

BIOLASE TECHNOLOGY INC

Form 10-Q/A

November 10, 2004

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**UNITED STATES**  
**SECURITIES AND EXCHANGE COMMISSION**

Washington, D.C. 20549

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**FORM 10-Q/A**

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(Mark One)

**QUARTERLY REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934**

For the quarterly period ended September 30, 2004

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

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**BIOLASE TECHNOLOGY, INC.**

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(Exact Name of Registrant as Specified in Its Charter)

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**Delaware**  
(State or other jurisdiction of  
incorporation or organization)

**87-0442441**  
(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)

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

Indicate by check mark whether the registrant is an accelerated filer (as defined in Rule 12b-2 of the Exchange Act). Yes  No

Number of shares outstanding of the registrant's common stock, \$0.001 par value, as of October 29, 2004: 22,736,000.

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**EXPLANATORY NOTE**

This Form 10-Q/A is being filed to correct an erroneous reference to the outstanding number of shares as of October 29, 2004 on the cover page of the Form 10-Q filed on November 9, 2004. As of October 29, 2004, 22,736,000 shares were outstanding.

**BIOLASE TECHNOLOGY, INC.**

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**Table of Contents****PART I. FINANCIAL INFORMATION****ITEM 1. FINANCIAL STATEMENTS.****BIOLASE TECHNOLOGY, INC.****CONSOLIDATED BALANCE SHEETS (Unaudited)**

	<u>September 30, 2004</u>	<u>December 31, 2003</u>
<b>ASSETS</b>		
<b>Current assets:</b>		
Cash and cash equivalents	\$ 3,993,000	\$ 11,111,000
Short-term investments	32,175,000	
Accounts receivable, less allowance of \$65,000 and \$64,000 in 2004 and 2003, respectively	6,305,000	5,771,000
Inventories	7,132,000	3,752,000
Deferred tax asset	1,079,000	1,079,000
Prepaid expenses and other current assets	1,495,000	1,583,000
	<u>52,179,000</u>	<u>23,296,000</u>
<b>Total current assets</b>	<b>52,179,000</b>	<b>23,296,000</b>
Property, plant and equipment, net	2,169,000	1,973,000
Intangible assets, net	2,469,000	2,587,000
Goodwill	2,926,000	2,926,000
Deferred tax asset	12,583,000	12,678,000
Other assets	223,000	1,041,000
	<u>72,549,000</u>	<u>44,501,000</u>
<b>Total assets</b>	<b>\$ 72,549,000</b>	<b>\$ 44,501,000</b>
<b>LIABILITIES AND STOCKHOLDERS EQUITY</b>		
<b>Current liabilities:</b>		
Accounts payable	\$ 4,449,000	\$ 3,813,000
Accrued liabilities	5,104,000	5,152,000
Line of credit		1,792,000
Deferred revenue	1,819,000	932,000
Deferred gain on sale of building - current portion	63,000	63,000
Debt		888,000
	<u>11,435,000</u>	<u>12,640,000</u>
<b>Total current liabilities</b>	<b>11,435,000</b>	<b>12,640,000</b>
Deferred gain on sale of building	32,000	79,000
	<u>11,467,000</u>	<u>12,719,000</u>
<b>Total liabilities</b>	<b>11,467,000</b>	<b>12,719,000</b>
<b>Commitments and contingencies (Note 9)</b>		
<b>Stockholders equity:</b>		
Preferred stock, par value \$0.001, 1,000,000 shares authorized, no shares issued and outstanding		
Common stock, par value \$0.001, 50,000,000 shares authorized; 24,394,000 and 21,559,000 shares issued; 22,869,000 and 21,559,000 outstanding in 2004 and 2003, respectively	24,000	22,000

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Additional paid-in capital	101,796,000	59,188,000
Treasury stock (cost of 1,525,000 shares repurchased)	(13,435,000)	
Accumulated other comprehensive loss	(177,000)	(147,000)
Accumulated deficit	(27,126,000)	(27,281,000)
	<u>                    </u>	<u>                    </u>
<b>Total stockholders equity</b>	<b>61,082,000</b>	<b>31,782,000</b>
	<u>                    </u>	<u>                    </u>
<b>Total liabilities and stockholders equity</b>	<b>\$ 72,549,000</b>	<b>\$ 44,501,000</b>
	<u>                    </u>	<u>                    </u>

See accompanying notes to consolidated financial statements.

**Table of Contents****BIOLASE TECHNOLOGY, INC.****CONSOLIDATED STATEMENTS OF OPERATIONS (Unaudited)**

	Three Months Ended		Nine Months Ended	
	September 30,		September 30,	
	2004	2003	2004	2003
Revenue	\$ 12,038,000	\$ 13,453,000	\$ 41,426,000	\$ 33,042,000
Cost of sales	4,979,000	5,024,000	15,700,000	12,386,000
Gross profit	7,059,000	8,429,000	25,726,000	20,656,000
Operating expenses:				
Sales and marketing	5,931,000	3,729,000	17,534,000	10,962,000
General and administrative	2,387,000	1,527,000	5,838,000	3,407,000
Engineering and development	1,045,000	629,000	2,523,000	1,662,000
Total operating expenses	9,363,000	5,885,000	25,895,000	16,031,000
Income (loss) from operations	(2,304,000)	2,544,000	(169,000)	4,625,000
Non-operating income, net	272,000	23,000	423,000	135,000
Income (loss) before income taxes	(2,032,000)	2,567,000	254,000	4,760,000
Benefit (provision) for income taxes	799,000		(99,000)	
Net income (loss)	\$ (1,233,000)	\$ 2,567,000	\$ 155,000	\$ 4,760,000
Net income (loss) per share:				
Basic	\$ (0.05)	\$ 0.12	\$ 0.01	\$ 0.23
Diluted	\$ (0.05)	\$ 0.11	\$ 0.01	\$ 0.21
Shares used in the calculation of net income (loss) per share:				
Basic	23,409,000	21,535,000	23,380,000	20,796,000
Diluted	23,409,000	23,448,000	25,252,000	22,813,000

See accompanying notes to consolidated financial statements.

**Table of Contents****BIOLASE TECHNOLOGY, INC.****CONSOLIDATED STATEMENTS OF CASH FLOWS (Unaudited)**

	Nine Months Ended	
	September 30,	
	2004	2003
<b>Cash Flows From Operating Activities:</b>		
Net income	\$ 155,000	\$ 4,760,000
Adjustments to reconcile net income to net cash (used in) provided by operating activities:		
Depreciation and amortization	450,000	286,000
Gain on disposal of assets	(47,000)	(51,000)
Gain on foreign exchange contract		(22,000)
Provision for uncollectible accounts	1,000	(138,000)
Provision for inventory obsolescence	108,000	216,000
Deferred income tax	95,000	
Changes in assets and liabilities, net of acquisitions:		
Accounts receivable	(535,000)	(2,281,000)
Inventory	(3,488,000)	(835,000)
Prepaid expenses and other assets	906,000	689,000
Accounts payable and accrued liabilities	588,000	894,000
Deferred revenue	887,000	(2,671,000)
Net cash (used in) provided by operating activities	(880,000)	847,000
<b>Cash Flows From Investing Activities:</b>		
Purchase of investments	(32,181,000)	
Additions to property, plant and equipment	(492,000)	(286,000)
Business acquisition	(70,000)	(1,825,000)
Net cash used in investing activities	(32,743,000)	(2,111,000)
<b>Cash Flows From Financing Activities:</b>		
Borrowings on line of credit		1,792,000
Payment on line of credit	(1,792,000)	(1,792,000)
Payments on debt	(888,000)	
Proceeds from issuance of common stock, net of expenses	41,868,000	
Proceeds from exercise of stock options and warrants	977,000	3,513,000
Payment of dividends	(235,000)	
Repurchase of common stock	(13,435,000)	
Net cash provided by financing activities	26,495,000	3,513,000
Effect of exchange rate changes on cash	10,000	(66,000)
<b>Net (decrease) increase in cash and cash equivalents</b>	<b>(7,118,000)</b>	<b>2,183,000</b>
<b>Cash and cash equivalents at beginning of period</b>	<b>11,111,000</b>	<b>3,940,000</b>
<b>Cash and cash equivalents at end of period</b>	<b>\$ 3,993,000</b>	<b>\$ 6,123,000</b>

	<u>          </u>	<u>          </u>
<b>SUPPLEMENTAL CASH FLOW DISCLOSURE:</b>		
Cash paid during the period for interest	\$ 32,000	\$ 40,000
	<u>          </u>	<u>          </u>
Cash paid during the period for taxes	\$ 59,000	\$ 2,000
	<u>          </u>	<u>          </u>
<b>Noncash financing activities:</b>		
Business acquisition, net assets acquired	\$	\$ 5,846,000
	<u>          </u>	<u>          </u>

See accompanying notes to consolidated financial statements.



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**BIOLASE TECHNOLOGY, INC.**

**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Unaudited)**

**NOTE 1 BASIS OF PRESENTATION**

The unaudited consolidated financial statements include the accounts of BIOLASE Technology, Inc. and its consolidated subsidiaries and have been prepared on a basis consistent with the December 31, 2003 audited consolidated financial statements and include all material adjustments, consisting of normal recurring adjustments and the elimination of all material intercompany transactions and balances, necessary to fairly present the information set forth therein. These unaudited, interim, consolidated financial statements do not include all the footnotes, presentations and disclosures normally required by generally accepted accounting principles in the United States of America ( GAAP ) for complete financial statements. These financial statements should be read in conjunction with the audited consolidated financial statements for the year ended December 31, 2003 and notes thereto included in our Annual Report on Form 10-K filed with the Securities and Exchange Commission ( SEC ) on March 3, 2004.

The preparation of financial statements in conformity with GAAP requires us to make estimates and assumptions that affect the amounts reported in the financial statements and the accompanying notes. Due to the inherent uncertainty involved in making estimates, actual results reported in future periods may differ materially from those estimates.

