

BIOLASE TECHNOLOGY INC  
Form S-3/A  
February 24, 2004  
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As filed with the Securities and Exchange Commission on February 24, 2004

Registration No. 333-106260

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# SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

**Amendment No. 8**

to

**FORM S-3**

**REGISTRATION STATEMENT**

**UNDER**

**THE SECURITIES ACT OF 1933**

**BIOLASE TECHNOLOGY, INC.**

*(Exact Name of Registrant as Specified in Its Charter)*

**Delaware**

*(State or Other Jurisdiction*

*of Incorporation or Organization)*

**87-0442441**

*(I.R.S. Employer*

*Identification Number)*

**981 Calle Amanecer**

**San Clemente, California 92673**

**(949) 361-1200**

*(Address, Including Zip Code, and Telephone Number, Including Area Code, of Registrant's Principal Executive Offices)*

**Jeffrey W. Jones**

**President and Chief Executive Officer**

**BioLase Technology, Inc.**

**981 Calle Amanecer**

**San Clemente, California 92673**

**(949) 361-1200**

*(Name, Address, Including Zip Code, and Telephone Number, Including Area Code, of Agent For Service)*

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**Approximate date of commencement of proposed sale to the public:** As soon as practicable after the effective date of this registration statement.

If the only securities being registered on this form are being offered pursuant to dividend or interest reinvestment plans, please check the following box. "

If any of the securities being registered on this form are to be offered on a delayed or continuous basis pursuant to Rule 415 under the Securities Act of 1933, other than securities offered only in connection with dividend or interest reinvestment plans, check the following box. "

If this form is filed to register additional securities for an offering pursuant to Rule 462(b) under the Securities Act, please check the following box and list the Securities Act registration statement number of the earlier effective registration statement for the same offering. " \_\_\_\_\_

If this form is a post-effective amendment filed pursuant to Rule 462(c) under the Securities Act, check the following box and list the Securities Act registration statement number of the earlier effective registration statement for the same offering. " \_\_\_\_\_

If delivery of the prospectus is expected to be made pursuant to Rule 434, please check the following box. "

The registrant hereby amends this registration statement on such date or dates as may be necessary to delay its effective date until the registrant shall file a further amendment which specifically states that this registration statement shall thereafter become effective in accordance with Section 8(a) of the Securities Act of 1933, as amended, or until this registration statement shall become effective on such date as the Commission, acting pursuant to said Section 8(a), may determine.

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The information in this preliminary prospectus is not complete and may be changed. We may not sell these securities until the registration statement filed with the Securities and Exchange Commission becomes effective. This preliminary prospectus is not an offer to sell nor does it seek an offer to buy these securities in any jurisdiction where the offer or sale is not permitted.

**SUBJECT TO COMPLETION, DATED FEBRUARY 24, 2004**

**PRELIMINARY PROSPECTUS**

2,807,500 Shares

Common Stock

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We are offering 2,500,000 shares of our common stock and one of our stockholders is offering 307,500 shares of our common stock. We will not receive any proceeds from the sale of shares by the selling stockholder. Our common stock is traded on the Nasdaq National Market under the symbol BLTI. On February 3, 2004, the last reported sale price of our common stock on the Nasdaq National Market was \$20.13 per share.

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Investing in our common stock involves risks. See Risk Factors beginning on page 7.

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	Per Share	Total
Public Offering Price	\$	\$
Underwriting Discounts	\$	\$
Proceeds, before expenses, to BioLase Technology, Inc.	\$	\$
Proceeds, before expenses, to the selling stockholder	\$	\$

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The underwriters have the right to purchase up to 421,125 additional shares of common stock from us to cover over-allotments, if any.

The Securities and Exchange Commission and state securities regulators have not approved or disapproved of these securities or determined if this prospectus is truthful or complete. It is illegal for any person to tell you otherwise.

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Needham & Company, Inc.

William Blair & Company

Oppenheimer & Co. Inc.

The date of this prospectus is \_\_\_\_\_, 2004.

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You should rely only on the information contained in this prospectus. We have not, and the underwriters have not, authorized anyone to provide you with information different from that contained in this prospectus. We are not, and the underwriters are not, making an offer to sell or seeking offers to buy these securities in any jurisdiction where the offer or sale is not permitted. The information contained in this prospectus is accurate only as of the date of this prospectus, regardless of the time of delivery of this prospectus or any sale of these securities.

In this prospectus, BioLase, BLTI, we, us, our, or our company refer to BioLase Technology, Inc. and its subsidiaries and predecessors, collectively. BioLase®, Waterlase®, Millennium®, Laserbrush®, Lazersmile®, Flavorflow®, Hydrolase® and Vetlase® are our registered trademarks, and LaserSmile is our unregistered trademark. All other trademarks, servicemarks or trade names referred to in this prospectus are the property of their respective owners.

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**PROSPECTUS SUMMARY**

*This summary highlights our business and other selected information contained elsewhere in this prospectus. This summary does not contain all of the information that you should consider before making an investment decision. You should read the entire prospectus carefully, including Risk Factors, our consolidated financial statements and notes to these statements and other information incorporated by reference in this prospectus, before deciding to invest.*

**BioLase Technology, Inc.**

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. Our systems provide superior performance for many types of dental procedures, with less pain and faster recovery times than are generally achieved with high-speed drills and other dental instruments. We have clearances from the U.S. Food and Drug Administration to market our laser systems in the United States. We also have approvals 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.

Our primary product, the Waterlase system, is the best selling dental laser system. The Waterlase uses a patented combination of water and laser to precisely cut hard tissue, such as bone and teeth, and soft tissue, such as gums. We also offer the LaserSmile system, which uses a laser to perform soft tissue and cosmetic procedures, including tooth whitening. 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. These systems, together with our Waterlase and LaserSmile, offer 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.

According to the American Dental Association, there are over 160,000 practicing dentists in the United States. The World Federation of Dentistry, an international dental organization, estimates that there are at least 700,000 dentists worldwide. Although the use of lasers in dentistry is growing, only a small percentage of dentists currently use lasers. We believe this represents a significant opportunity for us to increase the sales of our laser systems worldwide.

Traditional dental instruments, such as high speed drills used on hard tissue, and scalpels, scissors and other cutting instruments used on soft tissue, cause discomfort, require anesthesia and result in unintended trauma to dental structure. Alternatives to traditional instruments in most cases are not suitable for performing a wide range of hard and soft tissue procedures. We believe these limitations create a significant opportunity for our laser systems, which can often perform common hard and soft tissue dental procedures more effectively and comfortably.

Our goal is to establish our laser systems as essential tools in dentistry for most common dental procedures. Our systems complement traditional tools, such as dental drills, which perform functions our systems do not address, such as cutting metal fillings and certain polishing and grinding functions. While our systems are more expensive than competing instruments, we believe that the superior performance of our systems, and the potential return on investment our systems offer practitioners, will enable us to increase our leading market position.

**The BioLase Solution**



We have developed our laser systems for the dental market to perform many common hard and soft tissue dental procedures, such as cavity preparations, root canals and cutting and reshaping gums. We believe our laser systems are positioned to become the preferred instruments for many dental procedures.

Our laser systems benefit practitioners by:

reducing the need for anesthesia, which can decrease the time required for each procedure;

allowing general dentists to perform more complex surgical and cosmetic procedures that they may have previously referred to specialists or simply not performed;

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improving patient retention and increasing the demand for elective procedures; and

reducing trauma, swelling and general discomfort.

