture and sell disposable products and accessories for our laser systems. Our Waterlase system uses disposable laser tips of differing sizes and shapes depending on the procedures being performed. We also market flexible fibers, handpieces, tooth whitening gel and aftercare products for our LaserSmile system. In connection with our acquisition of the American Dental Laser product line, we acquired a complete line of accessories for the Diolase and Pulsemaster systems, as well as other accessories marketed under the American Dental Laser brand name.

Warranties and Insurance

Our laser systems sold to end-users and distributors are covered by a one-year and fourteen-month warranty, respectively, against defects in material and workmanship. Our warranty covers parts and service for direct sales and parts only for distributor sales with additional coverage on certain components for up to two years. We sell service contracts 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. In addition, we maintain product liability insurance with respect to our products with a general coverage limit of $12 million in the aggregate. Since commencing the sale of our systems, no product liability claims have been initiated against us.

Manufacturing

We manufacture, assemble and test our products at manufacturing facilities located in San Clemente, California, and Floss, Germany. We acquired our German manufacturing facility in 2002. We manufacture and install our systems and provide maintenance services for products sold in Europe and other international markets

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through our German operations. Sales of products manufactured at our German facility accounted for 9% of our revenue in 2002.

We use an integrated approach to manufacturing, including the assembly of laser heads, electronics and cabinetry, which allows us to maintain high quality and control cost. We obtain components and subassemblies for our products from third party suppliers, most of which are located in the United States. We generally purchase components and subassemblies from a limited group of suppliers through purchase orders. We have no written supply contracts with our key suppliers. Three key components used in our Waterlase system, which accounted for approximately 77% of our revenue in 2002, are each supplied by a separate single-source supplier. The Waterlase hand pieces are made by a leading European supplier of precision hand tools, and the laser crystal and fiber components are each made by a separate supplier. We have not experienced material delays from the suppliers of these three key components, and we have identified and tested alternative suppliers for each of these components. However, an unexpected interruption in a single source supplier could create manufacturing delays, and disrupt sales as we sought to replace the supplier, which we estimate could take up to three months.

Our manufacturing facilities are ISO 9001 certified. ISO 9001 certification provides guidelines for quality of company systems associated with the design, manufacturing, installation and servicing of company products. In addition, both the U.S. and German facilities are registered with the U.S. Food and Drug Administration and are compliant with the FDA s Good Manufacturing Practice guidelines.

Marketing and Sales

Marketing

We currently market our laser systems in the United States, Canada, Australia and various countries throughout Europe and the Pacific Rim. Our marketing efforts are focused on increasing brand and specific product awareness among dental practitioners. We recently began efforts to increase awareness of the benefits of our products by marketing directly to patients.

Dental Practitioners. We currently market our laser systems directly to dental practitioners through regional, national and international trade shows 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 2002, we founded the World Clinical Laser Institute to formalize our efforts to educate and train dental practitioners in laser dentistry. The Institute conducts and sponsors educational programs domestically and internationally for dental practitioners, researchers and academicians, including two or three day seminars and training sessions involving in-depth discussions on the use of lasers in dentistry. In addition, we have developed relationships with research institutions, dental schools and clinical laboratories, which use our products in training and demonstrations. We believe these relationships will increase awareness of our products.

Patients. We recently began to market the benefits of our laser systems directly to patients through marketing and advertising programs, including print media and radio spots, sponsored jointly by dental practitioners and us in selected markets that we feel have strong growth potential. 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. The majority of the dentists in the United States, as well as the majority of our customers, are sole practitioners. As awareness of our laser systems increases, we expect an increase in demand for our products among group practices. We also expect our laser systems to gain acceptance among oral surgeons and other dental specialists, as they become better aware of the clinical benefits and new treatment options available through use of our laser systems.

International sales account for a significant portion of our revenue. International sales accounted for approximately 23% of our revenue in 2002, 20% of our revenue in 2001 and 41% of our revenue in 2000. Sales in Asia, Pacific Rim countries and Australia accounted for approximately 12% of our revenue in 2002, while sales in

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Europe and Canada accounted for 11% and 1% of our 2002 revenue, respectively. In 2001, sales in Europe accounted for approximately 9% of revenue for the year, whereas sales in Asia and Pacific Rim countries accounted for approximately 8% of the revenue. In 2000, sales in Europe accounted for approximately 24% of our revenue for the year, and sales in Asia and Pacific Rim countries accounted for approximately 11% of the revenue for the year.

Direct Sales. We sell products in the United States and Canada through our direct sales force, which is organized by region and consists of two regional managers and approximately 25 sales representatives. Each of our direct sales employees receives a base salary and commissions on sales. We plan to expand our direct sales force in territories that represent growing markets. We sell products in Germany through independent sales representatives who receive commissions on sales.

Distributors. Except for sales in Canada and Germany, we sell products outside the United States primarily through a network of independent distributors located in Europe, Asia and Australia. Generally, our distributors enter into exclusive agreements in which they purchase systems and disposables from us at a wholesale dealer price 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. We have exclusive arrangements with certain distributors for select territories, under which distributors are generally required to satisfy certain minimum purchase requirements to maintain exclusivity. Sales to distributors are generally paid in advance or secured with a letter of credit.

Seasonality. We have experienced a distinct seasonal pattern over the past several years. The fourth quarter, ending December 31, has generally been the strongest quarter, and in 2002 accounted for approximately 30% of our revenue. By contrast, the first quarter is generally the slowest sales quarter and in 2002 accounted for only 18% of 2002 revenue. The second quarter is generally stronger than the first quarter and in 2002 accounted for approximately 27% of our 2002 revenue. The third quarter has generally been flat compared to the second quarter and accounted for approximately 25% of our revenue in 2002. We believe the seasonality demonstrated in the fourth and first quarters is due to the buying patterns of many dentists, including the response to certain tax advantages offered in the United States for capital equipment purchases. We also believe the lack of growth in the third quarter compared to the second quarter is due to general practice patterns in which vacations occur in the third quarter of the year. As a result of this seasonality, our growth metrics compare growth in a quarter to the same quarter in the prior year and is not focused on growth in consecutive quarters which has been and we expect will continue to be skewed by this seasonality effect.