The results of operations for the three and nine months ended September 30, 2004 are not necessarily indicative of the results to be expected for the full fiscal year.

**NOTE 2 SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES**

**Revenue Recognition**

We sell products domestically to customers through our direct sales force, and internationally through a direct sales force and through distributors. We recognize revenue in accordance with SEC Staff Accounting Bulletin No. 104 which requires that four basic criteria must be met before revenue can be recognized: (1) persuasive evidence of an arrangement exists; (2) delivery has occurred and title and the risks and rewards of ownership have been transferred to our customer or services have been rendered; (3) the price is fixed and determinable; and (4) collectibility is reasonably assured.

Through August 2003, we recognized revenue for products sold domestically when we received a purchase order, the price was fixed or determinable, and payment was received due to a clause in our purchase order that stated title transferred upon payment in full. We recognized revenue for products sold internationally through our direct sales force when we received a purchase order, the price was fixed or determinable, collectibility of the resulting receivable was probable and installation was completed, which was when the customer became obligated to pay. We recognized revenue for products sold through our distributors internationally when we received a purchase order, the price was fixed or

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determinable, collectibility of the resulting receivable was probable and the product was delivered. 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. Beginning in August 2003, we have been recording revenue for all sales upon shipment.

We adopted EITF 00-21, *Accounting for Revenue Arrangements with Multiple Deliverables*, on July 1, 2003, which requires us to evaluate whether the separate deliverables in our arrangements can be unbundled. We determined that the sales of our Waterlase® includes separate deliverables consisting of the product, disposables used with the Waterlase, installation and training. We apply the residual value method, which requires us to allocate the total arrangement consideration less the fair value of the undelivered elements to the delivered element. Included in deferred revenue as of September 30, 2004 and December 31, 2003 was \$1,275,000 and \$590,000, respectively, of deferred revenue attributable to advanced training courses and undelivered elements.

Extended warranty contracts, which are sold to our non-distributor customers, are recorded as revenue on a straight-line basis over the period of the contracts, which is one year. Included in deferred revenue as of September 30, 2004 and December 31, 2003 is \$544,000 and \$342,000, respectively, of deferred revenue for our extended warranty contracts.

Although all sales are final, we accept returns of products in certain, limited circumstances and record a provision for sales returns based on historical experience concurrent with the recognition of revenue. The sales returns allowance is recorded as a reduction of accounts receivable, revenue and cost of goods sold. As of September 30, 2004 and December 31, 2003, respectively, \$234,000 and \$327,000 was recorded as a reduction of accounts receivable.

We recognized revenue for royalties under licensing agreements for our patented technology. On a quarterly basis, we estimate and recognize the amount earned based on historical performance and current knowledge about the business operations of the licensees. Our estimates have been historically consistent with amounts recorded. Revenue from royalties was \$135,000 and \$407,000 for the three and nine months ended September 30, 2004, respectively, and \$20,000 for the three and nine months ended September 30, 2003.

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**Provision for Warranty Expense**

Products sold directly to end-users are under 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 estimate warranty costs at the time of product shipment based on historical experience. Estimated warranty expenses are recorded as an accrued liability, with a corresponding provision to cost of sales.

Changes in the product warranty accrual for the nine months ended September 30, 2004 and 2003 were as follows:

	<b>Nine Months Ended September 30,</b>	
	<b>2004</b>	<b>2003</b>
Beginning balance	\$ 727,000	\$ 625,000
Provision for estimated warranty cost	1,816,000	970,000
Warranty expenditures	(1,644,000)	(853,000)
Ending balance	<b>\$ 899,000</b>	<b>\$ 742,000</b>

**Stock-based compensation**

We measure compensation expense for stock-based employee compensation plans using the intrinsic value method in accordance with Accounting Principles Board Opinion No. 25. As the exercise price of all options granted under these plans was equal to the fair market price of the underlying common stock on the grant date, no stock-based employee compensation cost is recognized in the consolidated statements of income.

On December 31, 2002, the Financial Accounting Standards Board ( FASB ) issued Statement of Financial Accounting Standards ( SFAS ) No. 148, Accounting for Stock Based Compensation Transition and Disclosure, which amends SFAS No. 123. SFAS No. 148 requires more prominent and more frequent disclosures about the effects of stock-based compensation by presenting pro forma net income (loss), pro forma net income (loss) per share and other disclosures concerning our stock-based compensation plan.

The following table illustrates the effect on net income (loss) and net income (loss) per share if we had applied the fair value recognition provisions of SFAS No. 123 to options granted under our stock-based employee compensation plans.

<b>Three Months Ended September 30,</b>	<b>Nine Months Ended September 30,</b>
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	2004	2003	2004	2003
Reported net income (loss)	\$ (1,233,000)	\$ 2,567,000	\$ 155,000	\$ 4,760,000
Total stock-based employee compensation expense determined under the fair value based method for all awards, net of related tax effects	(520,000)	(418,000)	(1,452,000)	(1,079,000)
Pro-forma net income (loss)	\$ (1,753,000)	\$ 2,149,000	\$ (1,297,000)	\$ 3,681,000
Basic net income (loss) per share:				
Reported	\$ (0.05)	\$ 0.12	\$ 0.01	\$ 0.23
Pro-forma	\$ (0.07)	\$ 0.10	\$ (0.06)	\$ 0.18
Diluted net income (loss) per share:				
Reported	\$ (0.05)	\$ 0.11	\$ 0.01	\$ 0.21
Pro-forma	\$ (0.07)	\$ 0.09	\$ (0.06)	\$ 0.16

The pro forma amounts were estimated using the Black-Scholes option-pricing model with the following assumptions:

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2004	2003	2004	2003
Expected term (years)	3.50	3.50	3.50	3.50
Volatility	66%	80%	66%	80%
Annual dividend per share	0.02%	0.00%	0.02%	0.00%
Risk free interest rate	2.90%	2.30%	2.96%	2.02%
Weighted average fair value	\$ 4.23	\$ 6.41	\$ 5.91	\$ 5.67

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The Black-Scholes option valuation model was developed for use in estimating the fair value of traded options that have no vesting restrictions and are fully transferable. In addition, option valuation models require the input of highly subjective assumptions, including the expected stock price volatility. Our options have characteristics significantly different from those of traded options, and changes in the subjective input assumptions can materially affect the fair value estimate.

**Net Income (Loss) Per Share Basic and Diluted**

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

Stock options totaling 1,053,000 and 92,000 were not included in the diluted earnings (loss) per share amounts for the three and nine months ended September 30, 2004, respectively, as their effect would have been anti-dilutive.

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2004	2003	2004	2003
Weighted average shares outstanding basic	23,409,000	21,535,000	23,380,000	20,796,000
Dilutive effect of stock options and warrants		1,913,000	1,872,000	2,017,000
Weighted average shares outstanding diluted	23,409,000	23,448,000	25,252,000	22,813,000

**Inventories**

We value inventories at the lower of cost or market (determined by the first-in, first-out method). We periodically evaluate the carrying value of inventories and maintain an allowance for obsolescence to adjust the carrying value to the lower of cost or market, based on physical and technical functionality as well as other factors affecting the recoverability of the asset through future sales. The allowance for obsolescence is adjusted based on such evaluation, with a corresponding provision included in cost of sales. Components of inventories, net of an allowance for excess and obsolete items of \$354,000 and \$246,000 as of September 30, 2004 and December 31, 2003, respectively, were as follows:

	September 30,	December 31
	2004	2003
Materials	\$ 3,264,000	\$ 1,669,000
Work-in-process	991,000	894,000
Finished goods	2,877,000	1,189,000

Inventories	\$ 7,132,000	\$ 3,752,000
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**Property, Plant and Equipment**

We state property, plant and equipment at acquisition cost less accumulated depreciation and amortization. The cost of property, plant and equipment is depreciated using the straight-line method over the estimated useful lives of the respective assets, except for leasehold improvements, which are amortized over the lesser of the estimated useful lives of the respective assets or the related lease terms. Maintenance and repairs are expensed as incurred. Upon sale or disposition of assets, any gain or loss is included in the consolidated statements of income.

We continually monitor events and changes in circumstances, which could indicate that the carrying balances of property, plant and equipment may exceed the undiscounted expected future cash flows from those assets. If such a condition were to exist, we will recognize an impairment loss based on the excess of the carrying amount over the fair value of the assets.

Property, plant and equipment consisted of the following:

	September 30, 2004	December 31, 2003
Total cost	\$ 3,044,000	\$ 2,576,000
Accumulated depreciation	(875,000)	(603,000)
Net property, plant and equipment	\$ 2,169,000	\$ 1,973,000

**Table of Contents****Intangible Assets and Goodwill**

Costs incurred to establish and defend patents, trademarks and licenses and to acquire products and process technologies are capitalized and amortized over their estimated useful lives. Useful lives are based on our estimate of the period that the assets will generate revenue or otherwise productively support our business.

Goodwill and other intangible assets with indefinite lives are no longer subject to amortization but are tested for impairment annually or whenever events or changes in circumstances indicate that the assets might be impaired. We conducted our annual impairment test on June 30, 2004, and no impairment was noted. We will continue to test for impairment annually as of June 30th or when events occur that may trigger an impairment. Intangible assets with finite lives continue to be subject to amortization and any impairment is determined in accordance with SFAS No. 144 Accounting for the Impairment or Disposal of Long-Lived Assets. We believe no event has occurred that would trigger an impairment of these intangible assets. We recorded amortization expense for the three and nine months ended September 30, 2004, of \$62,000 and \$187,000, respectively, and \$58,000 and \$95,000, respectively, for the same periods of 2003.

The following table presents details of our intangible assets, related accumulated amortization, expected useful lives, and goodwill. Other intangible assets consist of acquired customer lists and a non-compete agreement.