Our laser systems benefit patients by:

improving comfort and reducing trauma for many common procedures;

eliminating or reducing the need for anesthesia in many cases, and the associated pain of injections and numbness;

enabling multiple procedures to be performed in one visit; and

making many elective procedures more comfortable and convenient.

## **Business Strategy**

Our objectives are to increase our leadership position and expand our penetration in the dental laser market. Our strategy consists of the following key elements:

increasing awareness of our laser systems among dental practitioners and patients;

expanding our sales and distribution capabilities in the United States and abroad;

expanding our products and applications in dentistry;

continuing to provide high quality manufacturing and customer service; and

strengthening and defending our technology leadership in the dental laser market.

## **Key Strengths**

We believe we can strengthen our leading position in the dental laser market because of the following advantages over our competitors:

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our Waterlase is the only commercially available dental laser that uses water and a unique crystal laser optimized for dental applications;

our Waterlase system is the best selling dental laser system;

we have established relationships with leading dental practitioners and academic leaders worldwide who help us increase awareness of our systems among dental professionals; and

we have a strong patent portfolio covering a broad range of dental technologies.

### **Recent Developments (Unaudited)**

On February 24, 2003, we announced the results of operations for the quarter and year ended December 31, 2003. Net sales for the quarter and year ended December 31, 2003 were \$16.1 million and \$49.1 million, respectively. Net sales for the quarter and year ended December 31, 2002 were \$8.1 million and \$27.3 million, respectively.

Gross margin for the quarter and year ended December 31, 2003 was 68.0% and 64.3%, respectively. Gross margin for the quarter and year ended December 31, 2002 was 64.1% and 61.5%, respectively. Gross margin in the fourth quarter of 2003 reflects the increased percentage of domestic sales relative to sales to international distributors and may not be indicative of gross margins in the future.

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Net income for the quarter and year ended December 31, 2003 was \$14.3 million and \$19.1 million, respectively, and includes a one-time tax benefit of \$11.4 million. The tax benefit is the result of the recognition of deferred tax assets, which consists primarily of net operating loss carryforwards. The deferred tax assets previously had been offset by a full valuation reserve due to the uncertainty of their future realization. Under generally accepted accounting principles, we are required to reduce the valuation reserve and recognize deferred tax assets if it is more likely than not that we will realize the benefit from the deferred tax assets in future years. The recognition of these deferred tax assets will not affect our operating results, cash flow or the timing of income taxes payable in the future. As a result of recording the deferred tax assets at December 31, 2003, we expect to record a provision for income taxes in future periods. At December 31, 2003, an estimated \$32.5 million in net operating loss carryforwards were available to offset federal taxable income in future years.

Income before taxes for the quarter and year ended December 31, 2003 was \$2.9 million and \$7.7 million, respectively. Income before taxes for the quarter and year ended December 31, 2002 was \$332,000 and \$1.5 million, respectively.

Cash flow from operating activities for the year ended December 31, 2003 was approximately \$6.3 million compared to \$477,000 for the year ended December 31, 2002.

Net income per fully diluted share for the fourth quarter and year ended December 31, 2003 was \$0.61 and \$0.83, respectively. The per-share amount for 2003 includes the one-time tax benefit as discussed above. Net income per fully diluted share for the quarter and year ended December 31, 2002 was \$0.02 and \$0.07, respectively.

At December 31, 2003, we had cash of \$11.1 million, working capital of \$10.7 million, stockholders' equity of \$31.8 million and total assets of \$44.5 million.

As discussed more fully in Management's Discussion and Analysis of Financial Condition and Results of Operations included elsewhere in this prospectus, due to the change in accounting for revenue recognition in August 2003, results of operations between periods are not directly comparable.

In August 2003, we modified our sales arrangements with our customers and began recognizing revenue upon shipment for our domestic sales, or on an accrual basis, which previously had been recognized upon receipt of payment in full, or on a cash basis. Additionally, we began to recognize revenue upon shipment for our international direct sales, which previously had been recognized after completion of installation. Revenue for the year ended December 31, 2003 included \$18.3 million of domestic sales recognized on a cash basis and \$20.4 million of domestic sales recognized on an accrual basis. Revenue for the year ended December 31, 2002 included \$20.2 million of domestic sales recognized on a cash basis. Revenue for the year ended December 31, 2003 included \$1.6 million of international direct sales recognized after completion of installation and \$1.7 of international direct sales recognized on shipment. Revenue for the year ended December 31, 2002 included \$463,000 of international direct sales recognized upon completion of installation.

During the fourth quarter of 2003, we recognized approximately \$400,000 of revenue that was previously deferred at September 30, 2003. Other than the possible recognition of the \$143,000 deferred revenue balance as of December 31, 2003, the positive impact to our net sales for the year ended December 31, 2003 that resulted from the change in our revenue recognition policy will not occur in future periods.

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The following tables summarize selected results of operations and balance sheet data for the periods indicated:

**BIOLASE TECHNOLOGY, INC.****SELECTED CONSOLIDATED FINANCIAL DATA****(unaudited)****Selected Consolidated Statements of Operations Data:**

	<b>Years Ended</b>		<b>Three Months Ended</b>	
	<b>December 31,</b>		<b>December 31,</b>	
	<b>2003</b>	<b>2002</b>	<b>2003</b>	<b>2002</b>
Net sales	\$ 49,081,000	\$ 27,257,000	\$ 16,090,000	\$ 8,123,000
Gross profit	31,551,000	16,772,000	10,946,000	5,207,000
Income from operations	7,441,000	1,412,000	2,816,000	275,000
Income before income tax benefit	7,667,000	1,498,000	2,907,000	332,000
Income tax benefit	11,391,000		11,391,000	
Net income	\$ 19,058,000	\$ 1,498,000	\$ 14,298,000	\$ 332,000
Net income per share:				
Basic	\$ 0.91	\$ 0.08	\$ 0.66	\$ 0.02
Diluted	\$ 0.83	\$ 0.07	\$ 0.61	\$ 0.02
Shares used in computing net income per share:				
Basic	20,993,000	19,929,000	21,550,000	20,078,000
Diluted	22,978,000	21,303,000	23,534,000	21,755,000

**Selected Consolidated Balance Sheet Data:**

	<b>December 31,</b>	<b>December 31,</b>
	<b>2003</b>	<b>2002</b>
Cash and cash equivalents	\$ 11,111,000	\$ 3,940,000
Working capital	10,656,000	1,418,000
Total assets	44,501,000	16,003,000
Total debt	2,680,000	3,209,000
Stockholders' equity	31,782,000	3,121,000

**Additional Information**

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We are a Delaware corporation. Our principal executive office is at 981 Calle Amanecer, San Clemente, California 92673, and our telephone number is (949) 361-1200. Our corporate web site is [www.biolase.com](http://www.biolase.com). The information on our web site is not part of this prospectus.

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**The Offering**

Common stock offered by us	2,500,000 shares
Common stock offered by selling stockholder	307,500 shares
Common stock outstanding after the offering	24,088,727 shares
Use of proceeds	For general corporate purposes, working capital, potential repayment of debt, of which approximately \$1.8 million is currently outstanding, capital expenditures and potential acquisitions. We will not receive any proceeds from the sale of shares by the selling stockholder.
Nasdaq National Market symbol	BLTI

The number of shares of common stock outstanding after this offering is based on 21,588,727 shares outstanding as of December 31, 2003, and excludes 3,635,088 shares consisting of:

3,329,131 shares issuable upon exercise of outstanding options at a weighted average exercise price of \$5.43 per share; and

305,957 additional shares of common stock reserved for future grant or issuance under our equity incentive compensation plans.