Customer Service. We provide maintenance and support services through our support hotline, service personnel and network of factory-trained service technicians. We provide maintenance and support services in the United States and Germany through our employee service technicians. We train and maintain a network of service technicians trained at our factory locations, who provide maintenance and support services in all other countries where we do business. Our 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 or banks. In these transactions, we receive payment in full from the leasing company or bank, or occasionally, from the dentist, who receives funds from the leasing company or bank. We understand the dentist pays the leasing company or bank in installments and 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 dentist s failure to make payments. Approximately 36% of our revenue in 2002 was generated from dentists who financed their purchase through National Technology Leasing Corporation, an equipment-leasing broker. National Technology Leasing arranges financing through banks. We have an agreement with National Technology Leasing, which requires us to refer to National Technology Leasing dentists who request a referral to a leasing company. In exchange, National Technology Leasing agreed to publish specific lease rates to be used for lease contracts submitted to it on certain terms and conditions. Additionally, National Technology Leasing has agreed to be available at our trade shows, seminars, symposiums and other sales events, participate in product promotions and otherwise be available to our customers. Our customers are under no obligation to finance the purchase or lease of any equipment through National Technology Leasing and we refer only those customers that request a referral from us. If leasing arrangements were no longer available through National Technology Leasing or the banks with which it deals, we believe our customers would be able to obtain

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financing through a variety of other leasing companies or banks that frequently approach us to provide financing for our products.

Research and Product Development

Research and development activities are essential to maintaining and enhancing our business. We believe our research and development team has demonstrated its ability to develop innovative products that meet evolving market needs. Our research and development group consists of 12 individuals with medical device and laser development experience and other relevant backgrounds, the majority of whom have degrees in physics or engineering, including three Ph.D.s. During the years ended December 31, 2002, 2001 and 2000, our research and development expenses were approximately $1.7 million, $1.5 million and $2.3 million, respectively. We intend to focus our research and development activities on improving our existing products and extending our product range in order to provide dental practitioners and patients with less painful and clinically superior laser systems.

Intellectual Property and Proprietary Rights

We rely, in part, on a combination of patents, trademarks, trade secrets, copyright and other intellectual property rights to protect our technology. We have over 60 issued patents and numerous pending patents. More than half of our existing patents were issued in the United States, and the rest were issued in Europe and in other countries. Our patents are directed to the use of laser and water in dentistry, laser energy exciting water, laser characteristics, fluid conditioning, laser accessories, laser technology development and other technologies for dental and medical applications. We have patent applications pending and plan to apply for other patents in the future as we develop new technologies. While we hold a variety of patents covering a broad range of technologies incorporated in our products, we rely on approximately one half of our patents in particular to protect the core technology incorporated in our systems, including our Waterlase system, which accounted for approximately 77% of our revenue in 2002. Four of these patents expire in 2009, and the balances have expiration dates ranging from 2010 to 2015.

We are currently involved in two patent lawsuits related to our Waterlase system with Diodem, LLC, a privately held California limited liability company. In May 2003, we initiated a lawsuit against Diodem, in which we are seeking a judicial declaration that technology in our Waterlase does not infringe four patents owned by Diodem. Diodem was founded by the former chief executive officer of Premier Laser Systems, Inc., a medical laser company which filed for bankruptcy protection in March 2000. Diodem claims to have acquired the four patents at issue in the case from Premier Laser. Also, in May 2003, Diodem added us as a party to a patent infringement lawsuit it had previously filed. Diodem alleges that the technology in our Waterlase system infringes the four patents it acquired from Premier Laser. Diodem s suit seeks monetary damages, an injunction and other relief. Both of these lawsuits are in their preliminary stages, and may proceed for an extended period of time. Although the outcome of these actions cannot be determined with certainty, we believe our technology and products do not infringe any valid patent rights owned by Diodem, and we intend to continue to vigorously defend against Diodem s infringement action and pursue our declaratory relief action against Diodem.

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 product primarily competes with laser systems manufactured by Hoya ConBio, a subsidiary of Hoya Photonics, a large Japanese manufacturer primarily of optics and crystals, and OpusDent Ltd., a subsidiary of Lumenis, an Israeli company. In the international market, our Waterlase system competes primarily with products manufactured by several other companies, including KaVo, Deka Dental Corporation and Fotona d.d.

The Waterlase system also competes with non-laser based systems, including traditional high and low-speed dental drills and air abrasion systems that are used for dental procedures. Our LaserSmile system competes with other laser systems, as well as with scalpels, scissors and a variety of other cutting tools that have been traditionally used to perform soft tissue procedures. The LaserSmile also competes directly with a number of laser systems manufactured by a variety of companies, including the companies named above. In the market for tooth

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whitening, the LaserSmile competes with other products and instruments used by dentists, as well as tooth 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 drill or an electrosurge device can be purchased for less than $1,000 each. However, we believe our systems offer substantial benefits that outweigh cost concerns. 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. High speed drills will still be needed for these functions, and our systems are not intended to replace all applications of the high speed drill.

We also compete on the basis of proprietary technology, product features, performance, service and reputation. Some of the manufacturers that develop competing laser systems have greater financial, marketing and 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.

Government Regulation

Our products are regulated as medical devices. Accordingly, our product development, testing, labeling, manufacturing, processes and promotional activities are regulated extensively by government agencies in the United States and other countries in which we market and sell our products. We have clearance from the U.S. Food and Drug Administration, or FDA, to market our laser systems in the United States. We also have the approvals necessary to sell our laser systems in Canada, the European Union and other international markets. We are currently pursuing regulatory approval to market and sell our products in Japan.

United States

In the United States, the FDA regulates the design, manufacture, distribution, quality standards and marketing of medical devices. We have clearance from the FDA to market our Waterlase and LaserSmile systems in the United States for dental procedures on both adult and pediatric patients. In 1998, we received FDA clearance to market the Millennium, the earlier generation of our current Waterlase system, for certain dental hard tissue applications. This clearance allowed us to commence domestic sales and marketing of our technology for hard and soft tissue applications. During 1999 and 2000, to meet the demand for soft-tissue and cosmetic dentistry applications, we designed a semiconductor diode laser system, which is now marketed as our LaserSmile system. We received FDA clearance to market the system for a variety of soft-tissue medical applications in September 1999. In 2001, we received FDA clearance to market the LaserSmile system for cosmetic tooth whitening.