	As of September 30, 2004			As of December 31, 2003		
	Gross	Accumulated Amortization	Net	Gross	Accumulated Amortization	Net
Patents (10 years)	\$ 1,284,000	\$ (248,000)	\$ 1,036,000	\$ 1,284,000	\$ (150,000)	\$ 1,134,000
Trademarks (6 years)	69,000	(68,000)	1,000	69,000	(60,000)	9,000
Trade names (Indefinite life)	979,000		979,000	979,000		979,000
Other (4 to 6 years)	593,000	(140,000)	453,000	523,000	(58,000)	465,000
<b>Total</b>	<b>\$ 2,925,000</b>	<b>\$ (456,000)</b>	<b>\$ 2,469,000</b>	<b>\$ 2,855,000</b>	<b>\$ (268,000)</b>	<b>\$ 2,587,000</b>
Goodwill (Indefinite life)	\$ 2,926,000	\$	\$ 2,926,000	\$ 2,926,000	\$	\$ 2,926,000

The following table presents the amortization of the intangible assets over the next five years.

	Remaining of					
	2004	2005	2006	2007	2008	2009
Patents (10 years)	\$ 33,000	\$ 130,000	\$ 121,000	\$ 117,000	\$ 117,000	\$ 117,000
Trademarks (6 years)	1,000					
Other (4 to 6 years)	27,000	109,000	109,000	109,000	100,000	
<b>Total</b>	<b>\$ 61,000</b>	<b>\$ 239,000</b>	<b>\$ 230,000</b>	<b>\$ 226,000</b>	<b>\$ 217,000</b>	<b>\$ 117,000</b>

**Non-operating income, net**

Non-operating income, net consists of interest income and expense and foreign currency gains and losses. The operations and cash flows of our German subsidiary, for which the euro is the functional currency, are translated to U.S. dollars at average exchange rates during the period and its assets and liabilities are translated using the end-of-period exchange rates. Translation gains or losses related to our Germany subsidiary are shown as a component of accumulated other comprehensive income (loss) in stockholders' equity. Foreign currency gains or losses relating to sales and purchase transactions which are denominated in other than the functional currency are shown as a net gain or loss in the consolidated statements of operations.

The following table presents details of non-operating income, net:

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2004	2003	2004	2003
Gain on foreign currency transactions	\$ 12,000	\$ 27,000	\$ 46,000	\$ 135,000
Gain on forward exchange contract				22,000
Gain on sale of marketable securities	95,000		95,000	
Interest income	177,000	8,000	315,000	21,000
Interest expense	(12,000)	(12,000)	(33,000)	(43,000)
	<u>\$ 272,000</u>	<u>\$ 23,000</u>	<u>\$ 423,000</u>	<u>\$ 135,000</u>

**New Accounting Pronouncements**

In December 2003, the FASB issued FASB Interpretation No. 46R, Consolidation of Variable Interest Entities ( FIN 46R ). FIN 46R requires the application of either FIN 46 or FIN 46R by Public Entities to all Special Purpose Entities ( SPE ) created prior to February 1, 2003 as of December 31, 2003 for calendar year-end companies. FIN 46R is applicable to all non-SPEs created prior to February 1, 2003 at the end of the first interim or annual period ending after March 15, 2004. For all entities created subsequent to January 31, 2003, Public Entities were required to apply the provisions of FIN 46R. The adoption of FIN 46R did not have an impact to our consolidated financial position, results of operations or cash flows.

In March 2004, the Financial Accounting Standards Board (FASB) approved the consensus reached on the Emerging Issues Task Force (EITF) Issue No. 03-1, The Meaning of Other-Than-Temporary Impairment and Its Application to Certain Investments. The Issue's objective is to provide guidance for identifying other-than-temporarily impaired investments. EITF 03-1 also provides new disclosure requirements for investments that are deemed to be temporarily impaired. The accounting provisions of EITF 03-1 are effective for all reporting periods beginning after June 15, 2004, while the disclosure requirements are effective for annual periods ending after June 15, 2004. In September 2004, the FASB issued a FASB Staff Position (FSP) EITF 03-1-1 that delays the effective date of the measurement and recognition guidance in EITF 03-1 on certain impaired debt securities until after further deliberations by the FASB. The adoption of this pronouncement did not impact the Company's results of operations or financial position.





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Our investments are comprised of U.S. government notes and bonds and have been categorized as available-for-sale. We have classified our available-for-sale securities as either short-term or long-term based on management's expectations of when the funds will be used. Unrealized gains (losses) on the investments are included in the other comprehensive income (loss) in stockholders' equity. As of September 30, 2004, we recorded an unrealized loss of \$6,000. The following summarizes our investments as of September 30, 2004:

	<u>Amortized Cost</u>	<u>Unrealized Gain/(Loss)</u>	<u>Fair Value</u>
Short-term			
U.S. Government bond	\$ 32,181,000	\$ (6,000)	\$ 32,175,000
<b>Total investments in marketable securities</b>	<b>\$ 32,181,000</b>	<b>\$ (6,000)</b>	<b>\$ 32,175,000</b>

**NOTE 4 ACCOUNTS PAYABLE AND ACCRUED LIABILITIES**

Accounts payable includes \$34,000 and \$223,000 of customer deposits at September 30, 2004 and December 31, 2003, respectively.

Components of accrued liabilities were as follows:

	<u>September 30, 2004</u>	<u>December 31, 2003</u>
Payroll and benefits	\$ 1,753,000	\$ 1,894,000
Warranty expense	899,000	727,000
Sales taxes	344,000	897,000
Amounts due to customers	333,000	205,000
Other	1,775,000	1,429,000
<b>Total accrued liabilities</b>	<b>\$ 5,104,000</b>	<b>\$ 5,152,000</b>

We reimburse our customers for their costs related to certain marketing programs. On our purchase orders we state the amount that we will reimburse the customers, which is recorded as a reduction of revenue when revenue of the purchase order is recognized. Amounts due to customers represent our obligation to reimburse our customers for these programs.

**NOTE 5 ACQUISITIONS**

On May 21, 2003, we acquired the American Dental Laser ( ADL ) assets from American Medical Technologies, Inc. ( AMT ) for approximately \$5.8 million, in order to leverage our marketing, strengthen our portfolio of intellectual property and expand our product lines. The assets acquired included inventory, dental laser patents, customer lists, brand names and other intellectual property, as well as laser products. No liabilities of AMT were assumed in the transaction. The consideration paid by us consisted of approximately \$1.8 million in cash, \$215,000 in transaction costs directly attributable to the acquisition and 308,000 shares of common stock with a fair value of approximately \$3.8 million. For purposes of computing the purchase price, the value of the common stock of \$12.38 per share was determined by taking the average closing price of our common stock as quoted on NASDAQ between May 19, 2003 and May 23, 2003. The total purchase price has been allocated to the acquired tangible and intangible assets of ADL based on the fair values with the balance allocated to goodwill. The acquisition was accounted for as a purchase under SFAS No. 141, Business Combinations. The amount allocated to the intangible assets was determined using estimates of discounted cash flow for the patents, trademarks, trade name and non-competition agreement; and the cost approach was used to estimate the value of the customer list. The total intangible assets acquired include approximately \$2.9 million for goodwill (which is deductible for tax purposes), \$979,000 for trade names and trademarks, \$1.2 million for patents, \$432,000 for a customer list and \$91,000 for a non-compete agreement. The patents are being amortized over ten years, the customer list over six years, and the non-compete agreement over four years. The trade names were determined to have indefinite lives.

The total consideration consisted of the following:

Cash	\$ 1,825,000
Stock consideration (307,500 shares at \$12.38 per share)	3,806,000
Acquisition costs	215,000
	<hr/>
Total	\$ 5,846,000
	<hr/>

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The components of the purchase price and allocation are as follows:

Tangible assets acquired	\$ 246,000
Identifiable intangible assets acquired	2,674,000
Goodwill	2,926,000
	<hr/>
Total	\$ 5,846,000
	<hr/>

The following unaudited data summarizes the results of operations for the period indicated as if the ADL acquisition had been completed as of the beginning of the period presented. The pro forma data gives effect to actual operating results prior to the acquisition, adjusted to include the pro forma effect of amortization of identifiable intangible assets:

	<b>Nine Months Ended September 30, 2003</b>
	<hr/>
Pro forma:	
Revenue	\$ 33,592,000
Net income	\$ 4,489,000
Net income per share:	
Basic	\$ 0.22
Diluted	\$ 0.20

In January 2004, we acquired PAClive, a continuing education program for dentists, from Discus Dental, Inc. for \$70,000. The assets acquired were trademarks and a customer list along with minor equipment and supplies. We have recorded this acquisition as an increase in intangible assets with a useful life of five years.

**NOTE 6 STOCKHOLDERS EQUITY**

In March 2004, as a result of the completion of a public underwritten offering, we issued 2,500,000 shares of common stock at an offering price of \$18.50 per share. Gross proceeds from the offering were \$46,250,000, before deducting underwriting discount of \$2,875,000. In connection with the offering, we incurred direct expenses of \$1,507,000, which had been included in other assets and were reclassified as a reduction of additional paid-in capital after the closing of the offering.

Shares issued as a result of stock option exercises for the three and nine months ended September 30, 2004 totaled 90,000 and 335,000, respectively, which resulted in proceeds of approximately \$284,000 and \$977,000, respectively.

On July 19, 2004, we announced that our Board of Directors authorized a 1.25 million share repurchase program. Pursuant to the authorization, we may purchase shares from time to time in the open market or through privately negotiated transactions over the next 12 months. On August 9, 2004, we announced that our Board of Directors authorized the repurchase of an additional 750,000 shares of our common stock, increasing

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the total shares repurchase program to 2.0 million shares of our common stock. These additional shares may be purchased from time to time in the open market or through privately negotiated transactions over the next 12 months. As of September 30, 2004, we repurchased approximately 1.5 million shares at an average price of \$8.81 per share.

