BIOLASE TECHNOLOGY INC
Form 424B4
February 27, 2004
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Filed Pursuant to Rule 424b(4)

Registration No. 333-106260

PROSPECTUS

2,807,500 Shares

Common Stock

We are offering 2,500,000 shares of our common stock and one of our stockholders is offering 307,500 shares of our common stock. We will not receive any proceeds from the sale of shares by the selling stockholder. Our common stock is traded on the Nasdaq National Market under the symbol BLTI. On February 26, 2004, the last reported sale price of our common stock on the Nasdaq National Market was $18.91 per share.

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

	Per Share	Total
Public Offering Price	*$ 18.50*	*$ 51,938,750*
Underwriting Discounts	*$ 1.15*	*$ 3,228,625*
Proceeds, before expenses, to BioLase Technology, Inc.	*$ 17.35*	*$ 43,375,000*
Proceeds, before expenses, to the selling stockholder	*$ 17.35*	*$ 5,335,125*

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

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

Needham & Company, Inc.

William Blair & Company

Oppenheimer & Co. Inc.

The date of this prospectus is February 26, 2004.

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

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

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PROSPECTUS SUMMARY

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

BioLase Technology, Inc.

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

Our primary product, the Waterlase system, is the best selling dental laser system. The Waterlase uses a patented combination of water and laser to precisely cut hard tissue, such as bone and teeth, and soft tissue, such as gums. We also offer the LaserSmile system, which uses a laser to perform soft tissue and cosmetic procedures, including tooth whitening. In May 2003, we acquired the American Dental Laser product line of American Medical Technologies, Inc., including the Diolase and Pulsemaster systems, which can be used for common soft tissue procedures. These systems, together with our Waterlase and LaserSmile, offer a broad product line with a range of features and price points. We also manufacture and sell accessories and disposables for our laser systems, such as handpieces, laser tips and tooth whitening gel.

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

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

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

The BioLase Solution

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

Our laser systems benefit practitioners by:

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

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

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

reducing trauma, swelling and general discomfort.

Our laser systems benefit patients by:

improving comfort and reducing trauma for many common procedures;

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

enabling multiple procedures to be performed in one visit; and

making many elective procedures more comfortable and convenient.

Business Strategy

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

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

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

expanding our products and applications in dentistry;

continuing to provide high quality manufacturing and customer service; and

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

Key Strengths

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

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

our Waterlase system is the best selling dental laser system;

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

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

Recent Developments (Unaudited)

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

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

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

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

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

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

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

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

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

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

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

BIOLASE TECHNOLOGY, INC.

SELECTED CONSOLIDATED FINANCIAL DATA

(unaudited)

Selected Consolidated Statements of Operations Data:

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

Selected Consolidated Balance Sheet Data:

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

Additional Information

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

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The Offering

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

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

- 3,329,131 shares issuable upon exercise of outstanding options at a weighted average exercise price of $5.43 per share; and
- 305,957 additional shares of common stock reserved for future grant or issuance under our equity incentive compensation plans.

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

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Summary Consolidated Financial Data

(in thousands, except per share data)

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

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

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

The following table presents our consolidated balance sheet data as of September 30, 2003, which we derived from our unaudited financial statements included elsewhere in this prospectus. The as adjusted for the offering data gives effect to the sale of 2,500,000 shares of common stock by us in this offering at the public offering price of $18.50 per share, and after deducting underwriting discounts and commissions, and estimated offering expenses payable by us.

	September 30, 2003	
	Actual	As Adjusted for Offering
Consolidated Balance Sheet Data:		
Cash and cash equivalents	$ 6,123	$ 48,193
Working capital	7,349	49,419
Total assets	26,315	68,385
Total debt	2,937	2,937
Stockholders equity	15,129	57,199

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RISK FACTORS

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

Risks Relating to Our Business

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

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

- variation in demand for our products, including variation due to seasonality;
- our ability to research, develop, introduce, market and gain market acceptance of new products and product enhancements in a timely manner;
- our ability to control costs;
- the size, timing, rescheduling or cancellation of orders from distributors;
- the introduction of new products by competitors;
- long sales cycles and fluctuations in sales cycles;
- the availability and reliability of components used to manufacture our products;
- changes in our pricing policies or those of our suppliers and competitors, as well as increased price competition in general;
- the mix of our domestic and international sales, and the risks and uncertainties associated with our international business;

costs associated with any future acquisitions of technologies and businesses;

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

developments concerning the protection of our proprietary rights; and

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

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

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

We recently restated our previously issued financial statements to reflect a change in the timing of revenue recognition. Staff Accounting Bulletin No. 101, Revenue Recognition in Financial Statements, as adopted by the Securities and Exchange Commission, requires the transfer of title and the risks and rewards of ownership to the customer before the recognition of revenue. We originally prepared our financial statements on the basis that this transfer of title occurred upon shipment. After the issuance of our consolidated financial statements as of and for the year ended December 31, 2002, it was determined, with respect to sales to domestic customers, that title transferred upon receipt of full payment, due to a clause in our purchase orders. As a result, we restated our consolidated financial statements as of December 31, 2002 and December 31, 2001, and for each of the three years in the period ended December 31, 2002, and the interim periods in 2002 and the quarter ended March 31, 2003, to defer revenue upon shipment and to recognize it upon receipt of full payment for our domestic customers. It was also determined that revenue recognition for products shipped directly to customers in Europe which we commenced in 2002, was appropriate at the time of installation, which was when the customer became obligated to pay, and not at the time of shipment as recognized in the previously filed financial statements. In conjunction with these revisions, we deferred the revenue, the related cost of inventory and related sales commissions. In August 2003, we modified the sales arrangements with our customers so that title transfers to the customer upon shipment for domestic sales, and there is an enforceable obligation to pay upon shipment for international direct sales. As a result, we changed our revenue recognition policy in the third quarter of 2003 to recognize revenue upon shipment for both domestic sales and international direct sales.

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

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

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

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

We have experienced fluctuations in sales from quarter to quarter due to seasonality. In our experience, sales in the first quarter typically are lower than average and sales in the fourth quarter typically are stronger than average due to the buying patterns of dental professionals. For example, the fourth quarter of 2002 accounted for 30% of our net sales for the year, whereas the first quarter of 2002 accounted for 18% of net sales for the year. In addition, sales in the third quarter of the year may be affected by vacation patterns which can cause sales to be flat or lower than in the second quarter of the year. As a result, sequential quarter-to-quarter comparisons of our operating results may not be an indication of our performance for the year and may cause our results of operations and stock price to fluctuate.

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

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

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

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

We may have difficulty managing our growth.

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

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

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

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

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

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

We are currently involved in a patent lawsuit with Diodem, LLC, a California limited liability company, which was founded by Collete Cozean, the former chief executive officer of Premier Laser Systems, Inc. The claims in this lawsuit were originally part of two separate lawsuits initiated in U.S. District Court. On May 2, 2003, we initiated a civil action in the U.S. District Court for the Central District of California against Diodem to obtain a judicial declaration against Diodem that technology used in our laser systems does not infringe four patents owned by Diodem. Diodem claims to have acquired the patents from Premier Laser Systems, Inc., which filed for bankruptcy protection in March 2000. On May 5, 2003, Diodem added us as a party to an infringement lawsuit it had previously filed in the U.S. District Court for the Central District of California. These lawsuits were consolidated into the currently pending lawsuit in August 2003. Diodem alleges that our technology, including the technology used in our Waterlase system, infringes four patents it acquired from Premier. Diodem seeks treble damages, a preliminary and permanent injunction from further alleged infringement, attorneys fees and other unspecified damages. This lawsuit is in the discovery phase of litigation, and may proceed for an

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

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

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

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

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

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

- adverse changes in tariffs;
- political, social and economic instability and increased security concerns;
- fluctuations in currency exchange rates;

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

exposure to different legal standards;

ineffectiveness of international distributors;

reduced protection for our intellectual property in some countries;

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burdens of complying with a variety of foreign laws;

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

trade restrictions;

the imposition of governmental controls;

unexpected changes in regulatory or certification requirements;

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

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

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

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

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

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

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

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

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

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

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

- we may encounter difficulties in assimilating and integrating the operations, products and workforce of the acquired companies;
- acquisitions may negatively impact our results of operations because they may require large one-time charges or could result in increased debt or contingent liabilities, adverse tax consequences, substantial depreciation or deferred compensation charges, or the amortization or write down of amounts related to deferred compensation, goodwill and other intangible assets;
- acquisitions may be dilutive to our existing stockholders;
- acquisitions may disrupt our ongoing business and distract our management; and
- key personnel of the acquired company may decide not to work for us.

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

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

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

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payable. If we were unable to repay those amounts, our lender could proceed against the collateral granted to it to secure that indebtedness, which includes our intellectual property. The results of such action would have a significant negative impact on our results of operations and financial condition. Due to the restatement of our financial statements, we were not in compliance with three covenants under the credit facility at June 30, 2003. The bank waived our non-compliance with these covenants as of June 30, 2003, so that we were not in default under the credit facility. We were in compliance with these covenants as of September 30, 2003, and as of December 31, 2003, the most recent evaluation date for determining compliance with the covenants. We cannot assure you that we will be in compliance with our financial covenants on future evaluation dates for determining compliance with these covenants.

Material increases in interest rates may harm our sales.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

The issuance of any preferred stock may:

- delay, defer or prevent a change in control of BioLase;
- discourage bids for the common stock at a premium over the market price of our common stock;

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

discourage acquisition proposals or tender offers for our shares.

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Risks Relating to Our Industry

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

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

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

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

Risks Relating to This Offering

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

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

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

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

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

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

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

Our net tangible book value at September 30, 2003, was approximately $9.6 million, or approximately $0.44 per share of common stock, without giving effect to any exercise of options then outstanding. Our net tangible book value per share has been determined by dividing the net tangible book value, which is total tangible assets less total liabilities, by the number of shares of common stock outstanding at September 30, 2003. After giving effect to the sale of 2,500,000 shares of our common stock by us in this offering at the public offering price of $18.50 per share, and after deduction of the underwriting discount and estimated offering expenses, our net tangible book value immediately after the offering would have been approximately $51.6 million or $2.15 per share. Accordingly, the offering price of our common stock will be substantially higher than the net tangible book value per share of our existing capital stock. As a result, if you purchase common stock in this offering, you will incur immediate and substantial dilution of approximately $16.35 in net tangible book value per share of common stock, based on the public offering price of $18.50 per share. You also could experience additional dilution upon the exercise of outstanding stock options.