In 2002 and 2003, our Waterlase system became the first laser system to receive FDA clearance for three new types of procedures. In 2002, we received clearance to market the Waterlase system for root canal, encompassing all four of the fundamental steps of the procedure. We also received clearance in 2002 to market this system for cutting, shaving, contouring and resection of oral osseous tissues, or bone. In January 2003, we received FDA clearance to market the Waterlase for use in apicoectomy surgery, a procedure for root canal infections and complications that includes cutting gum, bone (to access the infected area) and the apex of the tooth to access the infected area. The clearance also relates to flap surgical procedures. Flaps are frequently performed in conjunction with many procedures, including periodontal, implant placement and recovery, extraction of wisdom teeth, exposure of impacted teeth for orthodontics as well as additional procedures.

Our newly acquired Diolase system received FDA clearances in 1997 to be marketed for a variety of soft tissue dental applications. FDA clearances were issued in 1994 to market the Pulsemaster system for a number of soft tissue procedures. We are in the process of transferring those clearances to our company.

As we develop new products and applications or make any significant modifications to our existing products, we will need to obtain the regulatory approvals necessary to market such products for dental, cosmetic and other medical procedures in our target markets. There are two principal methods by which FDA regulated devices may be marketed in the United States: pre-market approval, or PMA, and 510(k) clearance. A PMA application is required for a device that does not qualify for consideration for 510(k) clearance. The review period for a PMA

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application is fixed at 180 days, but the FDA typically takes much longer to complete the review. As part of the approval of a PMA application, the FDA typically requires human clinical testing to determine safety and efficacy of the device. To conduct human clinical testing, typically the FDA must approve an Investigational Device Exemption, or an IDE. To date, none of our products have required a PMA application.

To obtain 510(k) clearance, we must demonstrate that our device for which clearance is sought is substantially equivalent to a previously cleared 510(k) device or other appropriate predicate device. The FDA s stated intention is to review 510(k) notifications as quickly as possible, generally within 90 days. However, the complexity of a submission or a requirement for additional information will typically extend the review period beyond 90 days. Domestic marketing of the product must be deferred until clearance is received from the FDA. In some instances, an IDE is required for clinical trials for a 510(k) clearance. If a request for 510(k) clearance is turned down by the FDA, then a PMA may be required. We intend to utilize the 510(k) notification procedure whenever possible. To date, all of our products that have been subject to regulation by the FDA have qualified for 510(k) clearance.

After a device receives 510(k) clearance, any modification that could significantly affect its safety or effectiveness, or that would constitute a major change in its intended use, will require a new 510(k) clearance, or could even 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 a PMA is obtained.

The FDA also imposes various requirements on manufacturers and sellers of products it regulates under its jurisdiction, such as labeling, manufacturing practices, record keeping and reporting. The FDA also may require post-marketing practices, record keeping and reporting requirements.

We also are subject to unannounced inspections by the FDA for both the U.S. and BIOLASE Europe offices, and the Food and Drug Branch of the California Department of Health Services, and these inspections may include the manufacturing facilities of our subcontractors.

We are also subject to regulation under the Radiation Control for Safety and Health Act of 1968, or the Safety Act, administered by the Center for Devices and Radiological Health, or CDRH, of the FDA. The CDRH controls energy emissions of light and sound and electronic waves from electronic products. These regulations require a laser manufacturer to file new product and annual reports, to maintain quality control, product testing and sales records, to distribute appropriate 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 from the laser. In addition, various warning labels must be affixed to the product and certain protective devices must be installed, depending upon the class of product. Under the Safety Act, we are also required to register with the FDA as a medical device manufacturer and are subject to inspection on a routine basis by the FDA for compliance with Good Manufacturing Practice, or GMP, regulations. The GMP regulations impose certain procedural and documentation requirements upon us relevant to our manufacturing, testing and quality control activities. We believe both of our facilities comply with the GMP guidelines. The CDRH is empowered to seek remedies for violations of these regulatory requirements under the Federal Food, Drug and Cosmetic Act. We believe that we are currently in substantial compliance with these regulations.

Various state dental boards are considering the adoption of restrictions on the use of lasers by dental hygienists. Approximately 30 states currently allow dental hygienists to use lasers to perform certain dental procedures. In addition, dental boards in a number of states are considering educational requirements regarding the use of dental lasers. The scope of these restrictions and educational requirements is not now known, and they could have an adverse effect on sales of our laser-based products.

Failure to comply with applicable regulatory requirements can result in an enforcement action by the FDA, which may include any of the following sanctions:

- fines, injuctions and civil penalties;

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recall or seizure of our products;

operating restrictions, partial suspension or total shutdown of production;

refusing our request for 510(k) clearance or PMA approval of new products;

withdrawing 510(k) clearance or PMA approvals that are already granted; and

criminal prosecution.

International

Foreign sales of our laser-based products are subject to the regulatory requirements of the foreign country or, if applicable, the harmonized standards of the European Union. These regulatory requirements vary widely among the countries and may include technical approvals, such as electrical safety, as well as demonstration of clinical efficacy. We have a CE Mark for our Waterlase and LaserSmile systems, which permits us to commercially distribute these systems throughout the European Union. We rely on export certifications from the FDA to comply with certain regulatory requirements in several foreign jurisdictions, such as New Zealand, Canada and countries in Western Europe. We also received clearance to market our Waterlase and LaserSmile systems in Canada and Australia for a variety of applications. We are currently working to meet certain foreign country regulatory requirements for certain of our products, including Japan. There can be no assurance that additional approvals in Japan or elsewhere will be obtained.

Other Regulatory Requirements

In addition to the regulatory framework for product clearances and approvals, we are subject to extensive and frequently changing regulations under many other laws administered by U.S. and foreign governmental agencies on the national, state and local levels, including requirements regarding occupational health and safety and the use, handling and disposing of toxic or hazardous substances.

Third Party Reimbursement

Many procedures performed with our laser systems are covered by insurance to the same extent as they would be if performed using traditional dental instruments. Most therapeutic procedures performed with our laser systems are reimbursable to a certain extent under dental insurance plans, whereas cosmetic procedures are not. International market acceptance for our products may depend, in part, on the availability of reimbursement within prevailing health care payment systems. Reimbursement and health care payment systems in international markets vary significantly by country, and include both government-sponsored health care and private insurance.