On July 27, 2004, we announced a dividend policy to pay a regular cash dividend of \$0.01 per share every other month payable to the stockholders of record at the time when declared by the Board of Directors. The dividend policy will remain in place for an indefinite period of time. The first dividend totalling \$235,000 was declared and paid on August 30, 2004 to stockholders of record on August 16, 2004.

### NOTE 7 COMPREHENSIVE INCOME (LOSS)

Components of comprehensive income were as follows:

	Three Months Ended		Nine Months Ended	
	September 30, 2004	September 30, 2003	September 30, 2004	September 30, 2003
Net income (loss)	\$ (1,233,000)	\$ 2,567,000	\$ 155,000	\$ 4,760,000
Other comprehensive income (loss) items:				
Unrealized gain (loss) on marketable securities	(6,000)		(6,000)	
Foreign currency translation adjustments	(119,000)	4,000	(24,000)	(73,000)
<b>Comprehensive income (loss)</b>	<b>\$ (1,358,000)</b>	<b>\$ 2,571,000</b>	<b>\$ 125,000</b>	<b>\$ 4,687,000</b>

**Table of Contents****NOTE 8 INCOME TAXES**

As of December 31, 2003, the valuation reserves on our deferred tax assets were reduced and we recognized an income tax benefit and established net deferred tax assets of \$13.8 million. We have recorded a benefit for income tax of \$799,000 and a provision for income tax expense of \$99,000 for the three and nine months ended September 30, 2004, respectively, which adjusted our deferred tax assets. Income taxes will not be payable, subject to any alternative minimum tax, until we have utilized our net operating loss carryforwards, which were approximately \$32.5 million as of December 31, 2003. For the three and nine months ended September 30, 2003, we realized our operating loss carryforwards to reduce our income tax liability to zero.

**NOTE 9 COMMITMENTS AND CONTINGENCIES***Leases*

We lease our manufacturing, administration and headquarter facilities in San Clemente, California under operating lease arrangements. Future minimum rental commitments under operating leases as of September 30, 2004 for each of the years ending December 31 are as follows:

Remainder of 2004	\$ 106,000
2005	421,000
2006	90,000
	<hr/>
Total	\$ 617,000
	<hr/>

*Litigation*

We are currently involved in a patent lawsuit with Diodem, LLC, a California limited liability company. The claims in this lawsuit were originally part of two separate lawsuits 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. In this lawsuit we are seeking a judicial declaration against Diodem that technology we use in laser systems does not infringe four patents owned by Diodem. 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 Systems, Inc. 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. ( AMT ), Lumemis 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 AMT. We acquired the licensed patents and related license agreements in our acquisition of the American Dental Laser assets from AMT. In July 2003, AMT was dismissed from the lawsuit without prejudice; however, we and other defendants remain in the suit.

Diodem's lawsuit against us alleges that our Waterlase product infringes upon the four patents that Diodem acquired from Premier Laser. Diodem also alleges that the products sold by OpusDent and Hoya ConBio also infringe upon the patents. Diodem's infringement suit seeks treble damages, a preliminary and permanent injunction from further alleged infringement, attorneys' fees and other unspecified damages. If Diodem successfully asserts an infringement claim against us, our operations may be significantly impacted, especially to the extent that it affects our right to use the technology incorporated in our Waterlase system, which accounted for approximately 81% of our revenue for the first nine months of 2004 and approximately 83% of our revenue for the year ended December 31, 2003. If Diodem successfully asserts an infringement claim against Hoya ConBio and OpusDent, it could reduce or eliminate royalties we might receive under licenses to those products, which have totaled approximately \$627,000 since the acquisition of the American Dental Laser assets in May 2003. The litigation is in the late stages of pre-trial preparation. No trial date has been set. A trial date in 2005 is likely. This combined lawsuit may proceed for an extended period of time. Although the outcome of these actions cannot be determined with any 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. No amounts have been recorded in the consolidated financial statements relating to the outcome of this matter.

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We and certain of our officers have been recently named as defendants in several putative shareholder class action lawsuits filed in the United States District Court for the Central District of California. The complaints purport to seek unspecified damages on behalf of an alleged class of persons who purchased our common stock between October 29, 2003 and July 16, 2004. The complaints allege that we and our officers violated federal securities laws by failing to disclose material information about the demand for our products and the fact that the Company would not achieve the alleged forecasted growth. The claimed misrepresentations include certain statements in our press releases and the registration statement we filed in connection with our public offering of stock in March 2004. In addition, three stockholders have filed derivative actions in the state court in California seeking recovery on behalf of Biolase, alleging, among other things, breach of fiduciary duties by those individual defendants and by the members of the Biolase board of directors.

We have not yet formally responded to any of the actions and no discovery has been conducted by any of the parties. However, based on the facts presently known, our management believes we have meritorious defenses to these actions and intend to vigorously defend them. As of September 30, 2004, no amounts have been recorded in the accompanying financial statements for these matters since management believes that it is not probable the Company has incurred a loss contingency.

From time to time, we are involved in other legal proceedings incidental to our business, but at this time we are not party to any such litigation that is material to our business.

### ***Securities and Exchange Commission Inquiry***

Following the restatement of our financial statements in September 2003, we received, in late October 2003, and subsequently, informal requests from the SEC to voluntarily provide information relating to the restatement. We have provided information to the SEC and, when we receive any additional requests, we would further cooperate in responding. In accordance with its normal practice, the SEC has not advised us when its inquiry might be concluded.

### **NOTE 10 CONCENTRATIONS**

Many of our customers finance their purchases through third-party leasing companies. In these transactions, the leasing company is considered the purchaser. Revenues generated from dentists who financed their purchase through one leasing company were approximately 33% and 32%, respectively, for the three and nine months ended September 30, 2004, and 30% and 32%, respectively, for the same periods of 2003. Other than these transactions, no distributor or customer accounted for more than 10% of consolidated sales for the three months ended September 30, 2004 and September 30, 2003.

Financial instruments that subject us to concentrations of credit risk consist principally of cash and cash equivalents and accounts receivable. We maintain our cash accounts with established commercial banks. Such cash deposits periodically exceed the Federal Deposit Insurance Corporation insured limit of \$100,000 for each account.

Accounts receivable concentrations have resulted from sales activity to the one leasing company mentioned above. Accounts receivable for the one leasing company totaled \$608,000 or 9.6% of accounts receivable at September 30, 2004 and \$742,000 or 12.9% of accounts receivable at December 31, 2003. No other single customer accounted for more than 10% of our accounts receivable at September 30, 2004 or December 31, 2003.



**NOTE 11 SEGMENT INFORMATION**

We currently operate in a single business segment. Revenue from the sale of Waterlase, our principal product, represented 81% and 81%, respectively, of total revenue for the three and nine months ended September 30, 2004 and 80% and 80%, respectively, for the same periods of 2003. Revenue by geographic location based on the location of customers were as follows:

	<b>Three Months Ended</b>		<b>Nine Months Ended</b>	
	<b>September 30,</b>	<b>September 30,</b>	<b>September 30,</b>	<b>September 30,</b>
	<b>2004</b>	<b>2003</b>	<b>2004</b>	<b>2003</b>
Domestic	\$ 10,059,000	\$ 10,722,000	\$ 33,094,000	\$ 25,959,000
International	1,979,000	2,731,000	8,332,000	7,083,000
	<b>\$ 12,038,000</b>	<b>\$ 13,453,000</b>	<b>\$ 41,426,000</b>	<b>\$ 33,042,000</b>

**NOTE 12 SUBSEQUENT EVENTS**

In November of 2004, we were notified by our bank that we were in default under our covenants for our \$10.0 million line of credit as of September 30, 2004 due to our operating loss for the three months ended September 30, 2004. In November of 2004, we obtained a waiver to this covenant as of September 30, 2004. There were no borrowings on the line of credit as of September 30, 2004. In November of 2004, we borrowed \$3.5 million under this line of credit.

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**ITEM 2. MANAGEMENT'S DISCUSSION AND ANALYSIS OF FINANCIAL CONDITION AND RESULTS OF OPERATIONS.**

**Cautionary Statement With Respect To Forward-looking Information**

You should read the following discussion and analysis in conjunction with our Unaudited Consolidated Financial Statements and related Notes thereto contained elsewhere in this quarterly report on Form 10-Q (the "Report"). 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 this Report and in our other reports filed with the Securities and Exchange Commission, including our Annual Report on Form 10-K for the year ended December 31, 2003, and other filings that discuss our business in greater detail. This Report contains forward-looking statements that can often be identified by words such as anticipates, expects, intends, plans, believes, seeks, estimates, will, should, would, potential, continue, and variations of these words or similar expressions. In addition, any statements that refer to expectations, projections or other characterizations of future events or circumstances, including any underlying assumptions, are forward-looking statements. Examples of these forward-looking statements include, but are not limited to, statements concerning our expected sales and operating results, market acceptance of our product, our ability to protect our intellectual property and succeed in our current litigation, our ability to attract and retain key personnel, the potential of our market and our position in it, our manufacturing capacity, estimates concerning asset valuation and loss contingencies and expectations concerning future costs and cash flow, and our ability to successfully finance our business. Our actual results could differ materially from those anticipated in the forward looking statements based on a variety of factors, including, among others: market acceptance of new products, continued acceptance of existing products, the timing of projects due to the variability in size, scope and duration of projects, clinical study results which lead to reductions or cancellations of projects, obtaining regulatory approvals for new products, regulatory delays, the availability of competitive products, risks associated with competition and competitive pricing pressures and economic conditions generally, any of which may cause revenues and income to fall short of anticipated levels, and other factors, including estimates made by management with respect to our critical accounting policies, adverse results in litigation, general economic conditions and regulatory developments not within our control and other risks detailed from time to time in the reports filed by us with the Securities and Exchange Commission, including our annual report on Form 10-K. These forward-looking statements are based on our current expectations, estimates and projections about our industry, and reflect our beliefs and certain assumptions made by us. These statements speak only as of the date of this Report and are based upon the information available to us at this time. Such information is subject to change, and we will not necessarily inform you of such changes. These forward-looking statements are not guarantees of future performance and are subject to risks, uncertainties and assumptions that are difficult to predict. Therefore, our actual results could differ materially and adversely from those expressed in any forward-looking statements as a result of various factors, some of which are set forth in "Risk Factors," below. We undertake no obligation to revise or update publicly any forward-looking statements for any reason.