Unless otherwise indicated, all information in this prospectus assumes no exercise by the underwriters of their over-allotment option to purchase up to 421,125 additional shares of common stock from us. Shares purchased by the underwriters to cover over-allotments, if any, will be offered for sale under this prospectus.

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(in thousands, except per share data)

The following tables set forth summary consolidated financial data for the periods indicated. You should read the data set forth below in conjunction with Management's Discussion and Analysis of Financial Condition and Results of Operations and our consolidated financial statements and related notes included elsewhere in this prospectus. We derived the consolidated statements of operations data for the years ended December 31, 2000, 2001 and 2002 from our audited financial statements included elsewhere in this prospectus. We derived the selected financial data with respect to the consolidated statements of operations data for the nine months ended September 30, 2002 and 2003, and with respect to the balance sheet data at September 30, 2003, from unaudited financial statements included elsewhere in this prospectus. The data set forth below for the years ended December 31, 2000, 2001 and 2002 and the nine months ended September 30, 2002, reflect the recent restatement of our financial statements to account for a change in the timing of revenue recognition, as more fully explained in Management's Discussion and Analysis of Financial Condition and Results of Operations, Risk Factors and Note 2 to the consolidated financial statements included elsewhere in this prospectus. The data for the nine months ended September 30, 2003, and as of September 30, 2003, reflect the change in our revenue recognition policy in August 2003, as more fully explained in the above referenced sections included elsewhere in this prospectus.

	Fiscal Years Ended			Nine Months Ended	
	December 31, (Restated)			September 30,	
	2000	2001	2002	2002 (Restated)	2003
<b>Consolidated Statements of Operations Data:</b>					
Net sales	\$ 9,495	\$ 16,546	\$ 27,257	\$ 19,134	\$ 32,991
Cost of sales	4,816	6,938	10,485	7,569	12,386
Gross profit	4,679	9,608	16,772	11,565	20,605
Other income		79	63	47	51
Operating expenses:					
Sales and marketing	4,211	7,314	10,729	7,255	10,962
General and administrative	1,841	2,011	3,010	2,072	3,407
Engineering and development	2,288	1,520	1,684	1,148	1,662
Total operating expenses	8,340	10,845	15,423	10,475	16,031
Income (loss) from operations	(3,661)	(1,158)	1,412	1,137	4,625
Non-operating income (loss)	(94)	(123)	86	29	135
Income (loss) before cumulative effect of change in accounting principle	(3,755)	(1,281)	1,498	1,166	4,760
Cumulative effect of change in accounting principle	(34)				
Net income (loss)	\$ (3,789)	\$ (1,281)	\$ 1,498	\$ 1,166	\$ 4,760
Income (loss) per share before cumulative effect of change in accounting principle:					
Basic	\$ (0.20)	\$ (0.07)	\$ 0.08	\$ 0.06	\$ 0.23
Diluted	\$ (0.20)	\$ (0.07)	\$ 0.07	\$ 0.05	\$ 0.21
Cumulative effect of change in accounting principle per share:					
Basic	\$ 0.00	\$	\$	\$	\$



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Diluted	\$ 0.00	\$	\$	\$	\$
Net income (loss) per share:					
Basic	\$ (0.20)	\$ (0.07)	\$ 0.08	\$ 0.06	\$ 0.23
Diluted	\$ (0.20)	\$ (0.07)	\$ 0.07	\$ 0.05	\$ 0.21
Shares used in computing net income (loss) per share					
Basic	19,171	19,510	19,929	19,878	20,796
Diluted	19,171	19,510	21,303	21,288	22,813

The following table presents our consolidated balance sheet data as of September 30, 2003, which we derived from our unaudited financial statements included elsewhere in this prospectus. The as adjusted for the offering data gives effect to the sale of 2,500,000 shares of common stock by us in this offering at an assumed public offering price of \$20.13 per share, which was the last reported sales price of our common stock on February 3, 2004, and after deducting underwriting discounts and commissions, and estimated offering expenses payable by us.

	September 30, 2003	
	Actual	As Adjusted for Offering
	Actual	As Adjusted for Offering
<b>Consolidated Balance Sheet Data:</b>		
Cash and cash equivalents	\$ 6,123	\$ 51,902
Working capital	7,349	53,128
Total assets	26,315	72,094
Total debt	2,937	2,937
Stockholders' equity	15,129	60,908

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**RISK FACTORS**

*Investing in our common stock involves a high degree of risk. You should carefully consider the following risks and all the other information in this prospectus before making an investment decision about our common stock. While the risks described below are the ones we believe are most important for you to consider, these risks are not the only ones that we face. If any of the following risks actually occurs, our business, operating results or financial condition could suffer, the trading price of our common stock could decline and you could lose all or part of your investment.*

**Risks Relating to Our Business**

**Our quarterly sales and operating results may fluctuate in future periods and we may fail to meet expectations, which may cause the price of our common stock to decline.**

Our quarterly sales and operating results have fluctuated and are likely to continue to vary from quarter to quarter due to a number of factors, many of which are not within our control. If our quarterly sales or operating results fall below the expectations of investors or securities analysts, the price of our common stock could decline substantially. Factors that might cause quarterly fluctuations in our sales and operating results include the following:

variation in demand for our products, including variation due to seasonality;

our ability to research, develop, introduce, market and gain market acceptance of new products and product enhancements in a timely manner;

our ability to control costs;

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

the introduction of new products by competitors;

long sales cycles and fluctuations in sales cycles;

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

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

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

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costs associated with any future acquisitions of technologies and businesses;

limitations on our ability to use net operating loss carryforwards under the provisions of Internal Revenue Code Section 382 and similar provisions under applicable state laws;

developments concerning the protection of our proprietary rights; and

general global economic and political conditions, including international conflicts and acts of terrorism.

The amount of expenses we incur, in part, depends on our expectations regarding future sales. In particular, we expect to continue incurring substantial expenses relating to the marketing and promotion of our products. Since many of our costs are fixed in the short term, if we have a shortfall in sales, we may be unable to reduce expenses quickly enough to avoid losses. Accordingly, you should not rely on quarter-to-quarter comparisons of our operating results as an indication of our future performance. Additionally, as a result of the change in our revenue recognition policy in the third quarter of 2003, our quarterly sales and operating results for each of the next four quarters ending September 30, 2004, may not be directly comparable to corresponding periods in the preceding year due to the difference in the timing of revenue recognition.

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**Regulatory proceedings relating to the restatement of our consolidated financial statements could divert management's attention and resources.**

We recently restated our previously issued financial statements to reflect a change in the timing of revenue recognition. Staff Accounting Bulletin No. 101, Revenue Recognition in Financial Statements, as adopted by the Securities and Exchange Commission, requires the transfer of title and the risks and rewards of ownership to the customer before the recognition of revenue. We originally prepared our financial statements on the basis that this transfer of title occurred upon shipment. After 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 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, and the interim periods in 2002 and the quarter ended March 31, 2003, to defer revenue upon shipment and to recognize it upon receipt of full payment for our domestic customers. It was also determined that revenue recognition for products shipped directly to customers in Europe which we commenced in 2002, was appropriate at the time of installation, which was when the customer became obligated to pay, and not at the time of shipment as recognized in the previously filed financial statements. In conjunction with these revisions, we deferred the revenue, the related cost of inventory and related sales commissions. In August 2003, we modified the sales arrangements with our customers so that title transfers to the customer upon shipment for domestic sales, and there is an enforceable obligation to pay upon shipment for international direct sales. As a result, we changed our revenue recognition policy in the third quarter of 2003 to recognize revenue upon shipment for both domestic sales and international direct sales.