Employees

At August 31, 2003, we had 135 full-time employees, including 11 employees in our German facility. This represents an increase of 26 employees or 24% from 109 employees a year ago. Our employees are not represented by any collective bargaining agreement and we believe our employee relations are good.

Available Information

Copies of our Annual Report on Form 10-K, Quarterly Reports on Form 10-Q, Current Reports on Form 8-K and amendments to those reports filed or furnished pursuant to Section 13(a) or 15(d) of the Securities Exchange Act of 1934 are available free of charge through our Web site (www.biolase.com) as soon as reasonably practicable after we electronically file the material with, or furnish it to, the Securities and Exchange Commission. Refer to the Introductory Note for previously filed financial statements which should not be relied upon.

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Item 3. Legal Proceedings

On October 31, 2002, we filed a lawsuit in the U. S. District Court for the Central District of California, Southern Division, against American Medical Technologies, Inc. (AMT). In the lawsuit, we alleged that AMT was infringing certain patents we own, which relate to the use of laser technology in the medical and dental fields. Our claims arose out of AMT s offer to sell and sale in the United States of a dental device that uses laser and water technology. We were seeking an award of monetary damages and injunctive relief against AMT. We settled the lawsuit in connection with our acquisition of the American Dental Laser product line from AMT in May 2003.

We are currently involved in two related patent lawsuits with Diodem, LLC, a California limited liability company. On May 2, 2003, we initiated a civil action in the U.S. District Court for the Central District of California against Diodem. In this lawsuit we are seeking a judicial declaration against Diodem that technology we use in our laser systems does not infringe four patents owned by Diodem. Diodem was founded by Collete Cozean, the former chief executive officer of Premier Laser Systems, Inc., a medical laser company which filed for bankruptcy protection in March 2000. Diodem claims to have acquired the four patents at issue in the case from Premier Laser. In 2000 we initiated a patent infringement lawsuit against Premier Laser seeking damages and to prevent Premier from selling competing dental lasers on the grounds that they infringed on certain of our patents. The lawsuit was stayed by the bankruptcy court after Premier filed for bankruptcy.

In response to our lawsuit against Diodem, on May 5, 2003, Diodem added us as a party to an infringement lawsuit it had previously filed in the U.S. District Court for the Central District of California. The other parties to this lawsuit are American Medical Technologies, Inc., Lumenis and its subsidiary OpusDent, Ltd., and Hoya Photonics and its subsidiary Hoya ConBio. OpusDent and Hoya ConBio manufacture and sell dental lasers pursuant to patents originally licensed to them by American Medical Technologies. We acquired the licensed patents and related license agreements in our acquisition of the American Dental Laser product line from American Medical Technologies. Diodem s lawsuit relates both to our Waterlase and to the patents and licenses we acquired from American Medical Technologies. Diodem alleges that technology used in our Waterlase infringes the four patents it acquired from Premier Laser. Diodem also alleges that the products sold by OpusDent and Hoya ConBio pursuant to the licenses we acquired from American Medical Technologies infringe on the patents Diodem acquired from Premier Laser. Diodem s infringement suit seeks treble damages, a preliminary and permanent injunction from further alleged infringement, attorneys fees and other unspecified damages. Both of these lawsuits are in their preliminary stages, and may proceed for an extended period of time.

Although the outcome of these actions cannot be determined with certainty, we believe our technology and products do not infringe any valid patent rights owned by Diodem, and we intend to continue to vigorously defend against Diodem s infringement action and pursue our declaratory relief action against Diodem.

We are not currently subject to any other material pending or threatened legal proceedings.

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PART II

Item 6. Selected Consolidated Financial Data

The following table sets forth selected consolidated financial data for the periods presented. You should read this data along with our Consolidated Financial Statements and related Notes contained elsewhere in this report and in our subsequent reports filed with the SEC, as well as the section of this report and our other reports entitled Management s Discussion and Analysis of Financial Condition and Results of Operations.

	Years Ended December 31,				
	2002	2001	2000	1999	1998
		(Restated) (2)			
	(in thousands, except per share data)				
Consolidated Statements of Operations Data:					
Net sales	$ 27,257	$ 16,546	$ 9,495	$ 7,004	$ 1,465
Gross profit	16,772	9,608	4,679	2,852	47
Operating expenses (1)	15,423	10,845	8,340	7,601	10,369
Income (loss) from operations	1,412	(1,158)	(3,661)	(4,749)	(10,322)
Cumulative effect of change in accounting principle			(34)		
Net income (loss)	1,498	(1,281)	(3,789)	(4,798)	(10,346)
Cumulative effect of change in accounting principle per share:					
Basic			0.00		
Diluted			0.00		
Net income (loss) per share:					
Basic	0.08	(0.07)	(0.20)	(0.28)	(0.69)
Diluted	0.07	(0.07)	(0.20)	(0.28)	(0.69)
Shares used in computing net income (loss) per share:					
Basic	19,929	19,510	19,171	17,254	15,062
Diluted	21,303	19,510	19,171	17,254	15,062

	December 31,				
	2002	2001	2000	1999	1998
		(Restated) (2)			
	(in thousands)				
Consolidated Balance Sheet Data:					
Working capital	$ 1,418	$ 201	$ (268)	$ (1,331)	$ 89
Total assets	16,003	8,253	6,822	2,672	3,911
Long-term liabilities	142	205	1,175		
Stockholders equity (deficit)	3,121	645	994	(939)	662

(1)

In 1998, there was a $5.1 million write-off of in-process research and development costs related to the purchase of the assets of Laser Skin Toner, Inc.

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(2) See Management s Discussion and Analysis of Financial Condition and Results of Operations under Restatement of Financial Statements.

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

The following discussion of our results of operations and financial condition should be read together with the consolidated financial statements and the notes to those statements included elsewhere in this report. This discussion may contain forward-looking statements that involve risks and uncertainties. Our actual results could differ materially from the results anticipated in any forward-looking statements as a result of a variety of factors, including those discussed in Risk Factors and elsewhere in this report.