**Critical Accounting Estimates**

The preparation of financial statements and related disclosures in conformity with accounting principles generally accepted in the United States of America requires management to make judgments, assumptions and estimates that affect the amounts reported. See the discussion of significant accounting policies in our Annual Report on Form 10-K for the year ended December 31, 2003 as well as the Summary of Significant Accounting Policies in Note 2 to the Consolidated Financial Statements included in this report. For the quarter ended September 30, 2004, there were no unusual uncertainties of a material nature involved in the application of these principles nor any unusual, material variation in estimates related to these principles.

**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. We believe our systems

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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 3,000 Waterlase® systems and approximately 4,100 laser systems in total in over 25 countries.

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We have the following product lines: (i) Waterlase system; (ii) LaserSmile system; (iii) American Dental Laser products, including the Diolase, the new DioLase Plus and Pulsemaster systems, and (iv) related accessories and disposables for use with our laser systems. Our principal 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. The Diolase, DioLase Plus 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.

In January 2004, we acquired PAClive from Discus Dental, Inc. for \$70,000. Assets acquired include trademarks and a customer list, which were recorded as an increase to intangible assets. PAClive is one of the leading live-patient, hands-on continuing dental education programs in the United States. The addition of PAClive is part of our commitment to education as a means of demonstrating the benefits of lasers in dentistry.

In February 2004, we received clearance from the Food and Drug Administration for several new bone, periodontal and soft tissue procedures: osteoplasty and osseous recontouring (removal of bone to correct osseous defects and create physiologic osseous contours); ostectomy (resection of bone to restore bony architecture, resection of bone for grafting, etc); osseous crown lengthening; flap preparation incision of soft tissue to prepare a flap and expose unerupted teeth (hard and soft tissue impactions); full thickness flap; partial thickness flap; split thickness flap; removal of granulation tissue from bony defects; and laser soft tissue curettage of the post-extraction tooth sockets and the periapical area during apical surgery. Additionally, we received clearance for our Waterlase system to perform soft tissue curettage. Our LaserSmile diode laser was previously cleared for laser soft tissue curettage in October 2003.

In March 2004, we leased additional office and manufacturing space next door to our headquarters in San Clemente, California. This facility gives us added capacity in manufacturing, customer support, and marketing to support our continued growth. This move brings our leased facilities in the U.S. to approximately 40,000 sq. ft. in addition to 20,000 sq. ft. of space we own in Germany.

In May of 2004, we introduced the DioLase Plus, our first dental laser product that results from the integration of the American Dental Laser value platform we acquired in May of 2003 with our own technology. The DioLase Plus is being marketed as an entry level laser with applications in cosmetic, soft tissue and periodontal dentistry.

For the nine months ended September 30, 2004 we saw a continuation of the increase in demand that we have been experiencing although a slowdown in demand accrued in the third quarter of 2004. Net sales increased for the nine months ended September 30, 2004 by 25.4% compared to the nine months ended September 30, 2003. For the third quarter ended September 30, 2004 we experienced a 10.5% decrease in net sales compared to the same period of 2003. Our priority continues to be on market penetration, which we believe is crucial given the large size of the potential market (over 500,000 practicing dentists in the developed countries of the world), the low penetration of our laser technology in dentistry, which we believe to be less than 3% of dentists in the United States and other developed countries. Based on the sales results for the first nine months, we now expect sales for 2004 to be in the range of approximately \$58.0 million to \$61.0 million, compared to \$49.1 million in 2003.

Operating income for the nine months ended September 30, 2004 was \$0.2 million compared to \$4.6 million for the same period of 2003. Operating loss for the three months ended September 30, 2004 was \$2.3 million compared to operating income of \$2.5 million for the same period of 2003. The decrease in operating income in 2004 related to higher fixed operating expenses in all functional areas of our business as a result of our overall growth during the past twelve months. Additionally, we have experienced higher operating expenses due to increases in marketing promotions and general and administrative expenses related to higher legal and professional fees, insurance costs and stockholder communication expenses associated with our proxy and annual report distribution. Legal fees include costs related to the Diodem patent litigation and the putative shareholder class action lawsuits. The legal costs of these lawsuits have affected and are expected to continue to affect

our operating income this year.

Net income for the nine months ended September 30, 2004 was \$ 0.2 million with earnings per diluted share of \$0.01 compared to net income of \$4.8 million with earnings per diluted share of \$0.21 for the same period of 2003. Net income included a provision for income tax expense of \$0.1 million for the nine months ended September 30, 2004 with no income tax provision for the same period of 2003. Income taxes will not be payable, subject to alternative minimum tax, until we have utilized our net operating loss carryforwards, which were approximately \$32.5 million as of December 31, 2003. Net loss for the three months ended September 30, 2004 was \$1.2 million with net loss per diluted share of \$0.05 compared to net income of \$2.6 million with net earnings per diluted share of \$0.11 for the same period of 2003.

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The completion of our public offering of 2.5 million shares of common stock in March of 2004 resulted in net proceeds of approximately \$41.9 million and strengthened our financial position and liquidity. We intend to use the majority of this capital over the next several years to support the continued growth of the Company. In July 2004, our Board of Directors approved a stock repurchase program which we believe is a use of capital that can enhance stockholder value. Therefore, in July of 2004, we announced a stock repurchase program to acquire up to 1.25 million shares over the next 12 months. Also in August of 2004, the Board of Directors authorized the repurchase of an additional 750,000 shares of our common stock, increasing the total share repurchase program to 2.0 million shares of our common stock. These shares may be purchased from time to time on the open market or through privately negotiated transactions over the next 12 months. As of September 30, 2004 we have repurchased approximately 1.5 million shares at an average price of \$8.81 per share. In July of 2004, the Board of Directors established a dividend policy that will remain in effect for an indefinite period of time and pays a regular cash dividend of \$0.01 per share every other month when declared by the Board of Directors. The first dividend totalling \$235,000 was declared and paid August 30, 2004 to stockholders of record on August 16, 2004 and a second declared dividend totalling \$229,000 was paid October 27, 2004 to stockholders of record on October 13, 2004.

**Results of Operations**

The following table sets forth comparative statements of operations data (\$000):

	Three Months Ended		Percent of Sales			
	September 30, 2004	September 30, 2003	Increase (Decrease)	Percent Increase (Decrease)	Three Months Ended September 30, 2004	Three Months Ended September 30, 2003
Revenue	\$ 12,038	\$ 13,453	\$ (1,415)	(10.5)%	100.0%	100.0%
Cost of sales	4,979	5,024	(45)	(0.9)	41.4	37.3
Gross profit	7,059	8,429	(1,370)	(16.3)	58.6	62.7
Operating expenses:						
Sales and marketing	5,931	3,729	2,202	59.1	49.3	27.7
General and administrative	2,387	1,527	860	56.3	19.8	11.4
Engineering and development	1,045	629	416	66.1	8.7	4.7
Total operating expenses	9,363	5,885	3,478	59.1	77.8	43.8
Income (loss) from operations	(2,304)	2,544	(4,848)	(190.6)	(19.2)	18.9
Non-operating income	272	23	249	1,082.6	2.3	0.2
Income (loss) before tax	(2,032)	2,567	(4,599)	(179.2)	(16.9)	19.1
Benefit for income tax	799		799	100.0	6.6	
Net income (loss)	\$ (1,233)	\$ 2,567	\$ (3,800)	(148.0)	(10.3)	19.1
	Nine	Nine			Percent of Sales	

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	Months Ended September 30, 2004	Months Ended September 30, 2003	Increase (Decrease)	Percent Increase (Decrease)	Nine Months Ended September 30, 2004	Nine Months Ended September 30, 2003
Revenues	\$ 41,426	\$ 33,042	\$ 8,384	25.4%	100.0%	100.0%
Cost of sales	15,700	12,386	3,314	26.8	37.9	37.5
Gross profit	25,726	20,656	5,070	24.5	62.1	62.5
Operating expenses:						
Sales and marketing	17,534	10,962	6,572	60.0	42.3	33.2
General and administrative	5,838	3,407	2,431	71.4	14.1	10.3
Engineering and development	2,523	1,662	861	51.8	6.1	5.0
Total operating expenses	25,895	16,031	9,864	61.5	62.5	48.5
Income (loss) from operations	(169)	4,625	(4,794)	(103.7)	(0.4)	14.0
Non-operating income	423	135	288	213.3	1.0	0.4
Income before tax	254	4,760	(4,506)	(94.7)	0.6	14.4
Provision for income tax	(99)		(99)	100.0	(0.2)	
Net income	\$ 155	\$ 4,760	\$ (4,605)	(96.7)	0.4	14.4

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Revenue increased for the nine months ended September 30, 2004 by 25.4% compared to the nine months ended September 30, 2003. This increase reflects the continued demand for our products, and our expanded marketing efforts to generate increased market penetration. For the third quarter ended September 30, 2004 we experienced a 10.5% decrease in net sales compared to the same period of 2003. We believe this decrease was attributed in part to two factors. The first factor was the pending introduction in the fourth quarter of our new advanced Waterlase MD that may have caused potential customers to postpone the purchase of a laser system. The second factor was the series of devastating hurricanes that struck the Gulf region of the United States resulting in the cancellation of the New Orleans Dental Conference and other scheduled sales events that are important vehicles for securing new orders. We expect increased net sales in the fourth quarter of 2004 from the third quarter as a result of generally stronger seasonal sales in the fourth quarter.