In late October 2003 and subsequently, we received informal requests from the Securities and Exchange Commission to voluntarily provide information relating to the restatement of our consolidated financial statements. We have provided information to the Securities and Exchange Commission and intend to continue to cooperate in responding to the inquiry. In accordance with its normal practice, the Securities and Exchange Commission has not advised us when its inquiry may be concluded, and we are unable to predict the outcome of this inquiry. If the Securities and Exchange Commission elects to request additional information from the company or commence further proceedings, responding to such requests or proceedings could divert management's attention and resources. Additionally, any negative developments arising from such requests or proceedings could harm our business and cause the price of our common stock to decline.

**The loss of or a substantial reduction in, or change in the size or timing of, orders from distributors could harm our business.**

Our international sales are principally comprised of sales through independent distributors, although we sell products in certain European countries through direct sales representatives. A significant amount of our sales may consist of sales through distributors. Net sales to distributors accounted for approximately 17% of our total sales in 2002. No distributor accounted for more than 6% of our net sales in 2002. The loss of a substantial number of our distributors or a substantial reduction in, cancellation of or change in the size or timing of orders from our current distributors could harm our business, financial condition and results of operations. The loss of a key distributor could affect our operating results due to the potential length of time that might be required to locate and qualify a new distributor or to retain direct sales representatives for the territory. In February of 2003, we terminated our distributor in Germany for failure to satisfy its obligations under its agreement with us, including failure to meet specified sales quotas. The agreement was originally signed in 2000 and renewed in 2002. The agreement required minimum sales of \$10,000,000 over the two-year term following the renewal. The average quarterly sales generated by our distributor from the time of the renewal until we terminated the distributor were nearly 50% less than the quota provided under the distribution agreement. To replace the distributor, we entered into contracts with independent sales agents within Germany. There is no assurance that our distributors will perform as expected and we may experience lengthy delays and incur substantial costs if we are required to replace distributors in the future.

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### **Variation in demand for our products due to seasonality can cause our operating results to fluctuate from quarter to quarter during the year.**

We have experienced fluctuations in sales from quarter to quarter 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. For example, 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. In addition, sales in the third quarter of the year may be affected by vacation patterns which can cause sales to be flat or lower than in the second quarter of the year. As a result, sequential quarter-to-quarter comparisons of our operating results may not be an indication of our performance for the year and may cause our results of operations and stock price to fluctuate.

### **Dentists and patients may be slow to adopt laser technologies, which could limit the market acceptance of our products.**

Our dental laser systems represent relatively new technologies in the dental market. Currently, only a small percentage of dentists use lasers to perform dental procedures. Our future success will depend on our ability to increase demand for our products by demonstrating to a broad spectrum of dentists and patients the potential performance advantages of our laser systems over traditional methods of treatment and over competitive laser systems. Dentists have historically been and may continue to be slow to adopt new technologies on a widespread basis. This leads to long sales cycles and requires us to invest a significant amount of time and resources to educate customers about the benefits of our products and how they compare to competing products and technologies. Our sales personnel may be required to spend a substantial amount of time answering questions from potential customers and attending multiple in-person meetings over the course of several months before completing a sale. In addition, on occasion, our customers ask to return products after completing the purchase. Although we treat all sales as final, we may accept product returns from customers in certain circumstances. If requests for product returns become more pervasive, they could seriously harm our reputation and results of operations.

Factors that may inhibit adoption of laser technologies by dentists include cost, and concerns about the safety, efficacy and reliability of lasers. For example, the selling price of our Waterlase product is approximately \$50,000, which is substantially above the cost of competing non-laser technologies. In order to make an investment in a Waterlase, a dentist generally would need to invest time to gain an understanding of the technology and how that technology will produce a return on investment. Similarly, although medical lasers are

generally accepted in other specialties, a dentist generally would want to understand how the use of laser technology can improve the clinical outcomes and satisfaction of his or her own patients before making a substantial investment. Absent an immediate competitive motivation, a dentist may not feel compelled to invest the time required to learn about the potential benefits of using a laser. In addition, a dentistry practice, like any business, needs to make capital allocation decisions in which our product might compete with an unrelated alternative capital expenditure. Economic pressure, caused for example by an economic slowdown or by competitive factors in a specific market place, may make dentists reluctant to purchase substantial capital equipment or invest in new technologies. Patient acceptance will depend in part on the recommendations of dentists and specialists as well as other factors, including without limitation, the relative effectiveness, safety, reliability and comfort of our systems as compared with those of other instruments and methods for performing dental procedures. The failure of dental lasers to achieve broad market acceptance would have an adverse effect on our business, financial condition and results of operations. We cannot assure you that we will successfully achieve broad market acceptance for our products.

### **We may have difficulty managing our growth.**

We have been experiencing significant growth in the scope of our operations and the number of our employees. This growth has placed significant demands on our management as well as our financial and



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operational resources. In order to achieve our business objectives, we anticipate that we will need to continue to grow. If this growth occurs, it will continue to place additional significant demands on our management and our financial and operational resources, and will require that we continue to develop and improve our operational, financial and other internal controls both in the United States and internationally. In particular, our growth has and, if it continues, will increase the challenges involved in implementing appropriate operational and financial systems, expanding manufacturing capacity and scaling up production, expanding our sales and marketing infrastructure and capabilities, providing adequate training and supervision to maintain high quality standards, and preserving our culture and values. The main challenge associated with our growth has been, and we believe will continue to be, our ability to recruit skilled sales, manufacturing and management personnel. Our inability to scale our business appropriately or otherwise adapt to growth would cause our business, financial condition and results of operations to suffer.

### **If we are unable to protect our intellectual property rights, our competitive position could be harmed or we could be required to incur expenses to enforce our rights.**

Our future success will depend, in part, on our ability to obtain and maintain patent protection for our products and technology, to preserve our trade secrets and to operate without infringing the intellectual property of others. In part, we rely on patents to establish and maintain proprietary rights in our technology and products. While we hold a number of issued patents and have other patent applications pending on our products and technology, we cannot assure you that any additional patents will be issued, that the scope of any patent protection will exclude competition or that any of our patents will be held valid if subsequently challenged. Other companies also may independently develop similar products, duplicate our products or design products that circumvent our patents. Additionally, the laws of foreign countries may not protect our products or intellectual property rights to the same extent as do the laws of the United States.

We face substantial uncertainty regarding the impact that other parties' intellectual property positions will have on the markets for dental and other medical lasers. Competitors may claim that we have infringed their current or future intellectual property rights. The medical technology industry has in the past been characterized by a substantial amount of litigation and related administrative proceedings regarding patents and intellectual property rights. We may not prevail in any future intellectual property infringement litigation given the complex technical issues and inherent uncertainties in litigation. Any claims, with or without merit, could be time-consuming and distracting to management, result in costly litigation, cause product shipment delays, or require us to enter into royalty or licensing agreements. Additionally, if an intellectual property claim against us is successful, we might not be able to obtain a license on acceptable terms or license a substitute technology or redesign our products to avoid infringement. Any of the foregoing adverse events could seriously harm our business, financial condition and results of operations.