Restatement of Financial Statements

Staff Accounting Bulletin No. 101 (SAB 101), Revenue Recognition in Financial Statements, requires the transfer of title and the risks and rewards of ownership to the customer prior to the recognition of revenue. We originally prepared our financial statements on the basis that this transfer of title occurred upon shipment. Subsequent to the issuance of our consolidated financial statements as of and for the year ended December 31, 2002, it was determined, with respect to sales to domestic customers, that title transferred upon receipt of full payment, due to a clause in our purchase orders. As a result, we have restated our consolidated financial statements as of December 31, 2002 and December 31, 2001 and for each of the three years in the period ended December 31, 2002 to defer revenue upon shipment and to recognize it upon receipt of full payment for our domestic customers. We have reflected the impact of this change, as measured at January 1, 2000, as the cumulative effect of a change in accounting principle for the adoption of SAB 101. The $34,000 cumulative effect of change in accounting principle was recognized as income during the year ended December 31, 2000. It was also determined that revenue recognition for products shipped directly to customers in Europe, which we commenced in 2002, is appropriate at the time of installation, which is when the customer is obligated to pay, and not at the time of shipment as recognized in the previously filed financial statements. In conjunction with these revisions, we have deferred the revenue, the related cost of inventory and related sales commissions. Our revenue recognition policy in Note 3 has been revised to reflect these changes.

As a result of the restatement, our net revenue for 2002 decreased by $1,942,000, our gross profit decreased by $1,325,000 and our net income was reduced by $1,132,000 ($0.05 per fully diluted share). For 2001, our net revenue decreased by $1,341,000 our gross profit decreased by $980,000 and our net loss increased by $873,000 ($0.05 per fully diluted share). In 2000 our net loss increased by $61,000 ($0.01 per fully diluted share).

The statements of operations have been restated as follows:

Year Ended December 31, 2002	As Reported	Restated
Net sales	$ 29,199,000	$ 27,257,000
Cost of sales	11,102,000	10,485,000
Operating expenses	15,616,000	15,423,000
Income from operations	2,481,000	1,412,000
Net income	$ 2,630,000	$ 1,498,000
Net income per share:		
Basic	$ 0.13	$ 0.08
Diluted	$ 0.12	$ 0.07

Year Ended December 31, 2001	As Reported	Restated
Net sales	$ 17,887,000	$ 16,546,000

Cost of sales	7,299,000	6,938,000
Operating expenses	10,952,000	10,845,000
Loss from operations	(364,000)	(1,158,000)
Net loss	$ (408,000)	$ (1,281,000)
Net loss per share:		
Basic	$ (0.02)	$ (0.07)
Diluted	$ (0.02)	$ (0.07)

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Year Ended December 31, 2000	As Reported	Restated
Net sales	$ 9,657,000	$ 9,495,000
Cost of sales	4,829,000	4,816,000
Operating expenses	8,462,000	8,340,000
Loss from operations	(3,634,000)	(3,661,000)
Loss before cumulative effect of change in accounting principle	(3,728,000)	(3,755,000)
Cumulative effect of change in accounting principle		(34,000)
Net loss	$ (3,728,000)	$ (3,789,000)
Cumulative effect of change in accounting principle per share:		
Basic	$ 0.00	$ 0.00
Diluted	$ 0.00	$ 0.00
Net loss per share:		
Basic	$ (0.19)	$ (0.20)
Diluted	$ (0.19)	$ (0.20)

The balance sheets have been restated as follows:

December 31, 2002	As Reported	Restated
Working capital	$ 3,484,000	$ 1,481,000
Total assets	14,395,000	16,003,000
Stockholders equity	5,187,000	3,121,000

December 31, 2001	As Reported	Restated
Working capital	$ 1,135,000	$ 201,000
Total assets	7,561,000	8,253,000
Stockholders equity	1,579,000	645,000

Overview

We are the world s leading dental laser company. We design, manufacture and market proprietary dental laser systems that allow dentists, oral surgeons and other specialists to perform a broad range of common dental procedures, including cosmetic applications. Our systems provide superior performance for many types of dental procedures, with less pain and faster recovery times than are generally achieved with drills and other dental instruments. We have clearance from the U. S. Food and Drug Administration to market our laser systems in the United States. We also have the approvals necessary to sell our laser systems in Canada, the European Union and other international markets. Since 1998, we have sold more than 2,000 laser systems in over 20 countries.

We have the following principal product lines: (i) Waterlase system; (ii) LaserSmile system; (iii) American Dental Laser products, including the Diolase and Pulsemaster systems, and (iv) related accessories and disposables for use with our laser systems. Our product, the Waterlase system, is used for hard and soft tissue dental procedures, and can be used to perform most procedures currently performed using dental drills, scalpels and other traditional dental instruments. The LaserSmile system is used for a range of soft tissue procedures and tooth whitening. Our newly acquired Diolase and Pulsemaster systems are primarily used for soft tissue procedures. We also manufacture and sell accessories and disposables, such as handpieces, laser tips and tooth whitening gel, for use with our dental laser systems.

Accounting Policies

Our discussion and analysis of our financial condition and results of operations are based upon our consolidated financial statements, which have been prepared in accordance with accounting principles generally accepted in the United States. The preparation of these financial statements requires us to make estimates and judgments that affect the reported amount of assets and liabilities and disclosure of contingent assets and liabilities at the date of the financial statements and the reported amount of revenues and expenses for each period.

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The following represents a summary of our critical accounting policies, defined as those policies that we believe are: (i) the most important to the portrayal of our financial condition and results of operations, and (ii) that require our most difficult, subjective or complex judgments, often as a result of the need to make estimates about the effects of matters that are inherently uncertain.

Revenue Recognition. We recognize revenue in accordance with SEC Staff Accounting Bulletin No. 101, Revenue Recognition in Financial Statements, or SAB 101, as amended by SAB 101A and 101B. SAB 101 requires that four basic criteria must be met before revenue can be recognized:

- persuasive evidence of an arrangement exists;
- delivery has occurred and title and the risks and rewards of ownership have been transferred to our customer or services have been rendered;
- the price is fixed and determinable; and
- collectibility is reasonably assured.

Assuming that all of the above criteria have been met, we record revenue for domestic sales when we receive payment in full, due to a clause in our purchase order that states title transfers upon payment in full; we record revenue for international direct sales when the product is installed, which is when the customer is obligated to pay; and we record revenue for sales to distributors upon delivery.

Valuation of Accounts Receivable. We maintain an allowance for uncollectible accounts receivable to estimate the risk of extending credit to customers. The allowance is estimated based on customer compliance with credit terms, the financial condition of the customer and collection history where applicable. Additional allowances could be required if the financial condition of our customers were to be impaired beyond our estimates.