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

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

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

Future sales of substantial amounts of shares of our common stock by our existing stockholders in the public market, or the perception that these sales could occur, may cause the market price of our common stock to decline. In addition, we may be required to issue additional shares upon

exercise of previously granted options that are currently outstanding. Our directors and executive officers have agreed to enter into lock up agreements with the underwriters, in which they will agree to refrain from selling their shares for a period of 120 days after this offering. Increased sales of our common stock in the market after exercise of currently outstanding options or expiration of the lock-up agreements could exert significant downward pressure on our stock price. These sales also might make it more difficult for us to sell equity or equity-related securities in the future at a time and price we deem appropriate.

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FORWARD-LOOKING STATEMENTS

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

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

USE OF PROCEEDS

The net proceeds to us from the sale of the 2,500,000 shares of common stock offered by us under this prospectus will be approximately $42,069,890 based on the public offering price of $18.50 per share, and after deducting estimated underwriting discounts and commissions, and expenses payable by us. We will not receive any proceeds from the sale of 307,500 shares by the selling stockholder. Our net proceeds will be approximately $49,376,409 if the underwriters fully exercise their over-allotment option to purchase 421,125 shares of our common stock from us.

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

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

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PRICE RANGE OF COMMON STOCK

Our common stock is listed on the Nasdaq National Market under the symbol BLTI. The following table sets forth the high and low closing sale prices of our common stock as reported by the Nasdaq SmallCap Market for the period from January 1, 2001 through May 21, 2002, and the Nasdaq National Market for the period from May 22, 2002 through February 26, 2004.

	High	Low
Fiscal Year Ended December 31, 2001		
First Quarter	$ 3.03	$ 1.53
Second Quarter	5.07	2.09
Third Quarter	6.59	3.47
Fourth Quarter	6.80	3.60
Fiscal Year Ended December 31, 2002		
First Quarter	$ 6.58	$ 5.11
Second Quarter	5.88	4.00
Third Quarter	5.14	3.80
Fourth Quarter	5.89	3.68
Fiscal Year Ended December 31, 2003		
First Quarter	$ 8.29	$ 5.30
Second Quarter	14.78	8.18
Third Quarter	14.93	10.50
Fourth Quarter	17.60	11.45
Fiscal Year Ending December 31, 2004		
First Quarter (through February 26, 2004)	$ 21.29	$ 18.25

On February 26, 2004, the last reported sale price of our common stock on the Nasdaq National Market was $18.91 per share. As of February 26, 2004, there were approximately 280 holders of record of our common stock. Based on information provided by our transfer agent and registrar, we believe that there are approximately 12,005 beneficial owners of our common stock.

DIVIDEND POLICY

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

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CAPITALIZATION

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

- actual basis; and
- as adjusted for the sale of 2,500,000 shares of our common stock offered by us under this prospectus at the public offering price of $18.50 per share, after deducting underwriting discounts and commissions and offering expenses payable by us.

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

	September 30, 2003	
	Actual	As Adjusted for Offering
	(in thousands)	
Cash and cash equivalents	$ 6,123	$ 48,193
Line of credit	1,792	1,792
Short-term debt	1,145	1,145
Total debt	2,937	2,937
Stockholders equity:		
Preferred stock, par value $0.001; 1,000,000 shares authorized, no shares issued and outstanding		
Common stock, $0.001 par value: 50,000,000 shares authorized actual and as adjusted; 21,544,571 shares issued and outstanding actual and 24,044,571 shares issued and outstanding as adjusted for offering[(1)]	22	25
Additional paid-in capital	56,816	98,883
Accumulated other comprehensive income	(130)	(130)
Accumulated deficit	(41,579)	(41,579)
Total stockholders equity	15,129	57,199
Total capitalization	$ 18,066	$ 60,136

(1) The outstanding share information excludes outstanding options to purchase 2,997,787 shares of common stock exercisable at a weighted-average exercise price per share, as of September 30, 2003, of $4.47 and an additional 649,040 shares of common stock reserved for future grant or issuance under our equity incentive compensation plans.

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SELECTED CONSOLIDATED FINANCIAL DATA

(In thousands, except per share data)

The following selected consolidated financial data should be read in conjunction with Management s Discussion and Analysis of Financial Condition and Results of Operations and our consolidated financial statements and related notes included elsewhere in this prospectus. The selected consolidated financial data set forth below with respect to the consolidated statements of operations data for the years ended December 31, 2000, 2001 and 2002 and the consolidated balance sheet data at December 31, 2001 and 2002, were derived from the audited consolidated financial statements included elsewhere in this prospectus. We derived the consolidated statement of operations data for the years ended December 31, 1998 and 1999 and the consolidated balance sheet data as of December 31, 1998 and 1999 from our audited financial statements not included in this prospectus. We derived the selected financial data with respect to the consolidated statements of operations data for the nine months ended September 30, 2002 and 2003, and with respect to the consolidated balance sheet data at September 30, 2003, from unaudited consolidated financial statements included elsewhere in this prospectus. The data set forth below as of December 31, 2001 and 2002 and for the three years then ended and as of September 30, 2002 and for the nine months then ended, reflects the recent restatement of our financial statements to account for a change in the timing of revenue recognition, as more fully explained in Management s Discussion and Analysis of Financial Condition and Results of Operation, Risk Factors and Note 2 to the consolidated financial statements included elsewhere in this prospectus. The data for the nine months ended September 30, 2003, reflect the change in our revenue recognition policy in August 2003, as more fully explained in the above referenced sections included elsewhere in this prospectus.

	Fiscal Years Ended December 31,					Nine Months Ended September 30,	
	1998	1999	2000	2001	2002	2002 (Restated)	2003[3]
				(Restated)			
Consolidated Statements of Operations Data:							
Net sales	$ 1,465	$ 7,004	$ 9,495	$ 16,546	$ 27,257	$ 19,134	$ 32,991
Cost of sales	1,418	4,152	4,816	6,938	10,485	7,569	12,386
Gross profit	47	2,852	4,679	9,608	16,772	11,565	20,605
Other income				79	63	47	51
Operating expenses:							
Sales and marketing	1,629	2,701	4,211	7,314	10,729	7,255	10,962
General and administrative	1,780	2,473	1,841	2,011	3,010	2,072	3,407
Engineering and development[1]	6,960	2,427	2,288	1,520	1,684	1,148	1,662
Total operating expenses	10,369	7,601	8,340	10,845	15,423	10,475	16,031
Income (loss) from operations	(10,322)	(4,749)	(3,661)	(1,158)	1,412	1,137	4,625
Non-operating income (loss)	(24)	(49)	(94)	(123)	86	29	135
Income (loss) before cumulative effect of change in accounting principle	(10,346)	(4,798)	(3,755)	(1,281)	1,498	1,166	4,760
Cumulative effect of change in accounting principle			(34)				
Net income (loss)	$ (10,346)	$ (4,798)	$ (3,789)	$ (1,281)	$ 1,498	$ 1,166	$ 4,760

Income (loss) per share before cumulative effect of change in accounting principle:							
Basic	$ (0.69)	$ (0.28)	$ (0.20)	$ (0.07)	$ 0.08	$ 0.06	$ 0.23
Diluted	$ (0.69)	$ (0.28)	$ (0.20)	$ (0.07)	$ 0.07	$ 0.05	$ 0.21
Cumulative effect of change in accounting principle per share:							
Basic	$	$	$ 0.00	$	$	$	$
Diluted	$	$	$ 0.00	$	$	$	$
Net income (loss) per share:							
Basic	$ (0.69)	$ (0.28)	$ (0.20)	$ (0.07)	$ 0.08	$ 0.06	$ 0.23
Diluted	$ (0.69)	$ (0.28)	$ (0.20)	$ (0.07)	$ 0.07	$ 0.05	$ 0.21
Shares used in computing net income (loss) per share:							
Basic	15,062	17,254	19,171	19,510	19,929	19,878	20,796
Diluted	15,062	17,254	19,171	19,510	21,303	21,288	22,813

	December 31,					September 30,
	1998	**1999**	**2000[4]**	**2001**	**2002**	**2003[3]**
			(Restated)			
Consolidated Balance Sheet Data:						
Cash and cash equivalents	$ 425	$ 1,181	$ 2,002	$ 2,670	$ 3,940	$ 6,123
Working capital (deficit)	89	(1,331)	(268)	201	1,418	7,349
Total assets	3,911	2,672	6,822	8,253	16,003	26,315
Total debt[2]	1,705	1,342	2,967	1,792	3,012	2,937
Stockholders equity (deficit)	662	(939)	994	645	3,121	15,129

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(1) Includes charges in 1998 of $5.1 million related to a write-off of in-process research and development.
(2) Includes line of credit and short-term debt.
(3) On May 21, 2003 we acquired the American Dental Laser product line and related dental laser assets of American Medical Technologies, Inc. for approximately $5.8 million. Refer to Note 10 in the notes to the consolidated financial statements included elsewhere in this prospectus.
(4) The consolidated balance sheet data as of December 31, 2000 previously reported a working capital deficit of $206,000, total assets of $6.6 million and stockholders equity of $1.1 million.

The following table presents our consolidated balance sheet data as of September 30, 2003, which we derived from our unaudited financial statements included elsewhere in this prospectus. The as adjusted for offering data gives effect to the sale of 2,500,000 shares of common stock by us in this offering at the public offering price of $18.50 per share, and after deducting underwriting discounts and commissions and estimated offering expenses payable by us.