### **We are a party to a patent infringement lawsuit involving patents relating to our core technology, which if determined adversely to us, could have a significant negative effect on our earnings.**

We are currently involved in a patent lawsuit with Diodem, LLC, a California limited liability company, which was founded by Collete Cozean, the former chief executive officer of Premier Laser Systems, Inc. The claims in this lawsuit were originally part of two separate lawsuits initiated in U.S. District Court. On May 2, 2003, we initiated a civil action in the U.S. District Court for the Central District of California against Diodem to obtain a judicial declaration against Diodem that technology used in our laser systems does not infringe four patents owned by Diodem. Diodem claims to have acquired the patents from Premier Laser Systems, Inc., which filed for bankruptcy protection in March 2000. 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. These lawsuits were consolidated into the currently pending lawsuit in August 2003. Diodem alleges that our technology, including the technology used in our Waterlase system, infringes four patents it acquired from Premier. Diodem seeks treble damages, a preliminary and permanent injunction from further alleged infringement, attorneys' fees and other unspecified damages. This lawsuit is in the discovery phase of litigation, and may proceed for an





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extended period of time. There can be no assurance that our technology will not be found to infringe any of Diodem's patents at issue in this proceeding or that we will not be liable for some or all of the damages alleged by Diodem or subject to some or all of the relief requested by Diodem.

In addition, this lawsuit could result in significant expenses and diversion of management's time and other resources. If Diodem successfully asserts an infringement claim against us in the lawsuit, our operations may be severely impacted, especially to the extent that it affects our right to use the technology incorporated in our Waterlase system, which accounted for approximately 77% of our revenue in 2002 and approximately 80% of our revenue for the nine months ended September 30, 2003. This proceeding could also result in significant limitations on our ability to manufacture, market and sell our products, including our Waterlase system, as well as delays and costs associated with redesigning our products and payments of license fees, monetary damages and other payments. Additionally, we may be enjoined from incorporating certain technology into our products, all of which could significantly impede our operations, increase operating expenses, reduce our revenue and cause us to incur losses.

**We depend on a limited number of suppliers and if we cannot secure alternate suppliers, the amount of sales in any period could be adversely affected.**

We purchase certain materials and components included in our Waterlase system and other products from a limited group of suppliers using purchase orders, and we have no written supply contracts with our key suppliers. Our business depends in part on our ability to obtain timely deliveries of materials and components in acceptable quality and quantities from our suppliers. The introduction of our LaserSmile system in 2001 was delayed due to an interruption in the supply of components for the system, however, we have not otherwise experienced material delays in the supply of components. Certain components of our products, particularly specialized components used in our lasers, are currently available only from a single source or limited sources. For example, the crystal, fiber and handpieces used in our Waterlase system, which accounted for approximately 77% of our revenue in 2002 and approximately 80% of our revenue for the nine months ended September 30, 2003, are each supplied by a separate single supplier. We have not experienced material delays from these suppliers, and we have identified and tested alternative suppliers for each of these three components. However, an unexpected interruption in a single source supplier could create manufacturing delays, and disrupt sales and cash flow as we sought to replace the supplier, which we estimate could take up to three months. Such an interruption could cause our business, financial condition and results of operations to suffer.

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

International sales comprise a significant portion of our net sales and we intend to continue to pursue and expand our international business activities. International sales accounted for approximately 23% of our revenue in 2002 and approximately 22% of our revenue for the nine months ended September 30, 2003. Political and economic conditions outside the United States could make it difficult for us to increase our international sales or to operate abroad. International operations, including our facility in Germany, are subject to many inherent risks, including:

adverse changes in tariffs;

political, social and economic instability and increased security concerns;

fluctuations in currency exchange rates;

longer collection periods and difficulties in collecting receivables from foreign entities;

exposure to different legal standards;

ineffectiveness of international distributors;

reduced protection for our intellectual property in some countries;

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burdens of complying with a variety of foreign laws;

import and export license requirements and restrictions of the United States and each other country in which we operate;

trade restrictions;

the imposition of governmental controls;

unexpected changes in regulatory or certification requirements;

difficulties in staffing and managing international manufacturing and sales operations; and

potentially adverse tax consequences and the complexities of foreign value added tax systems.

We believe that international sales will continue to represent a significant portion of our net sales, and we intend to further expand our international operations. Our sales in Europe are denominated principally in Euros, while our sales in other international markets are in dollars. As a result, an increase in the relative value of the dollar against the Euro 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. We realized a gain of \$135,000 on foreign currency transactions for the nine month period ended September 30, 2003, due to a decrease in the value of the dollar relative to the value of the Euro. We could experience losses from European transactions if the relative value of the dollar were to increase in the future. We do not currently engage in any transactions as a hedge against risks of loss due to foreign currency fluctuations, although we may consider doing so in the future. We also expect that sales of products manufactured at our facility in Germany will account for an increasing percentage of our revenue, which will further increase our exposure to the above-described risks associated with our international operations. Sales of products manufactured at our German facility accounted for 9% of our revenue in 2002 and approximately 13% of our revenue for the nine months ended September 30, 2003. Since expenses relating to our manufacturing operations in Germany are paid in Euros, an increase in the value of the Euro relative to the dollar would increase the expenses associated with our German manufacturing operations and reduce our earnings. In addition, we may experience difficulties associated with managing our operations remotely and complying with German regulatory and legal requirements for maintaining our manufacturing operations in that country. Any of these factors may adversely affect our future international sales and manufacturing operations and, consequently, negatively impact our business, financial condition and operating results. Despite these risks, we believe the market for our products outside the United States justifies our effort to expand our international operations.

**If we are unable to meet customer demand or comply with quality regulations, our sales will suffer.**

We manufacture our products at our California and German production facilities. In order to achieve our business objectives, we will need to significantly expand our manufacturing capabilities to produce the systems and accessories necessary to meet demand. We intend to finance the cost of expansion through operating income, funds available under our bank credit line and a portion of the proceeds from this offering. We may encounter difficulties in scaling-up production of our products, including problems involving production capacity and yields, quality control and assurance, component supply and shortages of qualified personnel. In addition, our manufacturing facilities are subject to periodic inspections by the U.S. Food and Drug Administration, state agencies and foreign regulatory agencies. Our success will depend in part upon our ability to manufacture our products in compliance with the U.S. Food and Drug Administration's Quality System regulations and other regulatory requirements. Our business will suffer if we do not succeed in manufacturing our products on a timely basis and with acceptable manufacturing costs while at the same time maintaining good quality control and complying with applicable regulatory requirements.

**Any failure to significantly expand sales of our products will negatively impact our business.**

We currently handle a majority of the marketing, distribution and sales of our laser systems. In order to achieve our business objectives, we will need to significantly expand our marketing and sales efforts on a

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nationwide and global basis. We will face significant challenges and risks in expanding, training, managing and retaining our sales and marketing teams, including managing geographically dispersed efforts. In addition, we use third party distributors to sell our products in a number of countries outside the United States, and are dependent on the sales and marketing efforts of these third party distributors. These distributors may not commit the necessary resources to effectively market and sell our products. If we are unable to expand our sales and marketing capabilities, we may not be able to effectively commercialize our products.