Valuation of Inventory. Inventory is valued at the lower of cost (estimated using the first-in, first-out method) or market. We periodically evaluate the carrying value of inventories and maintain an allowance for obsolescence to adjust the carrying value as necessary to the lower of cost or market. The allowance is based on physical and technical functionality as well as other factors affecting the recoverability of the asset through future sales. Unfavorable changes in estimates of obsolete inventory would result in an increase in the allowance and a decrease in gross profit.

Valuation of Long-Lived Assets. Property, plant and equipment, intangible and certain other long-lived assets are amortized over their 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. Long-lived assets are reviewed for impairment whenever events or changes in circumstances indicate that the carrying amount of an asset may not be recoverable through future business operations. In our estimate, no provision for impairment is currently required on any of our long-lived assets.

Warranty Cost. Products sold directly to end-users are covered by a warranty against defects in material and workmanship for a period of one year. Products sold internationally to distributors are covered by a warranty on parts for up to fourteen months with additional coverage on certain components for up to two years. We accrue a warranty reserve to estimate the risk of incurring costs to provide warranty services. The accrual is based on our historical experience and our expectation of future conditions. An increase in warranty claims or in the costs associated with servicing those claims would result in an increase in the accrual and a decrease in gross profit.

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 additional expense relating to contingencies. To be recorded as expense, a loss contingency must be both probable and measurable. If a loss contingency is material but is not both probable and estimable, we will disclose it in notes to the financial statements.

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Results of Operations

The following table sets forth certain data from our consolidated income statements for the years ended December 31, 2002, 2001 and 2000, expressed as a percentage of net sales:

	Years Ended December 31,		
	2002	2001	2000
		(Restated)	
Net sales	100.0 %	100.0 %	100.0 %
Cost of sales	38.5	41.9	50.7
Gross profit	61.5	58.1	49.3
Other income	0.2	0.5	
Operating expenses			
Sales and marketing	39.4	44.2	44.4
General and administrative	11.0	12.2	19.4
Engineering and development	6.2	9.2	24.1
Total operating expense	56.6	65.6	87.9
Income (loss) from operations	5.1	(7.0)	(38.6)
Non-operating income (loss)	0.4	(0.7)	(1.0)
Income (loss) before cumulative effect of change in accounting principle	5.5	(7.7)	(39.6)
Cumulative effect of change in accounting principle			(0.4)
Net income (loss)	5.5%	(7.7)%	(40.0)%

Net Sales. Net sales consists of sales of our laser systems, related disposables and accessories and service revenue. We have at various times experienced fluctuations in sales due to seasonality. In our experience, sales in the first quarter typically are lower than average, and sales in the fourth quarter typically are stronger than average, due to the buying patterns of dental professionals. The fourth quarter of 2002 accounted for 30% of our net sales for the year, whereas the first quarter of 2002 accounted for 18% of net sales for the year. Sales in the third quarter tend to be even with and may sometimes be lower than sales in the second quarter due to vacation patterns. The third quarter accounted for 25% of our net sales in 2002, whereas the second quarter accounted for 27% of our net sales in 2002. Our historical seasonality pattern is a recurring trend that we expect to continue. Consequently we do not necessarily match the timing of our expenditures to the expected quarterly seasonality effects on revenue but rather anticipate the expected sales over the full year as a determinant of our spending levels. Since many of our costs are fixed in the short term, if we have a shortfall in sales resulting from a change in our historical seasonality pattern, or otherwise, we may be unable to reduce expenses quickly enough to avoid losses.

Many dentists finance their purchases through third party leasing companies or banks. In these transactions, we receive payment in full from the leasing company or bank, or from the dentist, who receives funds from the leasing company or bank. The dentist pays the leasing company or bank in installments and 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 dentist s failure to make payments. Approximately 36% of our revenue in 2002, 43% of our revenue in 2001 and 38% of our revenue in 2000 were generated from dentists who financed their purchase through National Technology Leasing Corporation, an equipment

leasing company.

Cost of Sales. Cost of sales is comprised of all costs to manufacture our products, including materials, labor and related overhead costs such as depreciation, warranty and service costs.

Sales and Marketing. Sales and marketing expenses consist of salaries and benefits, commissions, and other costs related to our direct sales force, advertising costs and expenses related to trade shows and seminars.

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General and Administrative. General and administrative expenses consist of salaries and benefits of administrative personnel as well as insurance, professional and regulatory fees and provisions for doubtful accounts.

Engineering and Development. Engineering and development expenses consist of engineering personnel salaries and benefits, prototype supplies, contract services and consulting fees related to product development.

Non-Operating Income (Loss). Non-operating income (loss) consists of interest income and expense, foreign currency gains and losses and similar items not directly related to our operations. Interest income relates to interest earned on our cash balances, and interest expense relates to interest costs on our line of credit. We generate a substantial portion of our revenue from the sale of products outside the United States. Sales to customers or distributors outside the United States accounted for approximately 23% of our revenue for the year ended December 31, 2002. Sales in Europe and Canada accounted for approximately 11% of our revenue for the year ended December 31, 2002, while sales in Asia and countries in the Pacific Rim accounted for approximately 12% of our revenue for 2002. Our sales in Europe are denominated principally in Euros, and our sales in other international markets are denominated in dollars. As we do not engage in hedging transactions to offset foreign currency fluctuations, we are at risk for changes in the value of the dollar relative to the value of the Euro. An increase in the relative value of the dollar would lead to less income from sales denominated in Euros unless we increase prices, which may not be possible due to competitive conditions in Europe. Conversely, a decrease in the relative value of the dollar would lead to more income from sales denominated in Euros. Additionally, we are obligated to repay the debt on our German facility in Euros. Thus, we are also at risk for changes in the value of the dollar relative to the Euro with respect to our obligation to repay the debt on our German facility. An increase in the value of the dollar relative to the Euro would reduce the cost associated with repayment of the debt on our German facility, whereas a decrease in the relative value of the dollar would increase the cost associated with repayment of the debt on our German facility.

Income Taxes. At this time, no provision for income tax is recognized due to the availability of net operating loss carry forwards. At such times as the recoverability of deferred tax assets, including the net operating loss carry forwards, becomes more likely realizable than not, we will reduce the valuation allowance against our deferred tax assets, record an income tax benefit and subsequently record a provision for income taxes for financial statement purposes based on the amount of taxable net income.