Revenue generated outside of the United States were approximately 16% and 20% for the three and nine months ended September 30, 2004, respectively, compared to approximately 20% and 21% for the same periods of 2003. We continue to expand our international marketing efforts. During the nine months ended September 30, 2004, we hosted World Clinical Laser Institute symposiums and seminars in the Asia Pacific region, Mexico, Japan and India. We expect international sales to represent similar percentages of total revenue for the fourth quarter of 2004.

Product mix also stayed relatively constant. Revenue from Waterlase units, our principal product, represented 81% or \$33.7 million of total revenue for the first nine months of 2004 compared to 80% or \$26.4 million in the same period of 2003. We expect that our Waterlase system and our new Waterlase MD will continue to account for approximately 80% of total revenue for the fourth quarter of 2004.

Significant estimates affecting revenues include the reserve for sales returns. The reserve is based on historical experience from 1998 through the present. For the nine months ended September 30, 2004, the reserve decreased slightly from \$327,000 at December 31, 2003 to \$234,000 at September 30, 2004.

Gross margins decreased to 58.6% and 62.1% for the three and nine months ended September 30, 2004, respectively, compared to 62.7% and 62.5% for the same periods of 2003, respectively. The lower gross margins were the result of a lower level of revenue in the third quarter of 2004 to absorb our fixed manufacturing costs, together with lower margin revenue related to after-sale services primarily for advanced training. Our manufacturing cost structure, except for the cost of materials, is relatively fixed and increased slightly during the third quarter with the addition of a new manufacturing facility brought online in the second quarter of 2004. Significant estimates affecting gross margin include the allowance for inventory obsolescence and accrued warranty expense. During the first nine months of 2004, the allowance for inventory obsolescence increased from \$246,000 at December 31, 2003 to \$354,000. The provision for warranty expense was \$1.8 million in the first nine months of 2004 compared to \$970,000 for the first nine months of 2003. Warranty expenses are variable in nature and will fluctuate from time to time due to the number of units under warranty, product reliability and life cycle.

Sales and marketing expense for the three and nine months ended September 30, 2004 was \$5.9 million and \$17.5 million, respectively, compared to \$3.7 million and \$11.0 million, respectively, for the same periods of 2003. Sales and marketing expense as a percentage of sales for 2004 was 49.3% in the third quarter and 42.3% for the first nine months of 2004. The increase in sales and marketing expenses compared to the same periods of the prior year reflect our continued marketing efforts to expand consumer awareness to the benefits of our products and to develop new marketing territories, particularly in areas outside of the United States. We expect sales and marketing expense for the fourth quarter of 2004, as a percentage of revenues, to be lower than the third quarter of 2004.

Although we believe we are the market leader in laser dentistry, we must invest not only in traditional marketing but also in education to accomplish the broad adoption of lasers in dentistry that we seek. This is the reason we formed the World Clinical Laser Institute (WCLI) and why we continually seek to form alliances with teaching programs in the U.S. and globally. The WCLI is now the world's largest teaching institute for laser dentistry. In the first quarter of 2004, the WCLI held its largest ever conference with over 650 participants and over the course of 2004, through an additional six multi-day conferences, expects to reach a participation level of 1,700 of existing and potential customers as



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well as researchers and academicians. Although we charge a nominal tuition to offset the cost of these conferences, the increasing number and size of WCLI conferences represents a substantial share of our total sales and marketing expense.

In 2003, we began piloting consumer marketing campaigns in California and other selected markets in the U.S. These pilots often involve a sharing of cost on the part of participating customers. Based on the positive feedback we have received, we intend to continue these pilots and may increase these efforts depending on the results achieved.

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General and administrative expenses were \$2.4 million and \$5.8 million for the three and nine months ended September 30, 2004, respectively, compared to \$1.5 million and \$3.4 million for the same periods of 2003, respectively. In general, we are experiencing a need to increase human resources and organizational infrastructure necessary to support our growth. We expect that we will be able to leverage off of the fixed nature of these costs. In addition, specific increases in general and administrative expenses are primarily related to legal and professional fees, insurance costs, and stockholder communication expenses related to the proxy and annual report. For the three and nine months ended September 30, 2004, legal fees increased by approximately \$595,000 and \$1.2 million, respectively, compared to the same periods of 2003. The increase in legal fees was primarily related to the Diodem lawsuit and the putative shareholder class action lawsuits. Administrative wages, insurance, consulting fees related to our Section 404 Sarbanes-Oxley internal controls project and investor relations costs increased approximately \$286,000 and \$1.2 million, respectively, for the three and nine months ended September 30, 2004 compared to the same periods of 2003. We expect costs in these categories for the fourth quarter of 2004 to be slightly higher than the third quarter of 2004.

Engineering and development expenses include engineering personnel salaries, prototype supplies and contract services. Engineering and development expense for the three and nine months ended September 30, 2004 were \$1.0 million and \$2.5 million, respectively, compared to \$629,000 and \$1.7 million for the same periods of 2004, respectively. The increases are due to increased levels of activity in product development related to our new Waterlase MD product and general overall growth. We expect our spending in product development for the fourth quarter of 2004 to be similar to costs incurred in the third quarter of 2004 and will average between 5% to 6% of total net sales for 2004.

We experienced a non-operating gain of \$272,000 and \$423,000, respectively, for the three and nine months ended September 30, 2004 compared to a non-operating gain of \$23,000 and \$135,000, respectively, for the same periods of 2003, respectively. The increase is primarily due to higher interest income related to the increase in cash, cash equivalents and investments in marketable securities as a result of the \$41.9 million in net proceeds received from our public offering in the first quarter of 2004. Included in the non-operating gain were gains on foreign currency transactions of \$12,000 and \$46,000, respectively, for the three and nine months ended September 30, 2004 compared to \$27,000 and \$135,000, respectively, for the same periods of 2003. Due to the relatively low volume of transactions denominated in currencies other than the U.S. dollar, we have not engaged in hedging transactions to offset foreign currency fluctuations. Therefore, we are at risk for changes in the value of the dollar relative to the value of the euro, which is the only non-U.S. dollar denominated currency in which we have transacted business. The non-operating gain varies from quarter to quarter due to certain economic conditions such as interest rates and foreign currency exchange rates. Although we do not expect significant changes that may affect the non-operating gain, we do anticipate some variation in the gain during the fourth quarter of 2004, primarily due to lower interest income.

For the year ended December 31, 2003, we recorded an income tax benefit of \$11.4 million as a result of reducing the valuation allowance on deferred tax assets which was included in our consolidated statements of income and an income tax benefit for the exercise of stock options of \$2.3 million which was recorded to additional paid-in capital. The deferred tax assets consist primarily of net operating loss carryforwards. They had been fully reserved in prior periods due to the uncertainty of whether we would generate sufficient taxable income to realize the benefits of the assets. Based upon the level of our historical taxable income and the projection for future taxable income, we concluded that it was more likely than not that we would realize the benefits of these assets. We recorded a benefit for income tax of \$799,000 for the three months ended September 30, 2004 and a provision for income tax expense of \$99,000 for the nine months ended September 30, 2004 with a corresponding reduction of deferred tax assets. There was no provision for income tax expense in the three and nine months ended September 30, 2003 due to the uncertainty at that time of whether we would generate sufficient taxable income to realize the benefits of the deferred tax assets. Although we record a provision for income taxes, income taxes will not be payable, subject to any alternative minimum tax, until we have utilized our net operating loss carryforwards, which were approximately \$32.5 million at December 31, 2003.

**LIQUIDITY AND CAPITAL RESOURCES**

At September 30, 2004, we had \$40.7 million in net working capital, an increase of \$30.0 million from \$10.7 million at December 31, 2003. Our principal source of liquidity at September 30, 2004 consisted of our cash balance of \$4.0 million and investments in marketable securities of \$32.2 million. For the nine months ended September 30, 2004, our sources of cash were net proceeds of \$41.9 million from our public offering and \$977,000 from the exercise of stock options. Principal uses of cash for the nine months ended September 30, 2004 were investments in

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marketable securities of \$32.2 million, funds used to repurchase common stock of \$13.4 million, payments totaling approximately \$2.7 million to pay off debt outstanding at December 31, 2003, additions to long term assets of approximately \$492,000 and dividends paid of \$235,000. Operating activities used \$880,000 of cash for the nine months ended September 30, 2004, consisting of approximately \$762,000 in cash generated from net income adjusted for non-cash items, offset by approximately \$1.6 million of cash used through changes in assets and liabilities. For further details, see the Unaudited Consolidated Statements of Cash Flows included in this Report.

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Principal among the changes in assets and liabilities which used cash were increases in accounts receivable and inventory. Accounts receivable at September 30, 2004 increased approximately \$534,000 from December 31, 2003. Our days sales in accounts receivable increased from 46 days for the second quarter of 2004 to 48 days for the third quarter of 2004. Inventories increased approximately \$3.4 million from December 31, 2003. This increase was primarily due to increased levels of production in the third quarter which was geared to meet sales at a level comparable with our expected rates of growth. Since that level of sales did not occur in the third quarter, inventory turnover for the third quarter fell to 3.3 from 4.5 in the second quarter of 2004. Although we anticipate certain fluctuations in our inventory levels during the fourth quarter of 2004 to meet new product demands for the Waterlase MD and higher revenue growth, we expect our ending inventory at December 31, 2004 to be similar or slightly lower than the amount at September 30, 2004.