### **Acquisitions could have unintended negative consequences, which could harm our business.**

As part of our business strategy, we may acquire one or more businesses, products or technologies. In May 2003, we acquired the American Dental Laser product line and related dental laser assets of American Medical Technologies, Inc., including the Diolase and Pulsemaster systems, and related inventory, patents and other intellectual property rights. We are currently in the process of integrating the assets relating to the American Dental Laser product line into our operations. We must effectively integrate the American Dental Laser product line into our operations in order to achieve profitability from it. The pro forma data in Note 10 to the consolidated financial statements included in this prospectus show a net loss for the nine months ended September 30, 2002 and a reduction in net income for the nine months ended September 30, 2003 when the seller's historical losses from operating this product line are combined with our operations. However, we believe we can integrate the acquired assets into our sales and manufacturing infrastructure with minimal increase to our operating expenses because we acquired principally patents, brand names, customer lists and other intangibles and we did not assume the seller's personnel, facilities or other overhead.

Acquisitions could require significant capital infusions and could involve many risks, including, but not limited to, the following:

we may encounter difficulties in assimilating and integrating the operations, products and workforce of the acquired companies;

acquisitions may negatively impact our results of operations because they may require large one-time charges or could result in increased debt or contingent liabilities, adverse tax consequences, substantial depreciation or deferred compensation charges, or the amortization or write down of amounts related to deferred compensation, goodwill and other intangible assets;

acquisitions may be dilutive to our existing stockholders;

acquisitions may disrupt our ongoing business and distract our management; and

key personnel of the acquired company may decide not to work for us.

We cannot assure you that we will be able to identify or consummate any future acquisitions on acceptable terms, or at all. If we do pursue any acquisitions, it is possible that we may not realize the anticipated benefits from such acquisitions or that the market will not positively view such acquisitions.

**We may be unable to comply with covenants contained in our credit agreement, which could result in the impairment of our working capital and alter our ability to operate our business.**

In May 2003, we secured a new credit facility through Bank of the West. At December 31, 2003, the outstanding principal balance on this credit facility was \$1.8 million. To maintain the right to borrow under this credit facility and avoid a default under our credit agreement with Bank of the West, we are required to satisfy certain financial tests and comply with certain operating covenants contained in that agreement. Our ability to satisfy required financial ratios and tests can be affected by events beyond our control, including prevailing economic, financial and industry conditions, and we cannot assure you that we will continue to meet those ratios and tests in the future. A breach of any of these covenants, ratios or tests could result in a default under our credit agreement. If we default, our lender will no longer be obligated to extend credit to us and could elect to declare all amounts outstanding under the credit agreement, together with accrued interest, to be immediately due and

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payable. If we were unable to repay those amounts, our lender could proceed against the collateral granted to it to secure that indebtedness, which includes our intellectual property. The results of such action would have a significant negative impact on our results of operations and financial condition. Due to the restatement of our financial statements, we were not in compliance with three covenants under the credit facility at June 30, 2003. The bank waived our non-compliance with these covenants as of June 30, 2003, so that we were not in default under the credit facility. We were in compliance with the financial covenants as of September 30, 2003. No determination has been made as to our compliance with these covenants as of December 31, 2003, the most recent evaluation date for determining compliance with the covenants. We cannot assure you that we will be in compliance with our financial covenants as of December 31, 2003 or on future evaluation dates for determining compliance with these covenants.

### **Material increases in interest rates may harm our sales.**

We currently sell our products primarily to dentists in general practice. These dentists often purchase our products with funds they secure through various financing arrangements with third party financial institutions, including credit facilities and short term loans. If interest rates increase, these financing arrangements will be more expensive to our dental customers, which would effectively increase the price of our products to our customers and, thereby, may decrease overall demand for our products. Any reduction in the sales of our products would cause our business to suffer.

### **We may not be able to compete successfully against our current and future competitors.**

We compete with a number of foreign and domestic companies that market traditional dental products, such as dental drills, as well as other companies that market laser technologies in the dental and medical markets that we address, including companies such as Hoya ConBio, a subsidiary of Hoya Photonics, a large Japanese manufacturer primarily of optics and crystals, OpusDent Ltd., a subsidiary of Lumenis, Ka Vo, Deka Dental Corporation and Fotona d.d. Some of our competitors have greater financial, technical, marketing or other resources than us, which may allow them to respond more quickly to new or emerging technologies and to devote greater resources to the acquisition or development and introduction of enhanced products than we can. In addition, the rapid technological changes occurring in the healthcare industry are expected to lead to the entry of new competitors, especially as dental and medical lasers gain increasing market acceptance. Our ability to anticipate technological changes and to introduce enhanced products on a timely basis will be a significant factor in our ability to grow and remain competitive. New competitors or technological changes in laser products and methods could cause commoditization of such products, require price discounting or otherwise adversely affect our gross margins.

### **Rapid changes in technology could harm the demand for our products or result in significant additional costs.**

The markets in which our laser systems compete are subject to rapid technological change, evolving industry standards, changes in the regulatory environment, frequent new device introductions and evolving dental and surgical techniques. These changes could render our products uncompetitive or obsolete. The success of our existing and future products is dependent on the differentiation of our products from those of our competitors, the timely introduction of new products and the perceived benefit to the customer in terms of improved patient satisfaction and return on investment. The process of developing new medical devices is inherently complex and requires regulatory approvals or clearances that can be expensive, time consuming and uncertain. We cannot assure you that we will successfully identify new product opportunities, be financially or otherwise capable of completing the research and development required to bring new products to market in a timely manner or that products and technologies developed by others will not render our products obsolete.

### **The failure to attract and retain key personnel could adversely affect our business.**

Our future success depends in part on the continued service of certain key personnel, including our Chief Executive Officer, our Executive Vice President responsible for sales, our Chief Operating Officer, our Vice President of Research and Development and our Chief Financial Officer. We do not have employment



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agreements with any of our key employees, other than employment agreements with our Chief Executive Officer, our Executive Vice President responsible for sales and our Chief Operating Officer, each of which can be terminated at will by the executive or by us.

Our success will also depend in large part on our ability to continue to attract, retain and motivate qualified engineering and other highly skilled technical personnel. Competition for certain employees, particularly development engineers, is intense despite the effects of the economic slowdown. We may be unable to continue to attract and retain sufficient numbers of such highly skilled employees. Our inability to attract and retain additional key employees or the loss of one or more of our current key employees could adversely affect our business, financial condition and results of operations.

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

The sale of dental and medical devices involves the inherent risk of product liability claims against us. We currently maintain product liability insurance on a per occurrence basis with a limit of \$11 million per occurrence and \$12 million in the aggregate for all occurrences. The insurance is subject to various standard coverage exclusions, including damage to the product itself, losses from recall of our product and losses covered by other forms of insurance such as workers compensation. There is no assurance that we will be able to obtain such insurance in the future on terms acceptable to us, or at all. We do not know whether claims against us with respect to our products, if any, would be successfully defended or whether our insurance would be sufficient to cover liabilities resulting from such claims. Any claims successfully brought against us would cause our business to suffer.