Year Ended December 31, 2002 Compared With Year Ended December 31, 2001

Comparing the results of operations between the prior years, the most significant change affecting operating results is the increase in sales. Sales for the year ended December 31, 2002 increased 65% over sales for the year ended December 31, 2001.

Net Sales. Net sales for the year ended December 31, 2002 were $27.3 million, an increase of $10.8 million, as compared with net sales of $16.5 million for the year ended December 31, 2001. The increase in sales in both 2002 and 2001 resulted from the increased number of units sold of our laser systems. Our Waterlase system accounted for 77% of net sales in 2002 and 82% of net sales in 2001. Our LaserSmile system was introduced in the third quarter of 2001 and accounted for 18% of net sales in 2002 as compared with 16% of net sales in 2001.

International sales for the year ended December 31, 2002 were $6.2 million, or 23% of total net sales, as compared with $3.3 million, or 20% of total net sales, for the year ended December 31, 2001. The increase in international sales in 2002 was the result of a renewed effort to strengthen our network of international distributors after concentrating our resources in 2001 in the domestic market. The formation of BIOLASE Europe in 2002 and the acquisition of a production and service facility in Germany was an important step to increase our visibility in Europe as well as to improve our ability to service European customers. Sales of products manufactured at our German facility accounted for 9% of our revenue in 2002. In comparison, all of our revenue in 2001 was generated from the sale of products manufactured in the United States. We plan to continue

to add resources to our international sales program to take advantage of the large market potential and we expect that our international sales will continue to grow over time as a percentage of our total net sales. Although most of our international sales are made through independent distributors, we began making direct sales to dentists in Europe in 2002 with the support of our German distributor. Based on the overall increase and detailed review of sales, we have increased our allowance on accounts receivable from $108,000 at December 31, 2001 to $202,000 at December 31, 2002.

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Gross Profit. Gross profit for the years ended December 31, 2002 and 2001 was $16.8 million and $9.6 million, respectively. The gross margin on sales for those same periods was 62% and 58%, respectively. The increase in both gross profit and gross margin was attributable to leveraging the increase in our net sales against fixed and partially fixed manufacturing costs, reflecting better absorption of fixed manufacturing costs. The increase in gross profit is also due to increased manufacturing efficiencies and design changes through engineering and product development, which reduced the cost of materials by 10%. These efficiencies and cost savings were partially offset by the start-up costs for our German production and service facility of approximately $165,000 in 2002 and the addition of production resources of approximately $621,000 to support anticipated sales growth. While we believe there is additional leverage to be realized from future increases in sales, increases in fixed costs will also accompany growth and may constrain increases in gross margin. In addition, an increase in the mix of sales to international distributors will also tend to decrease gross profit since such sales are made at wholesale prices.

Other Income. Other income consists of gain on sale of assets. The gain on sale of assets for the year ended December 31, 2002 of $63,000 was related to the sale and leaseback of our manufacturing facility in San Clemente, California in March 2001. This sale resulted in a gain of $316,000, which is being recognized over the remaining term of the lease, which expires in 2006. Gain on sales of assets in 2001 included this amortization of deferred gain plus a gain on the sale of certain other assets.

Operating Expenses

Operating expenses for the year ended December 31, 2002 were $15.4 million, or 57% of net sales, as compared with $10.8 million, or 66% of net sales, for the year ended December 31, 2001. Most of the increases in operating expenses for each year were sales and marketing costs that were incurred to generate the increase in sales, including a growing sales force and related expenses.

Sales and Marketing. Sales and marketing expenses for the year ended December 31, 2002 was $10.8 million, or 39% of net sales, as compared with $7.3 million, or 44% of net sales, for the year ended December 31, 2001. The increase in absolute dollars from year to year was attributable to higher commission expense related to the increased sales and to the cost of additional sales personnel of approximately $600,000 in the United States. In addition during 2002, we expanded the scope of our nationwide seminar-marketing program and our sponsorship of education and training programs for existing and potential customers, as a result of which we incurred additional expenses of $871,000. Although growing 47% in 2002 in absolute dollars, sales and marketing expense as a percentage of net sales decreased from 44% in 2001 to 39% in 2002 due to the increase in sales generated by these efforts. In 2002, in addition to a number of local and regional symposiums, we sponsored two national and two international symposiums presented by the World Clinical Laser Institute, an organization that provides education and training in laser dentistry.

General and Administrative. General and administrative expenses for the year ended December 31, 2002 was $3.0 million, or 11% of net sales, as compared with $2.0 million, or 12% of net sales, for the year ended December 31, 2001. The increase in absolute dollars in 2002 was due to administrative costs associated with the operations of BIOLASE Europe of $140,000, increases in the costs of legal fees relating to regulatory compliance and various legal proceedings in the amount of $201,000, and increases in the infrastructure needed to support the growth of our sales. Insurance premiums increased in 2001 as a result of the increase in net sales and increased by $328,000 in 2002 both as a result of the increase in sales and as a result of general insurance market conditions. We expect additional increases in 2003 due to adverse markets for workers compensation, group health insurance and liability insurance.

Engineering and Development. Engineering and development expenses for the year ended December 31, 2002 was $1.7 million, or 6% of net sales, as compared with $1.5 million, or 9% of net sales, for the year ended December 31, 2001. The increase in absolute dollars in 2002 was related to new product development and enhancements. The decrease in research and development expenses as a percent of net sales reflects the larger sales base and fluctuations in the scope of current research and development projects.

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Non-Operating Income (Loss)

Unrealized Gain on Forward Exchange Contract. In the year ended December 31, 2002, we recognized an unrealized gain on forward contracts of $152,000 due to the increase in the fair market value of our forward exchange contract.

Interest Income. Interest income for the year ended December 31, 2002 was $18,000 compared with $44,000 in 2001. Even though our cash balances have increased over this period, continuing reductions in interest rates have resulted in lower interest income.

Interest Expense. Interest expense was $135,000 for the year ended December 31, 2002 compared with $167,000 in 2001. Interest expense in 2002 included the amortization of the cost of issuing stock in connection with the extension of our line of credit in December 2001. Interest expense in 2001 included three months of interest on the note payable on our San Clemente manufacturing facility, which was sold and leased back in March 2001.