On March 3, 2004, we completed a public offering of 2.5 million shares of common stock. Net proceeds from the offering were \$41.9 million. We have subsequently invested the proceeds in marketable securities consisting of US Treasury bills with durations of less than one year. We also incurred legal, accounting and related costs of approximately \$1.5 million which we had capitalized in Other Assets. After the closing of the offering, we reclassified these capitalized costs from Other Assets to Additional Paid-in Capital. We used a portion of the net proceeds to repay \$1.8 million on the line of credit and \$888,000 in debt and expect to use the balance of the net proceeds of the offering for general corporate purposes, working capital, and capital expenditures, including expenditures for expansion of our production capabilities, acquisition or investment in complementary businesses or products or the right to use complementary technologies. The proceeds have been invested, pending their use as described, in short-term, interest bearing securities and debt instruments in compliance with our investment policy. In addition, the Board of Directors concluded that a stock repurchase program currently represents a use of capital that can enhance stockholder value. Therefore, in July of 2004, we announced a stock repurchase program to acquire up to 1.25 million shares over the next 12 months. In August of 2004, the Board of Directors authorized the repurchase of an additional 750,000 shares of our common stock, increasing the total share repurchase program to 2.0 million shares of our common stock. These shares may be purchased from time to time on the open market or through privately negotiated transactions over the next 12 months. As of September 30, 2004 we have repurchased approximately 1.5 million shares at an average price of \$8.81 per share. Also in July of 2004, the Board of Directors established a dividend policy that will remain in effect for an indefinite period of time and pays a regular cash dividend of \$0.01 per share every other month when declared by the Board of Directors. The first dividend totalling \$235,000 was declared and paid on August 30, 2004 to stockholders of record on August 16, 2004.

At December 31, 2003 we had \$1.8 million outstanding under a \$5.0 million revolving credit facility with a bank, which was due to expire at June 30, 2004. In the first quarter of 2004 we used a portion of the net proceeds from our March 3, 2004 public offering to repay the \$1.8 million outstanding on the line of credit. The credit facility has been extended to June 30, 2005 and increased to \$10.0 million. As of September 30, 2004, there were no amounts borrowed on the credit facility. Borrowings under the facility bear interest at LIBOR plus 2.25% and are payable on demand upon expiration of the facility. Borrowings also subject us to certain covenants, including, among other things, maintaining a minimum balance of cash (including investments in US Treasuries) and tangible net worth and a covenant to remain profitable. We were compliant with the covenants under the agreement with the exception to remain profitable on a quarterly basis. In November of 2004, we were notified by our bank that we were in default under our covenants as of September 30, 2004 due to our operating loss for the three months ended September 30, 2004. In November of 2004, we obtained a waiver to this covenant as of September 30, 2004. There were no borrowings on the line of credit as of September 30, 2004. In November of 2004, we borrowed \$3.5 million under this line of credit.

We had no material commitments for capital expenditures as of September 30, 2004 and have not entered into any material commitments after that date. The following table presents our expected cash requirements for contractual obligations outstanding as of September 30, 2004 for the years ending December 31:

	September 30,	Three Months Ending December 31,	Years Ending December 31,	
	2004	2004	2005	2006
Operating leases	\$ 617,000	\$ 106,000	\$ 421,000	\$ 90,000

We believe that our current cash balances and marketable securities plus cash expected to be generated from our operations will be adequate to meet our capital requirements and sustain our operations, including the payment of our planned dividend and payments under the stock repurchase plan, for at least the next twelve months. Our future capital requirements will depend on many factors, including the extent and timing of the deployment of the capital raised in our public offering and the rate at which our business continues to grow, with corresponding demands for working capital and manufacturing capacity. We could be required or may elect to seek additional funding through public or private equity or debt financing. However, additional funds may not be available on terms acceptable to us or at all.

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### **New Accounting Pronouncements**

In December 2003, the Financial Accounting Standards Board ( FASB ) issued FASB Interpretation No. 46R, Consolidation of Variable Interest Entities ( FIN 46R ). FIN 46R requires the application of either FIN 46 or FIN 46R by Public Entities to all Special Purpose Entities ( SPE ) created prior to February 1, 2003 as of December 31, 2003 for calendar year-end companies. FIN 46R is applicable to all non-SPEs created prior to February 1, 2003 at the end of the first interim or annual period ending after March 15, 2004. For all entities created subsequent to January 31, 2003, Public Entities were required to apply the provisions of FIN 46R. The adoption of FIN 46R did not have an impact to our consolidated financial position, results of operations or cash flows.

In March 2004, the Financial Accounting Standards Board (FASB) approved the consensus reached on the Emerging Issues Task Force (EITF) Issue No. 03-1, The Meaning of Other-Than-Temporary Impairment and Its Application to Certain Investments. The Issue's objective is to provide guidance for identifying other-than-temporarily impaired investments. EITF 03-1 also provides new disclosure requirements for investments that are deemed to be temporarily impaired. The accounting provisions of EITF 03-1 are effective for all reporting periods beginning after June 15, 2004, while the disclosure requirements are effective for annual periods ending after June 15, 2004. In September 2004, the FASB issued a FASB Staff Position (FSP) EITF 03-1-1 that delays the effective date of the measurement and recognition guidance in EITF 03-1 on certain impaired debt securities until after further deliberations by the FASB. The adoption of this pronouncement did not impact the Company's results of operations or financial position.

### **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 report, in addition to other information contained in our other filings with the Securities and Exchange Commission, 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 events anticipated by any of the following risks actually occur, 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, securities analysts or our previously stated financial guidance, the price of our common stock could decline substantially. Factors that might cause quarterly fluctuations in our sales and operating results include, but are not limited by the following:

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

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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;

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, political, international conflicts, and acts of terrorism.

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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 three 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.

### **We may not have effective internal controls if we fail to remedy any deficiencies we may identify in our system of internal controls.**

In preparation for the annual report of management regarding our evaluation of our internal controls that is required to be included in our annual report for the year ended December 31, 2004 by Section 404 of the Sarbanes-Oxley Act of 2002, we have engaged outside consultants and adopted a project work plan to assess the adequacy of our internal control, remediate any weaknesses that may be identified, validate that controls are functioning as documented and implement a continuous reporting and improvement process for internal controls. We may discover deficiencies that require us to improve our procedures, processes and systems in order to ensure that our internal controls are adequate and effective and that we are in compliance with the requirements of Section 404 of the Sarbanes-Oxley Act. If the deficiencies are not adequately addressed, or if we are unable to complete all of our testing and any remediation in time for compliance with the requirements of Section 404 of the Sarbanes-Oxley Act and the SEC rules under it, we would be unable to conclude that our internal controls over financial reporting are designed and operating effectively, which could adversely affect our investor confidence in our internal controls over financial reporting. If we do not complete our testing with sufficient time for our independent accountants to complete their audit of internal controls, we may not be compliant with all of the requirements under Section 404 of the Sarbanes-Oxley Act since we may not receive an independent accountants report.

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

We restated our previously issued financial statements in September of 2003 to reflect a change in the timing of revenue recognition. In late October of 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, when we receive any additional requests for information, we will continue to do so. In accordance with its normal practice, the Securities and Exchange Commission has not advised us when its inquiry might be concluded. If the Securities and Exchange Commission elects to request additional information from us or commences 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. For the first nine months of 2004, net sales to distributors accounted for approximately 13% of our total sales. No distributor accounted for more than 10% of our net sales in 2004. 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. 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.



**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 2003 accounted for 33% of our net sales for the year, whereas the first quarter of 2003 accounted for 19% of net sales for the year. In addition, sales in the third quarter of the year

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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 all sales are final, we may accept product returns from customers in certain, limited circumstances. If requests for product returns become more pervasive, they could seriously harm our reputation, business, financial condition 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, changes in healthcare reimbursement 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 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 increased growth has and, if it continues, will further 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 and integrate 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 be effective in helping us address our 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.

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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 allegedly 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 the four noted patents. 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 extended period of time. There can be no assurance that our technology will not be found to infringe any of the 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, 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 81% of our revenue for the nine months ended September 30, 2004, approximately 83% of our revenue in 2003 and approximately 77% of our revenue in 2002. 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 are party to securities and derivative litigation that distracts our management, is expensive to conduct and seeks a damage award against us.**

We and certain of our officers have been recently named as defendants in several putative shareholder class action lawsuits filed in the United States District Court for the Central District of California. The complaints purport to seek unspecified damages on behalf of an alleged class of persons who purchased our common stock between October 29, 2003 and July 16, 2004. The complaints allege that we and our officers violated federal securities laws by failing to disclose material information about the demand for our products and the fact that the Company would not achieve the alleged forecasted growth. The claimed misrepresentations include certain statements in our press releases and the registration statement we filed in connection with our public offering of stock in March 2004. In addition, three stockholders have filed derivative actions in the state court in California seeking recovery on behalf of Biolase, alleging, among other things, breach of fiduciary duties by those individual defendants and members of the Biolase board of directors. We have not yet formally responded to any of the actions and no discovery has been conducted by any of the parties. This litigation presents a distraction to our management, is expensive to conduct, and if we are unsuccessful in

defending this litigation, may result in damage awards against us that would harm our financial condition and operating results.

**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. For example, the introduction of our LaserSmile system in 2001 was delayed due to an interruption in the supply of components for the system. 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 are each supplied by a separate single supplier. We have not experienced material delays from these suppliers, 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. Such an interruption could cause our business, financial condition and results of operations to suffer.

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**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. For the nine months ended September 30, 2004, international sales accounted for approximately 20% of our revenue, approximately 20% of our revenue in our 2003 fiscal year and approximately 23% of our revenue in our 2002 fiscal year. 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;

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 direct sales in Europe are denominated principally in euros, while our sales in other international markets are in

U.S. 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 \$46,000 on foreign currency transactions for the the nine months ended September 30, 2004 and \$232,000 for the year ended December 31, 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 8% of our revenue for nine months ended September 30, 2004, 12% of our revenue in our 2003 fiscal year and approximately 9% of our revenue in our 2002 fiscal year. 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.

**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

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necessary to meet demand. 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 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 which could harm our business and cause the price of our common stock to decline.

### **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. 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.



**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, Ivoclar Vivadent AG, 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 if 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 our products, require price discounting or otherwise adversely affect our gross margins and our financial condition.

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### **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 or 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 (who is currently also our Interim Chief Financial Officer), our Executive Vice President responsible for sales, our Chief Technology Officer, and our Vice President of Research and Development. We do not have employment agreements with any of our key employees, other than employment agreements with our Chief Executive Officer, our Chief Technology Officer, our Executive Vice President responsible for sales and our newly hired Chief Financial Officer, who will be starting on November 23, 2004. The agreement with each of these individuals provides that we can terminate his employment at will subject to certain severance rights. Our senior management will continue to need to manage our growth and operations in order for us to be successful.