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

Section 382 of the Internal Revenue Code of 1986 generally imposes an annual limitation on the amount of net operating loss carryforwards that may be used to offset taxable income when a corporation has undergone significant changes in its stock ownership. We have completed an analysis to determine the applicability of the annual limitations imposed by Section 382 caused by previous changes in our stock ownership and have determined that such limitations should not be significant. Based on our analysis, we believe that, as of December 31, 2002, approximately \$33.8 million of net operating loss carryforwards was available to us for federal income tax purposes. Of this amount, approximately \$28.1 million is available to offset 2003 federal taxable income or the taxable income generated in future years. Additional net operating loss carryforwards will become available at the rate of approximately \$1.0 million per year for the years 2004 through 2009. However, any future ownership changes qualifying under Section 382 may similarly affect our ability to use our remaining net operating loss carryforwards. If we lose our ability to use net operating loss carryforwards, our income will be subject to tax earlier than it would be if we were able to use net operating loss carryforwards, resulting in lower profits.

### **We are exposed to risks associated with the recent worldwide economic slowdown and related uncertainties.**

Concerns about decreased consumer and investor confidence, reduced corporate profits and capital spending, and recent international conflicts and terrorist and military activity have resulted in a downturn in the equity markets and a slowdown in economic conditions, both domestically and internationally, and have caused concern about the strength or longevity of an economic recovery. These unfavorable conditions could ultimately cause a slowdown in customer orders or cause customer order cancellations. In addition, recent political and social turmoil related to international conflicts and terrorist acts may put further pressure on economic conditions in the United States and abroad. Unstable political, social and economic conditions make it difficult for our customers, our suppliers and us to accurately forecast and plan future business activities. If such conditions continue or worsen, our business, financial condition and results of operations could suffer.



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### **We may not be able to secure additional financing to meet our future capital needs.**

We expect to expend significant capital to further develop our products, increase awareness of our laser systems and our brand names and to expand our operating and management infrastructure as we increase sales in the United States and abroad. We may use capital more rapidly than currently anticipated. Additionally, we may incur higher operating expenses and generate lower revenue than currently expected, and we may be required to depend on external financing to satisfy our operating and capital needs, including the repayment of our debt obligations. We may be unable to secure additional debt or equity financing on terms acceptable to us, or at all, at the time when we need such funding. If we do raise funds by issuing additional equity or convertible debt securities, the ownership percentages of existing stockholders would be reduced, and the securities that we issue may have rights, preferences or privileges senior to those of the holders of our common stock or may be issued at a discount to the market price of our common stock which would result in dilution to our existing stockholders. If we raise additional funds by issuing debt, we may be subject to debt covenants, such as the debt covenants under our secured credit facility, which could place limitations on our operations including our ability to declare and pay dividends. Our inability to raise additional funds on a timely basis would make it difficult for us to achieve our business objectives and would have a negative impact on our business, financial condition and results of operations.

### **We have adopted anti-takeover defenses that could delay or prevent an acquisition of our company and may affect the price of our common stock.**

Certain provisions of our certificate of incorporation and stockholder rights plan could make it difficult for any party to acquire us, even though an acquisition might be beneficial to our stockholders. These provisions could limit the price that investors might be willing to pay in the future for shares of our common stock.

In December 1998, we adopted a stockholder rights plan pursuant to which one preferred stock purchase right is distributed to our stockholders for each share of our common stock held by them. In connection with the stockholder rights plan, the Board of Directors may issue up to 500,000 shares of Series B Junior Participating Cumulative Preferred Stock (which may be increased by up to 500,000 more shares out of undesignated preferred stock described in the paragraph below that is available under our certificate of incorporation). If any party acquires 15% or more of our outstanding common stock or commences a tender offer to acquire 15% or more of our outstanding stock, the holders of these rights will be able to purchase the underlying junior participating preferred stock as a way to discourage, delay or prevent a change in control of our company. Following the acquisition of 15% or more of our stock by any person, if we are acquired by or merged with any other entity, holders of these rights will be able to purchase shares of common stock of the acquiring or surviving entity as a further means to discourage, delay or prevent a change in control of our company.

In addition, under our certificate of incorporation, the Board of Directors has the power to authorize the issuance of up to 500,000 shares of preferred stock that is currently undesignated, and to designate the price, rights, preferences, privileges and restrictions, including voting rights, of those shares without further vote or action by the stockholders. Accordingly, our Board of Directors may issue preferred stock with terms that could have preference over and adversely affect the rights of holders of our common stock.

The issuance of any preferred stock may:

delay, defer or prevent a change in control of BioLase;

discourage bids for the common stock at a premium over the market price of our common stock;

adversely affect the voting and other rights of the holders of our common stock; and

discourage acquisition proposals or tender offers for our shares.

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### **Risks Relating to Our Industry**

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

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

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

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

### **Risks Relating to This Offering**

#### **Our common stock price has been volatile, which could result in substantial losses for stockholders.**

Our common stock is currently traded on the Nasdaq National Market and the Nasdaq Europe Market. While our average daily trading volume for the 52-week period ended January 30, 2004 was approximately 686,121 shares, we have in the past experienced, and may in the future experience, more limited daily trading volume. The trading price of our common stock has been and may continue to be volatile. The closing sale prices of our common stock, as reported by the Nasdaq National Market, have ranged from \$6.24 to \$21.29 for the 52-week period ended January 30, 2004. The market for technology companies, in particular, has at various times experienced extreme volatility that often has been unrelated to the operating performance of particular companies. These broad market and industry fluctuations may significantly affect the

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trading price of our common stock, regardless of our actual operating performance. The trading price of our common stock could be affected by a number of factors, including, but not limited to, changes in expectations of our future performance,

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changes in estimates by securities analysts (or failure to meet such estimates), quarterly fluctuations in our sales and financial results and a variety of risk factors, including the ones described elsewhere in this prospectus. Periods of volatility in the market price of a company's securities sometimes result in securities class action litigation. If this were to happen to us, such litigation would be expensive and would divert management's attention. In addition, if we needed to raise equity funds under adverse conditions, it would be difficult to sell a significant amount of our stock without causing a significant decline in the trading price of our stock.

### **Our shares may be delisted if our stock price drops below \$5.00 per share or if we otherwise fail to comply with applicable listing requirements.**

We are required to maintain a stock price of approximately \$5.00 per share in order to maintain our listing on the Nasdaq National Market. If our stock price drops below approximately \$5.00 per share for an extended period of time or we are otherwise unable to satisfy the continued listing requirements of the Nasdaq National Market, our shares could be delisted from the Nasdaq National Market and the marketability, liquidity and price of our common stock would be adversely affected.

### **Investors will experience immediate and substantial dilution in net tangible book value per share of common stock purchased in this offering.**

Our net tangible book value at September 30, 2003, was approximately \$9.6 million, or approximately \$0.44 per share of common stock, without giving effect to any exercise of options then outstanding. Our net tangible book value per share has been determined by dividing the net tangible book value, which is total tangible assets less total liabilities, by the number of shares of common stock outstanding at September 30, 2003. After giving effect to the sale of 2,500,000 shares of our common stock by us in this offering at the public offering price of \$20.13 per share, which was the last reported sales price of our common stock on the Nasdaq National Market on February 3, 2004, and after deduction of the underwriting discount and estimated offering expenses, our net tangible book value immediately after the offering would have been approximately \$55.3 million or \$2.30 per share. Accordingly, the offering price of our common stock will be substantially higher than the net tangible book value per share of our existing capital stock. As a result, if you purchase common stock in this offering, you will incur immediate and substantial dilution of approximately \$17.83 in net tangible book value per share of common stock, based on the public offering price of \$20.13 per share. You also could experience additional dilution upon the exercise of outstanding stock options.