Income Tax. No provision for income tax was recognized for the year ended December 31, 2002 due to the availability of net operating loss carry forwards. No income tax benefit was recognized in the year ended December 31, 2002 as there was no assurance that the benefit of the net operating loss carry forwards would be realized. At such time as the recoverability of deferred tax assets, including the net operating loss carry forward, becomes more likely realizable than not, we will reduce the valuation allowance against our deferred tax assets, record an income tax benefit and subsequently record a provision for income tax for financial statement purposes based on the amount of taxable net income. As of December 31, 2002, we had net operating loss carry forwards for federal and state purposes of approximately $34.9 million and $7.5 million, respectively, which began expiring in 2001. As of December 31, 2002, we had research and development credit carryforwards for federal and state purposes of approximately $332,000 and $170,000, respectively. The utilization of net operating loss and credit carry forwards may be limited under the provisions of Internal Revenue Code Section 382 and similar state provisions.

Year Ended December 31, 2001 Compared With Year Ended December 31, 2000

Comparing the results of operations between the prior years, the most significant change affecting operating results is the increase in sales. Sales for the year ended December 31, 2001 increased 74% over sales for the year ended December 31, 2000.

Net Sales. Net sales in 2001 were $16.5 million, an increase of $7.0 million, as compared with net sales of $9.5 million in 2000. This increase was due to a 176%, or $7.6 million growth in domestic sales of our Waterlase system. The Waterlase systems accounted for approximately 84% of net sales for the year ended December 31, 2001, as compared with 97% of net sales for the year ended December 31, 2000. Domestic sales also increased by $1.5 million in the third and fourth quarters of 2001 due to the introduction of our LaserSmile system. These increases were offset by a 28%, or $1.1 million decrease in international sales in 2001 as we concentrated our resources on growing sales in the domestic market.

Gross Profit. Gross profit increased 104% to $9.6 million in 2001 from $4.7 million in 2000. Gross margin increased from 49% of net sales in 2000 to 58% of net sales in 2001. This increase was the result of spreading the fixed costs of manufacturing over more units, an improvement in labor productivity, and engineering cost reductions, which collectively produced a 9% reduction in the material components of the products.

Other Income. Other income consists of gain on sale of assets. The gain on sale of assets of $79,000 in 2001 is related to two transactions. In 2000, we purchased our San Clemente manufacturing facility and offices in order to avoid moving our operations. In 2001, we sold the facility and leased it back for a five-year term with an additional five year option, resulting in a gain of $316,000. We are recognizing that gain for accounting purposes over the term of the lease. In 2001, we recognized $48,000 of this gain. We also sold inventory and assets relating to our inactive subsidiary, Societe Endo Technic, in 2001 for a gain of $31,000.

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Operating Expenses

Sales and Marketing. Sales and marketing expenses for the year ended December 31, 2001 was $7.3 million, or 44% of net sales, as compared with $4.2 million, or 44% of net sales, for the year ended December 31, 2000. The increase in absolute dollars was due to the 85% increase in net sales in 2001 and included increased sales commissions and increased cost of $536,000 associated with an increase in the number of sales representatives. Marketing costs also increased by $945,000 as we increased the number of trade shows, seminars and symposiums that we attended and sponsored.

General and Administrative. General and administrative expenses for the year ended December 31, 2001 was $2.0 million, or 12% of net sales, as compared with $1.8 million, or 19% of net sales, for the year ended December 31, 2000. The increase in absolute dollars in 2001 related to the cost of infrastructure needed to support the growth of the business.

Engineering and Development. Engineering and development expenses for the year ended December 31, 2001 was $1.5 million, or 9% of net sales, as compared with $2.3 million, or 24% of net sales, for the year ended December 31, 2000. This decrease was related to the change in the development cycle for our products. Engineering costs also decreased by approximately $100,000 as a result of process improvements, which reduced the number of employees needed to sustain the activities of the function.

Non-Operating Income (Loss)

Interest Income. Interest income for the year ended December 31, 2001 was $44,000 compared with $69,000 for the period ended December 31, 2000. Even though our cash balances have increased over this period, continuing reductions in interest rates have resulted in lower interest income.

Interest Expense. Although the variable interest rate on our line of credit decreased with other short-term interest rates in 2001, we incurred interest expense on the mortgage note payable that financed the purchase of our facility. The interest expense from the mortgage note for three months of 2001 offset the decrease in interest on our line of credit.

Cumulative Effect of Change in Accounting Principle

Effective January 1, 2000, we adopted SAB 101 resulting in a $34,000 cumulative effect of change in accounting principle. There was no change in accounting principle for the year ended December 31, 2001.

Liquidity and Capital Resources

At December 31, 2002 we had $1.4 million in net working capital as compared to $201,000 at December 31, 2001. Our principal source of liquidity at December 31, 2002 consisted of our cash balance of $3.9 million. Prior to 2001 we financed the development of our products and our operations through the private placement of common stock and the exercise of stock options and warrants. For the year ended December 31, 2002, our sources of cash were funds provided from operating activities of $635,000 and the exercise of stock options and warrants of $1.0 million. These sources of cash were reduced by investments in property and equipment of $478,000. The net effect on cash of operating, investing and financing transactions for the year ended December 31, 2002 was an increase of $1.3 million.

Accounts receivable, net, increased 127% to $5.0 million at December 31, 2002 from $2.2 million at December 31, 2001. This increase was due to the higher sales volume experienced in 2002. Inventories, net, increased 48% to $2.8 million at December 31, 2002 from $1.9 million at December 31, 2001. The increase was due to increased production to meet estimated sales demand.

As discussed in Note 7 to the Consolidated Financial Statements, 672,500 warrants with a weighted average exercise price of $2.46 are outstanding and are scheduled to expire in 2003. All of the warrants were exercised by June 30, 2003.

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Several key indicators of liquidity are summarized in the following table (in thousands, except ratio amounts):

	Years Ended December 31,		
	2002	**2001**	**2000**
Working capital (deficit) (restated)	$ 1,418	$ 201	$ (268)
Cash provided by (used in) operations	635	(1,037)	(3,778)
Proceeds from the exercise of stock options and warrants	1,035	803	3,201
Current ratio (restated)	1.1		