	September 30, 2003	
	Actual	As Adjusted for Offering
	(in thousands)	
Consolidated Balance Sheet Data:		
Cash and cash equivalents	$ 6,123	$ 48,193
Working capital	7,349	49,419
Total assets	26,315	68,385
Total debt	2,937	2,937
Stockholders equity	15,129	57,199

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MANAGEMENT S DISCUSSION AND ANALYSIS OF

FINANCIAL CONDITION AND RESULTS OF OPERATIONS

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

Restatement of Financial Statements

We recently restated our previously issued consolidated financial statements for each of the three years in the period ended December 31, 2002, the three months ended March 31, 2003, and interim periods ended in 2002 and 2001. The restated financial statements were included in an amendment to our Annual Report on Form 10-K/A for the year ended December 31, 2002, and amended quarterly reports on Form 10-Q/A for each of the quarterly periods ended in 2002 and the quarterly period ended March 31, 2003, which were filed with the Securities and Exchange Commission on September 17, 2003, and amended on December 16, 2003. On September 29, 2003, we also filed an amendment to our Current Report on Form 8-K originally filed on June 4, 2003, and amended on June 23, 2003 and August 1, 2003, to make corresponding changes to the pro forma financial statements that we filed in relation to our acquisition of the American Dental Laser product line and other dental laser assets of American Medical Technologies, Inc. in May 2003. The restatement of our financial statements had no effect on the financial statements of the business we acquired from American Medical Technologies, Inc., which are set forth in their entirety in the financial statements included elsewhere in this prospectus.

As reported in the above-referenced amended filings, the restatement related to a change in the timing of revenue recognition. Staff Accounting Bulletin No. 101 (SAB 101), Revenue Recognition in Financial Statements, requires the transfer of title and the risks and rewards of ownership to the customer before the recognition of revenue. We originally prepared our financial statements on the basis that this transfer of title occurred upon shipment. After the issuance of our consolidated financial statements as of and for the year ended December 31, 2002, it was determined, with respect to sales to domestic customers, that title transferred upon receipt of full payment, due to a clause in our purchase orders. As a result, we restated our consolidated financial statements as of December 31, 2001 and December 31, 2002 and for each of the three years in the period ended December 31, 2002 to defer revenue upon shipment and to recognize it upon receipt of full payment for our domestic customers. We reflected the impact of this change, as measured at January 1, 2000, as the cumulative effect of a change in accounting principle for the adoption of SAB 101. The $34,000 cumulative effect of change in accounting principle was recognized as income during the year ended December 31, 2000, which included $168,000 of revenue. We also restated our consolidated financial statements for the nine month period ended September 30, 2002 included elsewhere in this prospectus to defer revenue upon shipment and to recognize it upon receipt of full payment for our domestic customers. It was also determined that revenue recognition for products shipped directly to customers in Europe, which we commenced in 2002, is appropriate at the time of installation, which is when the customer becomes obligated to pay, and not at the time of shipment as recognized in the previously filed financial statements. In conjunction with these revisions, we have deferred the revenues, the related costs of inventory and related sales commissions associated with the sale of our products.

As a result of the restatement, our net revenue for 2002 decreased by $1,942,000, our gross profit decreased by $1,325,000 and our net income was reduced by $1,132,000, or $0.05 per fully diluted share. For 2001, our net revenue decreased by $1,341,000, our gross profit decreased by $980,000 and our net loss increased by $873,000, or $0.05 per fully diluted share. For 2000, our net revenue decreased by $162,000, our gross profit decreased by $149,000 and our net loss increased by $61,000, or $0.01 per fully diluted share. Also as a result of the restatement, our net revenue for the nine months ended September 30, 2002 decreased by $570,000, our gross profit decreased by $450,000, and our net income decreased by $394,000, or $0.02 per fully diluted share.

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The statements of operations were restated as follows (in thousands, except per share data):

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

Year Ended December 31, 2001	As Reported	Restated
Net sales	$ 17,887	$ 16,546
Cost of sales	7,299	6,938
Operating expenses	10,952	10,845
Loss from operations	(364)	(1,158)
Net loss	$ (408)	$ (1,281)
Net loss per share:		
Basic	$ (0.02)	$ (0.07)
Diluted	$ (0.02)	$ (0.07)

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

Nine Months ended September 30, 2002	As Reported	Restated
Net sales	$ 19,704	$ 19,134
Cost of sales	7,689	7,569
Operating expenses	10,531	10,475
Income from operations	1,484	1,137
Net income	$ 1,560	$ 1,166
Net income per share:		
Basic	$ 0.08	$ 0.06
Diluted	$ 0.07	$ 0.05

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The balance sheets were restated as follows (in thousands, except per share data):

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

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

The following discussion and analysis should be read in conjunction with the financial statements and related notes included in the amended filings referenced above.

Overview

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

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

Company Background

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

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

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Recent Developments (unaudited)

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

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

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

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

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

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

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

As discussed more fully below, due to the change in accounting for revenue recognition in August 2003, results of operations between periods are not directly comparable.

In August 2003, we modified our sales arrangements with our customers and began recognizing revenue upon shipment for our domestic sales, or on an accrual basis which previously had been recognized upon receipt of payment in full, or on a cash basis. Additionally, we began to

recognize revenue upon shipment for our international direct sales, which previously had been recognized after completion of installation. Revenue for the year ended December 31, 2003 included $18.3 million of domestic sales recognized on a cash basis and $20.4 million of domestic sales recognized on an accrual basis. Revenue for the year ended December 31, 2002 included $20.2 million of domestic sales recognized on a cash basis. Revenue for the year ended December 31, 2003 included $1.6 million of international direct sales recognized after completion of installation and $1.7 million of international direct sales recognized on shipment. Revenue for the year ended December 31, 2002 included $463,000 of international direct sales recognized upon completion of installation.

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

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

BIOLASE TECHNOLOGY, INC.

SELECTED CONSOLIDATED FINANCIAL DATA

(unaudited)

Selected Consolidated Statements of Operations Data:

	Years Ended December 31,		Three Months Ended December 31,	
	2003	2002	2003	2002
Net sales	$ 49,081,000	$ 27,257,000	$ 16,090,000	$ 8,123,000
Gross profit	31,551,000	16,772,000	10,946,000	5,207,000
Income from operations	7,941,000	1,412,000	2,816,000	275,000
Income before income tax benefit	7,667,000	1,498,000	2,907,000	332,000
Income tax benefit	11,391,000		11,391,000	
Net income	$ 19,058,000	$ 1,498,000	$ 14,298,000	$ 332,000
Net income per share:				
Basic	$ 0.91	$ 0.08	$ 0.66	$ 0.02
Diluted	$ 0.83	$ 0.07	$ 0.61	$ 0.02
Shares used in computing net income per share:				
Basic	20,993,000	19,929,000	21,550,000	20,078,000
Diluted	22,978,000	21,303,000	23,534,000	21,755,000

Selected Consolidated Balance Sheet Data:

	December 31, 2003	December 31, 2002
Cash and cash equivalents	$ 11,111,000	$ 3,940,000
Working capital	10,656,000	1,418,000

Total assets	44,501,000	16,003,000
Total debt	2,680,000	3,209,000
Stockholders equity	31,782,000	3,121,000

Recent Acquisitions

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

In December 2001, we formed BIOLASE Europe, GmbH, a wholly owned subsidiary based in Germany. In February 2002, BIOLASE Europe acquired a laser manufacturing facility in Germany and commenced manufacturing operations at that location. This acquisition has enabled us to initiate an expansion of our sales in

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Europe and neighboring regions. We purchased the facility for cash consideration of approximately Euros 1.2 million, which we agreed to pay in installments through 2003, subject to reduction if we were unable to conclude a patent license arrangement with the seller and another company. We did not conclude that arrangement and, in September 2003, the consideration was reduced to Euros 989,000 per the agreement. The purchase agreement provides for the payment of Euros 582,000 and of Euros 175,000 by April 1 and September 30, 2003, respectively, which were never paid due to subsequent discussions with the seller regarding a further reduction to the purchase price. The purchase agreement also provides for the payment of Euros 232,000 on December 1, 2003. Based on our further discussions with the seller, in September 2003, the maximum consideration due under the agreement was reduced to Euros 986,000. In October 2003, we paid the seller Euros 986,000 plus applicable taxes, as full and final payment to the seller under the purchase agreement.

On May 21, 2003, we acquired the American Dental Laser product line and other dental laser assets of American Medical Technologies, Inc., or AMT, for approximately $5.8 million, consisting of $1.8 million in cash, 307,500 shares of our common stock and $215,000 in costs directly attributable to the acquisition. As a part of the purchase transaction, we and AMT agreed to dismiss with prejudice the lawsuit we had filed in October 2002 against AMT which alleged infringement of certain of our patents. In the dismissal, AMT acknowledged that it had infringed our intellectual property rights as identified in our complaint and recognized that the patents we had asserted in the legal action are valid and enforceable. The acquired assets included dental laser patents, customer lists, brand names and other intellectual property as well as laser systems, including the Diolase and Pulsemaster systems. The purchase price will be allocated to the assets based on their fair value. We intend to sell the Diolase and Pulsemaster systems both domestically and internationally under the American Dental Laser brand name. Sales of the new systems began in the second half of 2003.

Accounting Policies

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

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

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

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

collectibility is reasonably assured.

As a result of our recent restatement of our financial statements, assuming that all of the above criteria were satisfied, for the period from January 1, 2000 to early August 2003, we recorded revenue for domestic sales when we received payment in full, due to a clause in our purchase order that states title transfers upon payment in full; we recorded revenue for international direct sales when the product was installed, which is when the customer became obligated to pay, and we recorded revenue for sales to distributors upon delivery.

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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. Since August 2003, we have been recording revenue for domestic sales and international direct sales upon shipment. We continue to record revenue for sales to distributors upon delivery. As a result, we recorded $4.0 million in revenue under the revenue recognition policy in effect before the modification to our sales arrangements and $6.2 million in revenue under our revenue recognition policy in effect after the modification to our sales arrangements, during the quarter ended September 30, 2003. Net revenues unaffected by the changes in our revenue recognition policy were $3.2 million for the quarter ended September 30, 2003. As a result of the change in our revenue recognition policy during the third quarter of 2003, our net sales, gross profit, operating income and other operating results for the nine months ended September 30, 2003 are not directly comparable to the nine months ended September 30, 2002. Similarly, for the same reason, our quarterly sales, gross profit, operating income and other operating results for each of the next four quarters ending September 30, 2004 will not be directly comparable to corresponding periods in the preceding year.

On July 1, 2003, we adopted EITF 00-21, Accounting for Revenue Arrangements with Multiple Deliverables. We concluded that certain of our arrangements include multiple units of accounting resulting in the allocation of the total consideration based on the residual value method. The adoption of EITF 00-21 did not have a material impact to our consolidated financial condition, results of operations or cash flows.