### **Our management will have broad discretion over the use of the capital resources made available by this offering and you may not agree with the way they are used.**

While we currently intend to use the net proceeds of this offering for general corporate purposes, working capital, potential repayment of debt, capital expenditures and potential future acquisitions or other investments, we may subsequently choose to use it for different purposes or not at all. The effect of the offering will be to increase capital resources available to our management, and our management may allocate these capital resources as it determines is necessary. You will be relying on the judgment of our management with regard to the use of the capital resources generated by this offering.

### **Our stock price may decline if additional shares are sold in the market after the offering.**

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Future sales of substantial amounts of shares of our common stock by our existing stockholders in the public market, or the perception that these sales could occur, may cause the market price of our common stock to decline. In addition, we may be required to issue additional shares upon exercise of previously granted options that are currently outstanding. Our directors and executive officers have agreed to enter into lock up agreements with the underwriters, in which they will agree to refrain from selling their shares for a period of 120 days after this offering. Increased sales of our common stock in the market after exercise of currently outstanding options or expiration of the lock-up agreements could exert significant downward pressure on our stock price. These sales also might make it more difficult for us to sell equity or equity-related securities in the future at a time and price we deem appropriate.



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**FORWARD-LOOKING STATEMENTS**

This prospectus contains forward-looking statements, including statements concerning the future of our industry, product and service development, business strategy, the possibility of future acquisitions, and continued acceptance and growth of our products. These statements may be identified by the use of forward-looking terminology such as may, will, expect, anticipate, estimate, continue or other similar words. These statements may discuss future expectations, contain projections of results of operations or of financial condition or include other forward-looking information. You should not place undue reliance on any forward-looking statements. When considering any forward-looking statements, you should keep in mind the risk factors and other cautionary statements in this prospectus. The risk factors noted above and other factors noted throughout this prospectus could cause our actual results to differ significantly from the results contained in any forward-looking statement. Except as required by Federal securities laws, we are under no obligation to update any forward-looking statements, whether as a result of new information, future events or otherwise.

In this prospectus, we rely on and refer to information, statistics and forecasts regarding the markets in which we compete. We obtained this information and these statistics and forecasts from various sources and publications that are not produced for the purposes of securities offerings or economic analysis. We have not independently verified the data and make no representation as to the accuracy of the data we have included.

**USE OF PROCEEDS**

The net proceeds to us from the sale of the 2,500,000 shares of common stock offered by us under this prospectus will be approximately \$45,778,765 based on an assumed public offering price of \$20.13 per share, which was the last reported sales price of our common stock on the Nasdaq National Market on February 3, 2004, and after deducting estimated underwriting discounts and commissions, and expenses payable by us. We will not receive any proceeds from the sale of 307,500 shares by the selling stockholder. Our net proceeds will be approximately \$53,704,990 if the underwriters fully exercise their over-allotment option to purchase 421,125 shares of our common stock from us.

We expect to use the net proceeds of the offering for general corporate purposes, working capital, potential repayment of debt, of which approximately \$1.8 million is currently outstanding, and capital expenditures, including expenditures for expansion of our production capabilities. A portion of the net proceeds of this offering may also be used to acquire or invest in complementary businesses or products or to obtain the right to use complementary technologies. Although we from time to time evaluate potential acquisitions of such businesses, products or technologies, and anticipate continuing to make these evaluations, we have no present understandings, commitments or agreements with respect to any acquisitions.

The amounts and timing of our actual expenditures will depend on numerous factors, including the status of our product development efforts, sales and marketing activities, technological advances, the amount of cash generated or used by our operations, and competition. We may find it necessary or advisable to use the net proceeds for other purposes, and we will have broad discretion in the application of the balance of the net proceeds. Pending the uses described above, we intend to invest the net proceeds in short-term, interest-bearing securities and debt instruments in compliance with our investment policy. We believe that our available cash, together with the net proceeds of this offering, will be sufficient to meet our capital requirements for at least the next twelve months.

**Table of Contents****PRICE RANGE OF COMMON STOCK**

Our common stock is listed on the Nasdaq National Market under the symbol BLTI. The following table sets forth the high and low closing sale prices of our common stock as reported by the Nasdaq SmallCap Market for the period from January 1, 2001 through May 21, 2002, and the Nasdaq National Market for the period from May 22, 2002 through February 3, 2004.

	<u>High</u>	<u>Low</u>
Fiscal Year Ended December 31, 2001		
First Quarter	\$ 3.03	\$ 1.53
Second Quarter	5.07	2.09
Third Quarter	6.59	3.47
Fourth Quarter	6.80	3.60
Fiscal Year Ended December 31, 2002		
First Quarter	\$ 6.58	\$ 5.11
Second Quarter	5.88	4.00
Third Quarter	5.14	3.80
Fourth Quarter	5.89	3.68
Fiscal Year Ended December 31, 2003		
First Quarter	\$ 8.29	\$ 5.30
Second Quarter	14.78	8.18
Third Quarter	14.93	10.50
Fourth Quarter	17.60	11.45
Fiscal Year Ending December 31, 2004		
First Quarter (through February 3, 2004)	\$ 21.29	\$ 18.36

On February 3, 2004, the last reported sale price of our common stock on the Nasdaq National Market was \$20.13 per share. As of February 3, 2004, there were approximately 280 holders of record of our common stock. Based on information provided by our transfer agent and registrar, we believe that there are approximately 12,005 beneficial owners of our common stock.

**DIVIDEND POLICY**

We have never declared or paid cash dividends on our common stock. We anticipate that we will retain earnings to support and to finance the growth and development of our business. As a result, we do not plan to pay any cash dividends in the near future. Our current policy is to retain all earnings to finance future growth. Any future determination relating to dividend policy will be made at the discretion of our Board of Directors and will depend on a number of factors, including our future earnings, capital requirements, financial condition, future prospects, and other factors as the Board of Directors may deem relevant.

**Table of Contents****CAPITALIZATION**

The following table sets forth our capitalization as of September 30, 2003 on an:

actual basis; and

as adjusted for the sale of 2,500,000 shares of our common stock offered by us under this prospectus at the public offering price of \$20.13 per share, the last reported sales price of our common stock on the Nasdaq National Market on February 3, 2004, after deducting underwriting discounts and commissions and offering expenses payable by us.

This capitalization table should be read in conjunction with our consolidated financial statements and related notes beginning on page F-1.

	<b>September 30, 2003</b>	
	<b>Actual</b>	<b>As Adjusted for Offering</b>
	<b>(in thousands)</b>	
Cash and cash equivalents	\$ 6,123	\$ 51,902
Line of credit	1,792	1,792
Short-term debt	1,145	1,145
<b>Total debt</b>	<b>2,937</b>	<b>2,937</b>
Stockholders' equity:		
Preferred stock, par value \$0.001; 1,000,000 shares authorized, no shares issued and outstanding		
Common stock, \$0.001 par value: 50,000,000 shares authorized actual and as adjusted; 21,544,571 shares issued and outstanding actual and 24,044,571 shares issued and outstanding as adjusted for offering <sup>(1)</sup>	22	25
Additional paid-in capital	56,816	102,592
Accumulated other comprehensive income	(130)	(130)
Accumulated deficit	(41,579)	(41,579)
<b>Total stockholders' equity</b>		