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 \$11.0 million per occurrence and \$12.0 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.**

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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. In 2003 we completed an analysis to determine the applicability of the annual limitations imposed by Section 382 caused by previous changes in our stock ownership and determined that such limitations should not be significant. Based on our analysis, we believe that, as of December 31, 2003, approximately \$32.5 million of net operating loss carryforwards were available to us for federal income tax purposes. Of this amount, approximately \$27.3 million is available to offset 2004 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 2005 through 2009. However, any ownership changes qualifying under Section 382 including changes resulting from or affected by our recent public offering or our stock repurchase plan may adversely affect our ability to use our remaining net operating loss carryforwards. If we lose our ability to use net operating loss carryforwards, any income we generate will be subject to tax earlier than it would be if we were able to use net operating loss carryforwards, resulting in lower profits.

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### **We are exposed to risks associated with worldwide economic slowdowns and related uncertainties.**

Concerns about decreased consumer and investor confidence, reduced corporate profits and capital spending, and international conflicts and terrorist and military activity have resulted in downturns in the equity markets and slowdowns in economic conditions, both domestically and internationally. Such unfavorable conditions could ultimately cause a slowdown in customer orders or cause customer order cancellations. In addition, 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 persist, our business, financial condition and results of operations could suffer.

### **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 future 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 (other than the party acquiring the 15% position or commencing the tender offer) 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 (other than the party acquiring the 15% position) 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.

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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 our Company;

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 otherwise harm our business and financial condition.

#### **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.

### **ITEM 3. QUANTITATIVE AND QUALITATIVE DISCLOSURES ABOUT MARKET RISK.**

We do not engage in transactions to offset currency fluctuations, and we are at risk for changes in the value of the dollar relative to the euro. Our sales in Europe are denominated principally in euros, and our sales in other international markets are denominated in dollars. As a result, an increase in the relative value of the dollar to 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. Additionally, 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 adversely affect our financial condition and results of operations.

### **ITEM 4. CONTROLS AND PROCEDURES.**

(a) Evaluation of disclosure controls and procedures. We maintain disclosure controls and procedures, as such term is defined in Rule 13a-15(e) under the Securities Exchange Act of 1934 (the Exchange Act), that are designed to ensure that information required to be disclosed by us in reports that we file or submit under the Exchange Act is recorded, processed, summarized, and reported within the time periods specified in Securities and Exchange Commission rules and forms, and that such information is accumulated and communicated to our management, including our Chief Executive Officer and Chief Financial Officer, as appropriate, to allow timely decisions regarding required disclosure. In designing and evaluating our disclosure controls and procedures, management recognized that disclosure controls and procedures, no matter how well conceived and operated, can provide only reasonable, not absolute, assurance that the objectives of the disclosure controls and procedures are met. Additionally, in designing disclosure controls and procedures, our management necessarily was required to apply its judgment in evaluating the cost-benefit relationship of possible disclosure controls and procedures. The design of any disclosure controls and procedures also is based in part on certain assumptions about the likelihood of future events, and there can be no assurance that any design will succeed in achieving its stated goals under all potential future conditions.

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Based on their evaluation as of the end of the period covered by this Quarterly Report on Form 10-Q for the quarterly period ended September 30, 2004, our Chief Executive Officer and Chief Financial Officer have concluded that, subject to the limitations noted above, our disclosure controls and procedures were effective to ensure that material information relating to us, including our consolidated subsidiaries, is made known to them by others within those entities, particularly during the period for which this Quarterly Report on Form 10-Q was being prepared.

(b) Changes in internal control over financial reporting. There was no change in our internal control over financial reporting (as defined in Rule 13a-15(f) under the Exchange Act) identified in connection with the evaluation described in Item 4(a) above that occurred during our last fiscal quarter that has materially affected, or is reasonably likely to materially affect, our internal control over financial reporting.



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### **PART II. OTHER INFORMATION**

#### **ITEM 1. LEGAL PROCEEDINGS.**

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 allegedly 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. 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. ( AMT ), 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 AMT. We acquired the licensed patents and related license agreements in our acquisition of the American Dental Laser product line from AMT. Diodem's lawsuit against us alleges that our Waterlase product infringes upon the four patents that Diodem allegedly acquired from Premier. Diodem also alleges that the products sold by OpusDent and Hoya ConBio infringe upon the patents. Diodem's infringement suit seeks treble damages, a preliminary and permanent injunction from further alleged infringement, attorneys' fees and other unspecified damages. If Diodem successfully asserts an infringement claim against us, our operations may be significantly impacted, especially to the extent that it affects our right to use the technology incorporated in our Waterlase system, which accounted for approximately 81% of our revenue for the nine months ended September 30, 2004 and approximately 83% of our revenue of the year ended December 31, 2003. If Diodem successfully asserts an infringement claim against Hoya ConBio and OpusDent, it could reduce or eliminate royalties we might receive under licenses to those products, which have totaled approximately \$627,000 since the acquisition of the American Dental Laser assets in May 2003. The litigation is in the late pre-trial preparation. No trial date has been set. A trial date in 2005 is likely. This combined lawsuit may proceed for an extended period of time. Although the outcome of these actions cannot be determined with any 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. No amounts have been recorded in the consolidated financial statements relating to the outcome of this matter.

We and certain of our officers have been recently named as defendants in several putative shareholder class action lawsuits filed in the United States District Court for the Central District of California. The complaints purport to seek unspecified damages on behalf of an alleged class of persons who purchased our common stock between October 29, 2003 and July 16, 2004. The complaints allege that we and our officers violated federal securities law by failing to disclose material information about the demand for our products and the fact that the Company would not achieve the alleged forecasted growth. The claimed misrepresentations include certain statements in our press releases and the registration statement we filed in connection with our public offering of stock in March 2004. In addition, three stockholders have filed derivative actions in the state court of California seeking recovery on behalf of Biolase, alleging, among other things, breach of fiduciary duties by those individual defendants and by the members of the Biolase board of directors.

We have not yet formally responded to any of these shareholder actions and no discovery has been conducted by any of the parties. However, based on the facts presently known, our management believes we have meritorious defenses to these actions and intend to vigorously defend them.

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

**ITEM 2. CHANGES IN SECURITIES, USE OF PROCEEDS, AND ISSUER PURCHASES OF EQUITY SECURITIES****Item 703. Purchases of Equity Securities by the Issuer and Affiliated Purchasers.**

In the third quarter of 2004, the Board of Directors authorized a repurchase program for the purchase of up to 2.0 million shares of our common stock. As of September 30, 2004 we repurchased 1.5 million shares in open-market transactions. Below is a summary of the repurchase activity:

<u>Period</u>	<b>Total Number of Shares Purchased</b>	<b>Average Price Paid per Share</b>	<b>Total Number of Shares Purchased as Part of Publicly Announced Plans or Programs</b>	<b>Maximum Number of Shares that May Yet Be Purchased Under the Plans or Programs</b>
July 1 31, 2004	860,900	\$ 9.08	860,900	1,139,100
August 1 31, 2004	616,100	\$ 8.41	616,100	523,000
September 1 30, 2004	48,000	\$ 9.03	48,000	475,000

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**ITEM 6. EXHIBITS AND REPORTS ON FORM 8-K.**

- (a) Exhibits:
- 31.1 Certification of Robert E. Grant Pursuant to Rule 13a-14(a) and Rule 15d-14(a), promulgated under the Securities Exchange Act of 1934, as amended.
  - 32.1 Certification of Robert E. Grant Pursuant to 18 U.S.C. Section 1350 as Adopted Pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.
- (b) Reports on Form 8-K:
- (1) On July 21, 2004, the registrant furnished a current report on Form 8-K to report matters under Item 7 and Item 12 of the report in relation to a press release issued by the registrant on July 16, 2004.
  - (2) On July 21, 2004, the registrant furnished a current report on Form 8-K to report matters under Item 5 and Item 7 of the report in relation to a press release issued by the registrant on July 19, 2004.
  - (3) On July 30, 2004, the registrant furnished a current report on Form 8-K to report matters under Item 5 and Item 7 of the report in relation to two press releases issued by the registrant on July 27, 2004.
  - (4) On July 30, 2004, the registrant furnished a current report on Form 8-K to report matters under Item 7 and Item 12 of the report in relation to a press release issued by the registrant on July 27, 2004.
  - (5) On August 11, 2004, the registrant furnished a current report on Form 8-K to report matters under Item 5 of the report in relation to the resignation of a member of the Board of Directors of the registrant effective July 31, 2004.
  - (6) On August 11, 2004, the registrant furnished a current report on Form 8-K to report matters under Item 5 and Item 7 of the report in relation to two press releases issued by the registrant on August 9, 2004.
  - (7) On October 7, 2004, the registrant furnished a current report on Form 8-K to report matters under Item 2.02 and Item 9.01 of the report in relation to a press release issued by the registrant on October 7, 2004.
  - (8) On October 27, 2004, the registrant furnished a current report on Form 8-K to report matters under Item 2.02 and Item 9.01 of the report in relation to a press release issued by the registrant on October 27, 2004.
  - (9) On October 28, 2004, the registrant filed a current report on Form 8-K to report matters under Item 1.01, Item 5.02 and Item 9.01 of the report in relation to a press release issued by the registrant on October 27, 2004.

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**SIGNATURES**

Pursuant to the requirements of the Securities Exchange Act of 1934, as amended, the Registrant has duly caused this report to be signed on its behalf by the undersigned thereunto duly authorized.

Dated: November 10, 2004

BIOLASE TECHNOLOGY, INC.,

a Delaware corporation

By: /s/ ROBERT E. GRANT

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Robert E. Grant

Chief Executive Officer and

Interim Chief Financial Officer

(Principal Financial and Accounting Officer)