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

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

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

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

Litigation and Other Contingencies. We regularly evaluate our exposure to threatened or pending litigation and other business contingencies. Because of the uncertainties related to the amount of loss from litigation and other business contingencies, the recording of losses relating to such exposures requires significant

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judgment about the potential range of outcomes. As additional information about current or future litigation or other contingencies becomes available, we will assess whether such information warrants the recording of additional expense relating to contingencies. To be recorded as expense, a loss contingency must be both probable and measurable. If a loss contingency is material but is not both probable and estimable, we will disclose it in notes to the financial statements.

Results of Operations

The following table sets forth certain data from our consolidated income statements for the years ended December 31, 2000, 2001 and 2002, and for the nine months ended September 30, 2002 and 2003, expressed as a percentage of net sales:

	Fiscal Years Ended December 31, (Restated)			Nine Months Ended September 30,	
	2000	2001	2002	2002	2003
Consolidated Statements of Operations Data:					
Net sales	100.0%	100.0%	100.0%	100.0%	100.0%
Cost of sales	50.7	41.9	38.5	39.6	37.5
Gross profit	49.3	58.1	61.5	60.4	62.5
Other income		0.5	0.2	0.2	0.2
Operating expenses:					
Sales and marketing	44.4	44.2	39.4	37.9	33.2
General and administrative	19.4	12.2	11.0	10.8	10.4
Engineering and development	24.1	9.2	6.2	6.0	5.1
Total operating expenses	87.9	65.6	56.6	54.7	48.7
Income (loss) from operations	(38.6)	(7.0)	5.1	5.9	14.0
Non-operating income (loss)	(1.0)	(0.7)	0.4	0.2	0.4
Income (loss) before cumulative effect of change in accounting principle	(39.6)	(7.7)	5.5	6.1	14.4
Cumulative effect of change in accounting principle	(0.4)			0.0	0.0
Net income (loss)	(40.0)%	(7.7)%	5.5%	6.1%	14.4%

Net Sales. Net sales consists of sales of our laser systems, related disposables and accessories and service revenue. We have at various times experienced fluctuations in sales due to seasonality. In our experience, sales in the first quarter typically are lower than average, and sales in the fourth quarter typically are stronger than average, due to the buying patterns of dental professionals. The fourth quarter of 2002 accounted for 30% of our net sales for the year, whereas the first quarter of 2002 accounted for 18% of net sales for the year. Sales in the third quarter tend to be even with and may sometimes be lower than sales in the second quarter due to vacation patterns. The third quarter accounted for 25% of our

net sales in 2002, whereas the second quarter accounted for 27% of our net sales in 2002. Our historical seasonality pattern is a recurring trend that we expect to continue. Consequently, we do not necessarily match the timing of our expenditures to the expected quarterly seasonality effects on revenue but rather anticipate the expected sales over the full year as a determinant of our spending levels. Since many of our costs are fixed in the short term, if we have a shortfall in sales resulting from a change in our historical seasonality pattern, or otherwise, we may be unable to reduce expenses quickly enough to avoid losses.

Many dentists finance their purchases through third party leasing companies or banks. In these transactions, the dentist first enters into a purchase order with us. We then enter into a purchase order with the leasing company, which purchases the product from us, and the dentist enters into a lease agreement with the leasing company. We receive payment in full for the product at the time of purchase by the leasing company, and we are not a party to the lease. The dentist pays the leasing company or bank in installments, and we do not bear the credit risk that the dentist might not make payments. The leasing companies and banks do not have recourse to us

for a dentist s failure to make payments, nor do we have any obligation to take back the product at the end of the lease. Approximately 38% of our revenue in 2000, 43% of our revenue in 2001, 36% of our revenue in 2002 and 32% of our revenue for the first nine months of 2003 were generated from dentists who financed their purchase through National Technology Leasing Corporation, an equipment leasing broker. We are regularly approached by leasing companies seeking to finance purchases of our products and do not believe the loss of National Technology Leasing or any other current financing source would materially harm our business.

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

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

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

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

Non-Operating Income (Loss). Non-operating income (loss) consists of interest income and expense, foreign currency gains and losses and similar items not directly related to our operations. Interest income relates to interest earned on our cash balances, and interest expense relates to interest costs on our line of credit. We generate a substantial portion of our revenue from the sale of products outside the United States. Sales to customers or distributors outside the United States accounted for approximately 23% of our revenue for the year ended December 31, 2002. Sales in Europe and Canada accounted for approximately 11% and 1% of our revenue for the year ended December 31, 2002, while sales in Asia and countries in the Pacific Rim accounted for approximately 12% of our revenue for 2002. Our sales in Europe are denominated principally in Euros, and our sales in other international markets are denominated in dollars. As we do not engage in hedging transactions to offset foreign currency fluctuations, we are at risk for changes in the value of the dollar relative to the value of the Euro. An increase in the relative value of the dollar would lead to less income from sales denominated in Euros unless we increase prices, which may not be possible due to competitive conditions in Europe. Conversely, a decrease in the relative value of the dollar would lead to more income from sales denominated in Euros. Additionally, we are obligated to pay expenses relating to our German facility in Euros. Thus, we are also at risk for changes in the value of the dollar relative to the Euro with respect to our obligation to pay expenses relating to our operations in Germany. An increase in the value of the dollar relative to the Euro would reduce the expenses associated with the operations of our German facility, whereas a decrease in the relative value of the dollar would increase the cost associated with the operations of our German facility.

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

The utilization of net operating loss and credit carryforwards may be limited under the provisions of Internal Revenue Code Section 382 and similar state provisions. Section 382 of the Internal Revenue Code of 1986 generally imposes an annual limitation on the amount of net operating loss (NOL) carryforwards that may be used to offset taxable income where a corporation has undergone significant changes in its stock ownership. In October 2003 we completed an analysis to determine the potential applicability of any annual limitations imposed by

Section 382. Based on our analysis, we believe that, as of December 31, 2002, we have, for federal income tax purposes, approximately $33.8 million of NOL carryforwards. Of this amount, approximately $28.1

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million is available immediately to offset 2003 federal taxable income or the taxable income generated in future years. Additional NOL carryforwards will become available at the rate of approximately $1.0 million per year for the years 2004 through 2009. However, any future ownership changes qualifying under Section 382 may limit an ability to use our remaining NOL carryforwards.

Nine Months Ended September 30, 2003 Compared With Nine Months Ended September 30, 2002

Comparing the results of operations between the nine months ended September 30, 2003 and September 30, 2002, the most significant change affecting operating results is the increase in net sales. Net sales for the nine months ended September 30, 2003 increased 73% over net sales for the nine months ended September 30, 2002.

Net Sales. Net sales for the nine months ended September 30, 2003 were $33.0 million, an increase of $13.9 million or 73%, as compared with net sales of $19.1 million for the nine months ended September 30, 2002. Approximately $10.1 million of the increase is due to a 53% increase in the number of products sold as a result of increased demand for our products. The remainder of the increase is due to a change in the timing of revenue recognition described below.

In August 2003, we modified our sales arrangements with our customers and began recognizing revenue upon shipment for our domestic sales, or on an accrual basis, which had previously been recognized upon receipt of payment in full, or on a cash basis. Additionally, we began to recognize revenue upon shipment for our international direct sales, which had previously been recognized after completion of installation. As a result of the change in our revenue recognition policy during the third quarter of 2003, our net sales are not directly comparable to the nine months ended September 30, 2002. During the nine months ended September 30, 2002, domestic sales were recognized on a cash basis and international direct sales were recognized after completion of installation.

Revenue during the nine months ended September 30, 2003 included $18.3 million of revenue for domestic sales recognized on a cash basis and $5.9 million recognized on an accrual basis. Revenue during the nine months ended September 30, 2003 included $1.6 million recognized for international direct sales upon completion of installation and $312,000 recognized upon shipment. As of September 30, 2003, our balance sheet reflects approximately $1 million of revenue that has been deferred on product shipments for which payment has not been received in full for domestic sales and where installation has not been completed for international direct sales. We cannot provide any assurance as to the timing or whether the deferred revenue will ultimately be collected, or when or whether installations will be completed. Other than the possible recognition of this deferred revenue balance, the positive impact to net sales for the nine months ended September 30, 2003 that resulted from the change in our revenue recognition policy will not occur in future periods.

The Waterlase and LaserSmile systems accounted for approximately 80% and approximately 13% of our net sales for the nine months ended September 30, 2003, respectively. We expect the Waterlase will continue to account for the majority of our sales. The recent decline in interest rates may have benefited purchasers of our products by reducing the interest expense to finance the purchase or lease of our products, although we do not believe it is possible to measure the effect of lower interest rates on our sales.

Many dentists finance their purchases through third party leasing companies. Approximately 32% of our net sales for the nine months ended September 30, 2003 and 38% of our net sales for the nine months ended September 30, 2002 were generated from dentists who financed their purchases through National Technology Leasing Corporation, an independent equipment leasing company.

International sales for the nine months ended September 30, 2003 were $7.3 million, or 22% of net sales, as compared with $3.9 million, or 20% of net sales, for the nine months ended September 30, 2002. Sales to Asia and Europe were $3.5 million and $2.9 million, respectively, for the nine months ended September 30, 2003 compared to $2.2 million and $1.2 million, respectively, for the nine months ended September 30, 2002.

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Gross Profit. Gross profit for the nine months ended September 30, 2003 was $20.6 million, or 63% of net sales, an increase of $9.0 million, as compared with gross profit of $11.6 million, or 60% of net sales for the nine months ended September 30, 2002. Gross profit during the nine months ended September 30, 2003 included $12.3 million of gross profit for domestic sales recognized on a cash basis and $4.0 million recognized on an accrual basis. Gross profit during the nine months ended September 30, 2003 included $1.1 million recognized for international direct sales upon completion of installation and $212,000 recognized upon shipment. The increase in gross profit is attributable to leveraging the increase in net sales against fixed and partially fixed manufacturing costs, reflecting better absorption of fixed manufacturing costs. Sales of the recently acquired Diolase and Pulsemaster systems have not had a significant impact on gross profit.

Other Income. Other income consists of gain on sales of assets. The gain on sales of assets for the nine months ended September 30, 2003 and September 30, 2002 of $51,000 and $47,000, respectively, consists of the amortization of the deferred gain relating to the sale and leaseback of our manufacturing facility in San Clemente, California, in March 2001.

Operating Expenses. Operating expenses for the nine months ended September 30, 2003 were $16.0 million, or 49% of net sales as compared with $10.5 million, or 55% of net sales for the nine months ended September 30, 2002. Approximately 66% of the increase, or $3.7 million, are sales and marketing costs that have been incurred to generate the increase in net sales.

Sales and Marketing. Sales and marketing expenses for the nine months ended September 30, 2003 were $11.0 million, or 33% of net sales, as compared with $7.3 million, or 38% of net sales, for the nine months ended September 30, 2002. The increase in absolute dollars was due to higher commission expense related to the increase in sales, including recognition of approximately $248,000 in deferred commission expense related to the revenue recognized in the third quarter that had been deferred, as well as increases of $226,000 in costs related to our national seminar marketing program, an increase of approximately $1.0 million in international sales and marketing and approximately $164,000 associated with an increase in the size and scope of the World Clinical Laser Institute symposium that we sponsored in January 2003. Incremental costs relating to the marketing and sale of the American Dental Laser products have not had a significant impact on total sales and marketing expense.

General and Administrative. General and administrative expenses for the nine months ended September 30, 2003 was $3.4 million, or 10% of net sales, as compared with $2.1 million, or 11% of net sales, for the nine months ended September 30, 2002. Professional expenses accounted for most of the dollar increase, including approximately $450,000 in expenses related to the restatement of our consolidated financial statements as well as expenses related to the preparation of our registration statement and to various consulting projects. The remaining increase in absolute dollars was due to a $396,000 increase in employee group and corporate insurance costs and $127,000 in bank charges relating to credit card sales. General and administrative costs have also increased to support the growth of the Company. No significant additional general and administrative costs have been incurred or are expected from the acquisition and production of the American Dental Laser products except for amortization expense related to certain intangible assets acquired. We recorded amortization expense for the nine months ended September 30, 2003 of $95,000, as compared with $18,000 for the nine months ended September 30, 2002.

Engineering and Development. Engineering and development expenses for the nine months ended September 30, 2003 was $1.7 million, or 5% of net sales, as compared with $1.1 million, or 6% of net sales, for the nine months ended September 30, 2002. The increase in absolute dollars is due to materials and consulting fees related to product development and enhancement. The change in engineering and development expenses as a percent of net sales reflects the larger sales base and normal fluctuations in the scope of current research and development projects.

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Gain on Foreign Currency Transactions. We realized a $135,000 gain on foreign currency transactions for the nine months ended September 30, 2003, compared to $14,000 for the nine months ended September 30, 2002 due to the changes in exchange rates between the United States dollar and Euro.

Gain on Forward Exchange Contracts. In the nine months ended September 30, 2003 and 2002, we realized gains of $22,000 and $102,000, respectively, due to the increase in the fair market value of our forward exchange contract which we purchased in connection of the debt incurred to acquire our facility in Germany. On February 3, 2003, the contracts expired and were not renewed.

Interest Income. Interest income relates to interest earned on our cash balances. Interest income for the nine months ended September 30, 2003 was $21,000 as compared with $13,000 for the nine months ended September 30, 2002 due to an increase in our cash balance.

Interest Expense. Interest expense decreased $57,000, or 57%, to $43,000 for the nine months ended September 30, 2003, as compared with September 30, 2002 due to a decrease in the effective interest rate on our credit facility. In May 2003, we entered into a $5.0 million credit facility with a bank to replace our existing line of credit. The new line of credit bears interest at LIBOR plus 2.25% as compared with the previous line of LIBOR plus 0.5%. Although the nominal rate on the new facility is higher, the previous facility was burdened by the amortization of the cost of a third-party guaranty.

Income Taxes. No provision for income tax was recognized for the nine months ended September 30, 2003 due to the availability of net operating loss carry forwards. No income tax benefit was recognized in the nine months ended September 30, 2002, as there was no assurance that the benefit of the net operating loss carry forwards would be realized. If in our judgment the recoverability of deferred tax assets, including the net operating loss carry forward, becomes more likely realizable than not, we will reduce the valuation allowance against our deferred tax assets, record an income tax benefit and subsequently record a provision for income tax for financial statement purposes based on the amount of taxable net income.

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

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

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

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

to add resources to our international sales program to take advantage of the large market potential and we expect that our international sales will continue to grow over time as a percentage of our total net sales. Although most of our international sales are made through independent distributors, we began making direct sales to dentists in Europe in 2002 with the support of our German distributor. Based on the overall increase and detailed review of

sales, we increased our allowance on accounts receivable from $108,000 at December 31, 2001 to $202,000 at December 31, 2002.

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

Other Income

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

Operating Expenses

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

Sales and Marketing. Sales and marketing expenses for the year ended December 31, 2002 was $10.7 million, or 39% of net sales, as compared with $7.3 million, or 44% of net sales, for the year ended December 31, 2001. The increase in absolute dollars from year to year was attributable to higher commission expense related to the increased sales and to the cost of additional sales personnel of approximately $600,000 in the United States. In addition during 2002, we expanded the scope of our nationwide seminar-marketing program and our sponsorship of education and training programs for existing and potential customers, as a result of which we incurred additional expenses of $871,000. Although growing 47% in 2002 in absolute dollars, sales and marketing expense as a percentage of net sales decreased from 44% in 2001 to 39% in 2002 due to the increase in sales generated by these efforts. In 2002, in addition to a number of local and regional symposiums, we sponsored two national and two international symposiums presented by the World Clinical Laser Institute, an organization that provides education and training in laser dentistry.

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

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

Non-Operating Income (Loss)

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

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

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

Income Tax. No provision for income tax was recognized for the year ended December 31, 2002 due to the availability of net operating loss carry forwards. No income tax benefit was recognized in the year ended December 31, 2002 as there was no assurance that the benefit of the net operating loss carry forwards would be realized. At such time as the recoverability of deferred tax assets, including the net operating loss carry forward, becomes more likely realizable than not, we will reduce the valuation allowance against our deferred tax assets, record an income tax benefit and subsequently record a provision for income tax for financial statement purposes based on the amount of taxable net income. As of December 31, 2002, we had net operating loss carry forwards for federal and state purposes of approximately $33.8 million and $7.5 million, respectively, which began expiring in 2001. As of December 31, 2002, we had research and development credit carryforwards for federal and state purposes of approximately $332,000 and $170,000, respectively. The utilization of net operating loss and credit carry forwards may be limited under the provisions of Internal Revenue Code Section 382 and similar state provisions.

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

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

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

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

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Other Income

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

Operating Expenses

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

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

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

Non-Operating Income (Loss)

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

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

Liquidity and Capital Resources

At September 30, 2003, we had $7.3 million in net working capital as compared with $1.4 million at December 31, 2002, $201,000 at December 31, 2001 and a working capital deficit of $268,000 at December 31, 2000. Our principal source of liquidity at September 30, 2003 consisted of our cash balance of $6.1 million. For the nine months ended September 30, 2003, our primary sources of cash were from operating activities of $847,000 and funds received in connection with the exercise of stock options and warrants of $3.5 million. These sources of cash were decreased by investments in property and equipment of $286,000 and our acquisition of the laser assets of American Medical Technologies of $1.8 million. The net effect on cash of operating, investing and financing transactions for the nine months ended September 30, 2003 was an increase of $2.2 million.

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For the year ended December 31, 2002, our sources of cash were from operating activities of $635,000 and the exercise of stock options and warrants of $1.0 million. These sources of cash were reduced by investments in property and equipment of $478,000. The net effect on cash of operating, investing and financing transactions for the year ended December 31, 2002 was an increase of $1.3 million.

In 2001, we incurred negative cash flow of $1.0 million from operating activities, substantially all resulting from the net increase in working capital. We financed our negative cash flow from operations through the exercise of warrants and stock options of $803,000 and from net cash received on the sale and leaseback of our San Clemente facility of $1.2 million.

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

	Fiscal Years Ended December 31,			Nine Months Ended September 30,
	2000	2001	2002	2003
Working capital (deficit) (2000, 2001 and 2002 restated)	$ (268)	$ 201	$ 1,418	$ 7,349
Cash provided by (used in) operations	(3,778)	(1,037)	635	847
Proceeds from the exercise of stock options and warrants	3,201	803	1,035	3,513
Current ratio (2000, 2001 and 2002 restated)	0.9	1.0	1.1	1.7
Accounts receivable collection period (days)	20.3	32.1	44.5	51.2
Inventory turnover	4.8	5.1	5.3	5.1

The accounts receivable collection period increased in the nine months ended September 30, 2003 due to a longer collection cycle on international accounts compared to the year ended December 31, 2002.

We purchased our production facility in Germany in February 2002 for cash consideration of approximately Euros 1.2 million payable in installments through 2003, subject to reduction in certain circumstances. The maximum consideration was reduced to Euros 989,000 in accordance with the terms of the agreement with the seller. The purchase agreement provided for a payment of Euros 582,000 by April 1, 2003 and Euros 175,000 on September 30, 2003, which were never paid due to subsequent discussions with the seller regarding a further reduction to the purchase price. The purchase agreement provided for the payment of Euros 232,000 on December 1, 2003. Based on our further discussions with the seller, in September 2003, the maximum consideration was reduced to Euros 986,000. In October 2003, we paid the seller Euros 986,000 plus applicable taxes, as full and final payment to the seller under the purchase agreement.

At September 30, 2003, we had $1.8 million outstanding under a $5.0 million revolving credit facility with Bank of the West. This same amount was outstanding at December 31, 2002 under a $1.8 million credit line with BSI AG. The facility with Bank of the West was entered into May 14, 2003 and is secured by all of our assets, is for a term of one year, bears interest at LIBOR plus 2.25%, and is payable on demand upon expiration of the stated term. Approximately $1.8 million was drawn immediately to pay off the bank line of credit with BSI AG. Under the terms of our credit line with Bank of the West, we are subject to certain covenants, which include, among other things, covenants to maintain a specified minimum tangible net worth and a specified ratio of current assets to current liabilities, and a covenant to maintain profitability. If we fail to satisfy these covenants and we fail to cure any breach of these covenants within a specified number of days after receipt of notice, Bank of the West could accelerate the entire amount borrowed by us and cancel the line of credit. Our credit line has an outstanding balance of approximately $1.8 million as of December 31, 2003. As a result of the restatement of our financial statements for the years ended December 31, 2000, 2001 and 2002, and the quarterly periods ended on March 31, June 30 and September 30, 2002, and March 31, 2003, as explained in our amended annual report on Form 10-K/A for the year ended December 31, 2002, and our amended quarterly reports on Form 10-Q/A for the quarters ended March 31, June 30 and September 30, 2002, and March 31, 2003, our accumulated deficit and our net tangible equity have decreased. Consequently, we were not in compliance with the following three covenants as of June 30, 2003: timely reporting of our financial statements for the period ended June 30, 2003; minimum tangible net equity, which is $6,897,000 compared with a minimum required tangible

net equity of $7,000,000;

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and the ratio of total liabilities to tangible net equity, which is 1.91 compared with a maximum allowed ratio of 1.75. We obtained waivers from the bank for each item of non-compliance as of June 30, 2003. We were in compliance with these covenants as of September 30, 2003, and as of December 31, 2003, the most recent evaluation date for determining compliance with the covenants. However, there is no assurance that we will be in compliance on future evaluation dates for determining compliance with these covenants. At September 30, 2003, we had $6.1 million in available cash. We used approximately $1.1 million of our available cash to pay off the debt on our German facility in October 2003. We believe any cancellation of our bank line would not have a material impact on our liquidity and that our cash from operations and the net proceeds of this offering will be sufficient to finance the cost of our operations.

On May 21, 2003 we acquired the American Dental Laser product line from American Medical Technologies, Inc., or AMT, for approximately $5.8 million. The assets acquired included dental laser patents, customer lists, brand names and other intellectual property as well as laser products. No outstanding debt of AMT was assumed in the transaction. The consideration paid by us consisted of approximately $1.8 million cash, $215,000 in transaction costs directly attributable to the acquisition and 307,500 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 the Nasdaq National Market between May 19, 2003 and May 23, 2003.

We had no material commitments for capital expenditures as of September 30, 2003 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, 2003, and for the periods ending on December 31 indicated below (in thousands):

	September 30, 2003	Three Months Ending December 31, 2003	Years Ending December 31, 2004	2005	2006
Line of credit	$ 1,792	$ 1,792	$	$	$
Short-term debt	1,145	1,145			
Operating leases	637	66	261	249	61
Total	$ 3,574	$ 3,003	$ 261	$ 249	$ 61

We believe that our current cash balances, cash expected to be generated from our operations, together with additional cash expected to be received through the exercise of stock options will be adequate to meet our debt service requirements and sustain our operations for at least the next twelve months. Beyond the next twelve months, if we continue to grow our sales volume at approximately the rate it has grown over the past several years, the adequacy of our cash balances to meet operating and capital needs will depend on our ability to be able to continue to generate sufficient cash flow from operations and our ability to borrow to support the funds necessary to support that growth rate. We believe the net proceeds of this offering, together with our cash balances and funds available under our bank credit line, will be sufficient to finance the cost of this growth.

Recent Accounting Pronouncements

In April 2002, the Financial Accounting Standards Board, or FASB, issued Statement of Financial Accounting Standards, or SFAS, No. 145, Rescission of SFAS Nos. 4, 44 and 64, Amendment of SFAS No. 13, and Technical Corrections. The significant items from SFAS 145 that are relevant to us are the provisions regarding extinguishment of debt and the accounting for sale-leaseback transactions. The provisions of this statement are applicable for financial statements issued on or subsequent to May 15, 2002. The adoption of this statement did not have an impact on our consolidated financial statements.

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In July 2002, the FASB issued SFAS No. 146, Accounting for Costs Associated with Exit or Disposal Activities. This statement addresses financial accounting and reporting for costs associated with exit or disposal activities and nullifies Emerging Issues Task Force, or EITF, Issue No. 94-3, Liability Recognition for Certain Employee Termination Benefits and Other Costs to Exit an Activity (including Certain Costs Incurred in a Restructuring). The provisions of this statement are effective for exit or disposal activities initiated after December 31, 2002. The adoption of this statement did not have an impact on our consolidated financial statements.

In November 2002, the EITF reached a consensus on Issue No. 00-21, Accounting for Revenue Arrangements with Multiple Deliverables. This Issue provides guidance on when and how to separate elements of an arrangement that may involve the delivery or performance of multiple products, services and rights to use assets into separate units of accounting. The guidance in the consensus is effective for revenue arrangements entered into in fiscal periods, interim or annual, beginning after June 15, 2003. We adopted Issue No. 00-21 on July 1, 2003. The adoption of Issue No. 00-21 did not have a material impact to our consolidated financial position, results of operations, or cash flows.

In November 2002, the FASB issued Interpretation No. 45, Guarantor s Accounting and Disclosure Requirements for Guarantees, Including Indirect Guarantees of Indebtedness of Others, or FIN 45. FIN 45 elaborates on the existing disclosure requirements for most guarantees, including loan guarantees such as standby letters of credit. It also requires that at the time a company issues a guarantee, our company must recognize an initial liability for the fair market value of the obligations it assumes under that guarantee and must disclose that information in our interim and annual financial statements. The initial recognition and measurement provisions of FIN 45 apply on a prospective basis to guarantees issued or modified after December 31, 2002. The adoption of FIN 45 did not have an impact on our consolidated financial statements.

In December 2002, the FASB issued SFAS No. 148, Accounting for Stock-Based Compensation-Transition and Disclosure-an amendment of FASB Statement No. 123. This amendment provides alternative methods of transition for a voluntary change to the fair value based method of accounting for stock-based employee compensation. In addition, this statement amends the disclosure requirement of Statement 123 to require prominent disclosures in both annual and interim financial statements about the method of accounting for stock-based employee compensation and the effect of the method used on reported results. SFAS 148 is effective for fiscal years ending after December 15, 2002. Since we are continuing to account for stock-based compensation according to APB 25, our adoption of SFAS No. 148 requires us to provide prominent disclosures about the effects of FAS 123 on reported income and will require us to disclose these affects in the interim financial statements as well.

In May 2003, the FASB issued SFAS 150, Accounting for Certain Financial Instruments with Characteristics of both Liabilities and Equity. SFAS 150 establishes standards for how an issuer classifies and measures certain financial instruments with characteristics of both liabilities and equity. It requires that an issuer classify a financial instrument that is within its scope as a liability (or an asset in some circumstances). Many of those instruments were previously classified as equity. This Statement is effective for financial instruments entered into or modified after May 31, 2003 (except for mandatorily redeemable noncontrolling interests). For all instruments that existed prior to May 31, 2003, the Standard is effective at the beginning of the first interim period beginning after June 15, 2003 (except for mandatorily redeemable noncontrolling interests). For mandatorily redeemable noncontrolling interests, the FASB has deferred the provisions of SFAS 150 until further notice. The provisions of SFAS 150 adopted thus far did not have a material effect on our financial statements and the adoption of the remaining provision of SFAS 150 is not expected to have a material effect on our financial statements.

Quantitative and Qualitative Disclosures about Market Risk

As discussed in Note 5 to the Consolidated Financial Statements, we acquired a production facility in Germany in February of 2002. The debt related to those assets was paid on October 10, 2003. In conjunction with

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a portion of the debt due in 2003, we entered into a forward contract to purchase approximately $700,000 of Euros at an exchange rate of 0.8575. On February 3, 2003, the contracts expired and were not renewed, resulting in a cumulative realized gain on the contracts of $174,000.

Since February 3, 2003, we have not engaged in transactions to offset currency fluctuations. In October 2003, we paid off the debt on our German facility. The value of the German facility itself as stated in dollars on our balance sheet will vary as the exchange rate of the dollar and the Euro varies.

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 reduce our earnings.

Our bank line of credit bears interest at a variable rate tied to LIBOR plus 2.25%, which makes the current effective interest rate 3.4% at September 30, 2003. A 10% increase in LIBOR would increase the effective interest rate from 3.4% to 3.5%, which would not result in a material difference to our interest expense on our outstanding bank debt of $1.8 million.

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BUSINESS

Overview

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

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

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

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

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

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Industry Background

General

More than 200 million hard tissue procedures are performed annually in the United States, according to a 1999 survey by the American Dental Association. Hard tissue procedures include cavity preparation, inlays, crowns, root canals and other procedures involving bone or teeth. Based on this survey, more than 1.2 million soft tissue procedures are performed annually in the United States. Soft tissue procedures include gum line alteration, gum grafts and other procedures involving soft dental tissue. According to statistics compiled by the American Dental Association, over 90% of hard tissue procedures and 60% of soft tissue procedures in the United States are performed by general dentists, and the rest are performed by oral surgeons, periodontists and other specialists.

The American Dental Association estimates that the demand for dental services in the United States will continue to grow due to population growth and the increased awareness of the benefits associated with preventive dentistry in reducing the incidence of oral disease. According to the U.S. Center for Medicare and Medicaid Services, annual expenditures in the United States in 2000 for dental services were $60 billion, and are expected to increase to approximately $100 billion by 2010.

Traditional Dental Instruments

Dental procedures are performed on hard tissue, such as bone and teeth, and soft tissue, such as gum and other oral tissue. Dentists and other specialists choose from a variety of instruments depending on the tissue involved and the type of procedure. Most procedures require the use of multiple instruments to achieve the desired result.

High Speed Drills. Most dentists use high speed drills for hard tissue procedures, such as preparing cavities for filling and gaining access for performing root canals. Adverse effects associated with drills include heat production, vibration and noise. The cutting and grinding action of high speed drills can cause damage to the patient s dental structure, including microfractures in teeth. Microfractures can provide an entry point for bacteria, which can cause tooth decay and weaken the tooth s underlying structure, which can lead to fractures and broken cusps. Crowns and root canals may become necessary as a result of damage caused during previous dental procedures.

Cutting Instruments. Soft tissue procedures, such as reshaping gum lines and grafting on new gum tissue, are typically performed by oral surgeons or periodontists using scalpels, scissors and other cutting tools. Due to the pain and discomfort associated with procedures performed with these instruments, most soft tissue procedures require the use of anesthetics, which cause numbness and discomfort, and often require stitches. Use of scalpels, scissors and other cutting tools typically cause bleeding, post-operative swelling and discomfort. Bleeding reduces the practitioner s visibility and efficiency, and generally makes procedures more cumbersome. Bleeding is a particular problem for patients with immune deficiencies or blood disorders, and patients taking blood-thinning medications.

Alternative Dental Instruments

Alternative technologies have been developed over the years to address the problems associated with traditional methods used in dentistry. Most alternatives have addressed either hard or soft tissue applications. The predominant alternative technologies and their limitations are discussed below.

Air Abrasion Systems. Air abrasion systems were introduced as an alternative to the high speed drill for hard tissue procedures. Air abrasion systems blow a powerful air stream of aluminum oxide particles to erode hard tissue and remove the harder forms of decay. Air abrasion is most commonly used to repair cracks and discolorations, clean out pits and fissures, prepare cavities to be filled with composites and prepare tooth surfaces

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for bonding. However, air abrasion is not suitable for a variety of hard tissue procedures including bone, and cannot be used on, or very near to, soft tissue. In addition, the use of air abrasion is time consuming and scatters particles that can be inhaled by patients and staff, and that can damage equipment and instruments. Due to these limitations, we believe the popularity of these systems has declined over the last few years.

Electrosurge Systems. A commonly used technology, known as electrosurge, was developed to cut soft tissue. Electrosurge systems use an electrical spark that simultaneously cuts and cauterizes tissue, resulting in less bleeding than occurs with scalpels. Traditional electrosurge results in deep penetration, which can cause unwanted damage to surrounding tissue, and is generally less precise than lasers. Electrosurge is not suitable for hard tissue procedures and, due to the depth of penetration, generally requires use of anesthesia and involves a lengthy healing process. Use of most electrosurge units is restricted near metal fillings and dental implants. Additionally, electrosurge generally cannot be used with patients with implanted pacemakers and defibrillators.

Traditional Laser Systems. More recently, lasers have gained acceptance for use in general and cosmetic dentistry. Most lasers used in dentistry have been adapted from other medical applications, such as dermatology, and were not designed to perform a wide range of common dental procedures. Most dental lasers use thermal energy to cut tissue and are used primarily for soft tissue procedures.

Due to the limitations associated with traditional and alternative dental instruments, we believe there is a large market opportunity for dental laser systems that provide superior clinical results and help reduce the trauma, pain and discomfort associated with dental procedures. We also believe there is a significant opportunity among dental practitioners for new, more effective tools that increase patient satisfaction, improve outcomes and enhance practice profitability.

The BioLase Solution

We believe the superior performance and ease of use of our systems will position them as the instruments of choice among practitioners and patients for a broad range of common dental procedures. We have developed our laser systems and related products specifically for the dental market to more effectively perform a broad range of dental procedures. The skill level and dexterity necessary to operate our laser systems are similar to those necessary to operate conventional drills and other dental equipment. Our laser systems also have the advantage of being able to perform procedures in narrow spaces where access for conventional instruments often is limited. Our systems are intended to complement traditional tools, such as dental drills, which perform functions that our systems do not address, such as cutting metal fillings and certain polishing and grinding functions.

Our primary product, the Waterlase system, is the best selling dental laser system. The Waterlase precisely cuts hard tissue, such as bone and teeth, and soft tissue, such as gums, with minimal or no damage to surrounding tissue and dental structure. Our LaserSmile system is designed to complement the Waterlase, and is used in soft tissue procedures and tooth whitening. We recently acquired the American Dental Laser product line, which includes the Diolase and Pulsemaster systems, primarily for use in soft tissue procedures. The Diolase and Pulsemaster, together with our Waterlase and LaserSmile systems, will offer practitioners a broad product line with a range of features and price points.

A small percentage of dental professionals worldwide currently use lasers, and our systems are more expensive than traditional dental tools. However, we believe that the significant performance advantages of our systems, the potential return on investment that our systems offer practitioners and the options available to finance the purchase of our systems will enable us to continue to increase our sales and leading market position.

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

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Benefits to Dental Professionals

Additional procedures through increased efficiency. Our systems often shorten and reduce the number of patient visits, providing dental professionals with the ability to service more patients. For hard tissue procedures, the Waterlase reduces the need for anesthesia and enables dental practitioners to perform multiple procedures in one visit. An advantage of the Waterlase is that it can be used to perform cavity preparations in multiple quadrants. In contrast, many dentists using high speed drills usually do not perform cavity preparations in more than one quadrant per visit because of concerns relating to use of anesthesia in multiple regions. For soft tissue procedures, the Waterlase and LaserSmile systems allow tissue to be cut more precisely and with minimal bleeding. The LaserSmile performs tooth whitening faster than competing non-laser systems due to its high power and the fast activation of our proprietary whitening gel.

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

Increased loyalty and expanded patient base. We believe the improved patient comfort and convenience offered by our systems will improve patient retention, attract new patients and increase demand for elective procedures.

Fewer post-op complications. Our laser systems can reduce trauma, swelling and general discomfort, resulting in fewer post-operative complications that require follow up treatment. Practitioners can devote time to new cases, rather than treating complications from prior procedures.

Benefits to Patients

Comfort. With our Waterlase system, patients experience dramatically improved comfort during and after most procedures. In most cases, procedures can be performed without anesthesia, which eliminates the pain associated with injections and the feeling of numbness following the procedure.

Convenience. Dentists generally prefer to perform procedures that require anesthesia in no more than one or two quadrants of the mouth in a single visit because of concerns related to the use of anesthesia in multiple quadrants. Our systems do not require anesthesia in most cases, which allows procedures to be performed in multiple quadrants during a single office visit. This reduces the number of visits necessary to complete the patient s treatment plan.

Reduced trauma. Trauma to the dental structure can be reduced because the laser avoids the vibration and microfractures associated with the high speed dental drill. For soft tissue applications, our laser systems cut with less bleeding than typically achieved with conventional instruments.

Broader range of available procedures. Due to the improved comfort and convenience of our systems, we believe patients are more likely to consider cosmetic and other elective procedures that would generally be time consuming and uncomfortable.

Business Strategy

Our objectives are to increase our leadership position in the dental laser market and to establish our laser systems as essential tools in dentistry. Our business strategy consists of the following key elements:

Increase awareness of our laser systems among dental practitioners and patients. We intend to further penetrate the dental market by educating dental practitioners and patients about the clinical benefits of our laser systems, particularly the Waterlase system. We plan to increase adoption of our laser systems by practitioners through our continued participation in key industry trade shows, the World Clinical

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Laser Institute, dental schools and other educational forums. We also intend to market our systems to practitioners through our direct sales force and advertising. We have recently begun and plan to continue marketing efforts aimed directly at patients.

Expand sales and distribution capabilities. In the United States, we intend to continue to build a direct sales force and marketing team. Internationally, we intend to use established dental and medical device distributors and to use a direct sales force in select countries. We are developing an infrastructure to support growth in sales and marketing. This infrastructure includes information technology systems and personnel to manage our sales force, compile sales and marketing data, and better serve our customers and distributors.

Expand product platform and applications. We plan to expand our product line and product applications by developing product enhancements and new laser technologies. Additionally, we may strategically acquire complementary products and technologies. We recently acquired the American Dental Laser product line, including the Diolase and Pulsemaster systems, which we believe will enable us to increase market penetration by offering a broad line of laser systems with a range of features and price points.

Continue high quality manufacturing and customer service. Our manufacturing operations in California and Germany are focused on producing high quality dental laser systems. We intend to continually develop and refine our manufacturing processes to increase production efficiencies and product quality. We provide high quality maintenance and support services through our support hotline and dedicated staff of in-house and field service personnel. Additionally, we plan to maintain and expand our network of factory-trained service technicians to provide maintenance and support services to customers in Europe and other markets outside the United States.

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

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Products

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

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

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

	Cosmetic: Gingivectomy and gingivoplasty.	
Pulsemaster System	*Soft Tissue*: Incision, excision and biopsy of soft tissue, frenectomy, troughing, gingivectomy, gingivoplasty and other soft tissue surgical applications.	Neodymium: Yttrium, Aluminum, Garnet (Nd:YAG), Crystal Laser
	Cosmetic: Gingivectomy and gingivoplasty.	

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BioLase Product Line

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

Waterlase System. The Waterlase laser uses an Er, Cr: YSGG crystal, which produces a unique wavelength optimized for dental applications. Using YSGG Laser Hydrokinetics, the Waterlase enables highly controlled cutting of bone and tooth with minimal to no damage to surrounding tissue, resulting in less trauma and pain than is achieved with dental drills or other dental instruments. The Waterlase can cut teeth or bone in narrow spaces with limited access for conventional instruments. By reducing or eliminating the water spray level, the Waterlase can also be used to perform a number of soft tissue procedures. Our Waterlase cuts soft tissue efficiently and provides effective coagulation in many types of soft tissue procedures. The approximate list price of the Waterlase system is $50,000.

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

American Dental Laser Product Line

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

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

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

Related Accessories and Disposable Products

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

complete line of accessories for the Diolase and Pulsemaster systems, as well as other accessories marketed under the American Dental Laser brand name.

Warranties and Insurance

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

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Manufacturing

We manufacture, assemble and test our products at manufacturing facilities located in San Clemente, California and Floss, Germany. We acquired our German manufacturing facility in 2002. We manufacture and install our systems and provide maintenance services for products sold in Europe and other international markets through our German operations. Sales of products manufactured at our German facility accounted for 9% of our revenue in 2002 and 13% of our revenue for the nine months ended September 30, 2003.

We use an integrated approach to manufacturing, including the assembly of laser heads, electronics and cabinetry, which allows us to maintain high quality and control cost. We obtain components and subassemblies for our products from third party suppliers, most of which are located in the United States. We generally purchase components and subassemblies from a limited group of suppliers through purchase orders. We have no written supply contracts with our key suppliers. Three key components used in our Waterlase system, which accounted for approximately 77% of our revenue in 2002 and approximately 80% of our revenue for the nine months ended September 30, 2003, are each supplied by a separate single-source supplier. The Waterlase hand pieces are made by a leading European supplier of precision hand tools, and the laser crystal and fiber components are each made by a separate supplier. We have not experienced material delays from the suppliers of these three key components, and we have identified and tested alternative suppliers for each of these components. However, an unexpected interruption in a single source supplier could create manufacturing delays, and disrupt sales as we sought to replace the supplier, which we estimate could take up to three months.

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

Marketing and Sales

Marketing

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

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

Patients. We recently began to market the benefits of our laser systems directly to patients through marketing and advertising programs, including print media and radio spots, sponsored jointly by dental practitioners and us in selected markets that we feel have strong growth

potential. We believe that making patients aware of our laser systems and their benefits will increase demand for our products.

Sales

We currently sell our products primarily to dentists in general practice. The majority of the dentists in the United States, as well as the majority of our customers, are sole practitioners. As awareness of our laser systems

increases, we expect an increase in demand for our products among group practices. We also expect our laser systems to gain acceptance among oral surgeons and other dental specialists, as they become better aware of the clinical benefits and new treatment options available through use of our laser systems.

International sales account for a significant portion of our revenue. International sales accounted for approximately 23% or our revenue in 2002, 20% of our revenue in 2001 and 41% or our revenue in 2000. Sales in Asia, Pacific Rim countries and Australia accounted for approximately 12% of our revenue in 2002, while sales in Europe and Canada accounted for 11% and 1% of our 2002 revenue, respectively. In 2001, sales in Europe accounted for approximately 9% of revenue for the year, whereas sales in Asia and Pacific Rim countries accounted for approximately 8% of the revenue. In 2000, sales in Europe accounted for approximately 24% of our revenue for the year, and sales in Asia and Pacific Rim countries accounted for approximately 11% of the revenue for the year.

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

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

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

Customer Service. We provide maintenance and support services through our support hotline, service personnel and network of factory-trained service technicians. We provide maintenance and support services in the United States and Germany through our employee service technicians. We train and maintain a network of service technicians trained at our factory locations, who provide maintenance and support services in all other countries where we do business. Our distributors are responsible for providing maintenance and support services for products sold by them. We provide parts to distributors at no additional charge for products covered under warranty.

Financing Options. Many dentists finance their purchases through third party leasing companies or banks. In these transactions, the dentist first enters into a purchase order with us. We then enter into a purchase order with the leasing company, which purchases the product from us, and the dentist enters into a lease agreement

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with the leasing company. We receive payment in full for the product at the time of purchase by the leasing company, and we are not a party to the lease. The dentist pays the leasing company or bank in installments, and we do not bear the credit risk that the dentist might not make payments. The leasing companies and banks do not have recourse to us for a dentist s failure to make payments, nor do we have any obligation to take back the product at the end of the lease. Approximately 36% of our revenue in 2002 was generated from sales to dentists who financed their purchase through National Technology Leasing Corporation, an equipment leasing broker. National Technology Leasing arranges financing through banks. We have an agreement with National Technology Leasing under which we agreed to offer National Technology Leasing first right of refusal when dentists desire to use a finance or lease company. Our customers are under no obligation to finance the purchase or lease of any equipment through National Technology Leasing, and we refer only those customers that request a referral from us. In exchange, National Technology Leasing agreed to give us first priority on scheduling personnel in support of our sales functions, and on processing lease or financing transactions for our customers. National Technology Leasing further agreed to sponsor marketing programs from time to time for our benefit and the benefit of our customers. Additionally, National Technology Leasing agreed to accept the terms of our customer purchase order in transactions in which it is a party pursuant to the revised agreement entered into August 5, 2003. The term of the agreement expires on August 5, 2004, and can be renewed for one-year periods after that time. The agreement also may be terminated by either party upon 45 days written notice. If leasing arrangements were no longer available through National Technology Leasing or the banks with which it deals, we believe our customers would be able to obtain financing through a variety of other leasing companies or banks that frequently approach us to provide financing for our products.

Research and Product Development

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

Intellectual Property and Proprietary Rights

We rely, in part, on a combination of patents, trademarks, trade secrets, copyright and other intellectual property rights to protect our technology. We have over 60 issued patents and numerous pending patents. More than half of our existing patents were issued in the United States, and the rest were issued in Europe and in other countries. Our patents are directed to the use of laser and water in dentistry, laser energy exciting water, laser characteristics, fluid conditioning, laser accessories, laser technology development and other technologies for dental and medical applications. We have patent applications pending and plan to apply for other patents in the future as we develop new technologies. While we hold a variety of patents covering a broad range of technologies incorporated in our products, we rely on approximately one half of our patents in particular to protect the core technology incorporated in our systems, including our Waterlase system, which accounted for approximately 77% of our revenue in 2002 and approximately 80% of our revenue for the nine months ended September 30, 2003. Four of these patents expire in 2009, and the balance have expiration dates ranging from 2010 to 2015.

We are currently involved in a patent lawsuit related to our Waterlase system with Diodem, LLC, a privately-held California limited liability company, which resulted from the consolidation of two separate lawsuits that were pending before the U.S. District Court for the Central District of California. In May 2003, we initiated a lawsuit against Diodem to obtain a judicial declaration that technology in our Waterlase does not

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infringe four patents owned by Diodem. Diodem was founded by the former chief executive officer of Premier Laser Systems, Inc., a medical laser company which filed for bankruptcy protection in March 2000. Diodem claims to have acquired the four patents at issue in the case from Premier Laser. Also, in May 2003, Diodem added us as a party to a patent infringement lawsuit it had previously filed. These two lawsuits initiated by us and Diodem were consolidated into the currently pending lawsuit in August 2003. Diodem alleges that the technology in our Waterlase system infringes the four patents it acquired from Premier Laser. Diodem seeks monetary damages, an injunction and other relief. The pending lawsuit is in its preliminary stages, and may proceed for an extended period of time. Although the outcome of this action cannot be determined with certainty, we believe our technology and products do not infringe any valid patent rights owned by Diodem, and we intend to continue to vigorously defend against Diodem s infringement claims and pursue our claims against Diodem.

Competition

We compete with a number of companies that market traditional dental products, such as dental drills, as well as other companies that market laser technologies in dental and other medical markets. In the domestic hard tissue dental market, we believe our Waterlase product primarily competes with laser systems manufactured by Hoya ConBio, a subsidiary of Hoya Photonics, a large Japanese manufacturer primarily of optics and crystals, and OpusDent Ltd., a subsidiary of Lumenis, an Israeli company. In the international market, our Waterlase system competes primarily with products manufactured by several other companies, including KaVo, Deka Dental Corporation and Fotona d.d.

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

Traditional and commonly used cutting tools are less expensive for performing dental procedures. For example, a high speed drill or an electrosurge device can be purchased for less than $1,000 each. However, we believe our systems offer substantial benefits that outweigh cost concerns. In addition, our systems are not designed to perform certain functions that high speed drills can perform, such as cutting metal fillings and certain polishing and grinding functions. High speed drills will still be needed for these functions, and our systems are not intended to replace all applications of the high speed drill.

We also compete on the basis of proprietary technology, product features, performance, service and reputation. Some of the manufacturers that develop competing laser systems have greater financial, marketing and technical resources than we do. In addition, some competitors have developed, and others may attempt to develop, products with applications similar to the those performed by our laser systems.

Government Regulation

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

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United States

In the United States, the FDA regulates the design, manufacture, distribution, quality standards and marketing of medical devices. We have clearance from the FDA to market our Waterlase and LaserSmile systems in the United States for dental procedures on both adult and pediatric patients. In 1998, we received FDA clearance to market the Millennium, the earlier generation of our current Waterlase system, for certain dental hard tissue applications. This clearance allowed us to commence domestic sales and marketing of our technology for hard and soft tissue applications. During 1999 and 2000, to meet the demand for soft-tissue and cosmetic dentistry applications, we designed a semiconductor diode laser system, which is now marketed as our LaserSmile system. We received FDA clearance to market the system for a variety of soft-tissue medical applications in September 1999. In 2001, we received FDA clearance to market the LaserSmile system for cosmetic tooth whitening. In October 2003, the LaserSmile received clearance for periodontal procedures for both early and advanced stages of periodontal disease.

In 2002, 2003 and 2004, our Waterlase system became the first laser system to receive FDA clearance for several new types of procedures. In 2002, we received clearance to market the Waterlase system for root canal, encompassing all four of the fundamental steps of the procedure. We also received clearance in 2002 to market this system for cutting, shaving, contouring and resection of oral osseous tissues, or bone. In January 2003, we received FDA clearance to market the Waterlase for use in apicoectomy surgery, a procedure for root canal infections and complications that includes cutting gum, bone (to access the infected area) and the apex of the tooth to access the infected area. The clearance also relates to flap surgical procedures. Flaps are frequently performed in conjunction with many procedures, including periodontal, implant placement and recovery, extraction of wisdom teeth, exposure of impacted teeth for orthodontics as well as additional procedures. In January 2004, our Waterlase system received FDA clearance for several new bone, laser periodontal and soft tissue procedures, including removal of bone to correct defects and create physiologic contours of bone tissue, resection of bone to restore bony architecture, resection of bone for grafting, preparing full, partial and split thickness flaps for periodontal surgery and removal of granulation tissue from bony defects. Additionally, the Waterlase became the first hard tissue laser to receive clearance for laser soft tissue curettage.

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

As we develop new products and applications or make any significant modifications to our existing products, we will need to obtain the regulatory approvals necessary to market such products for dental, cosmetic and other medical procedures in our target markets. There are two principal methods by which FDA regulated devices may be marketed in the United States: pre-market approval, or PMA, and 510(k) clearance. A PMA application is required for a device that does not qualify for consideration for 510(k) clearance. The review period for a PMA application is fixed at 180 days, but the FDA typically takes much longer to complete the review. As part of the approval of a PMA application, the FDA typically requires human clinical testing to determine safety and efficacy of the device. To conduct human clinical testing, typically the FDA must approve an Investigational Device Exemption, or an IDE. To date, none of our products have required a PMA application.

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

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After a device receives 510(k) clearance, any modification that could significantly affect its safety or effectiveness, or that would constitute a major change in its intended use, will require a new 510(k) clearance, or could even require a PMA application. The FDA requires each manufacturer to make this determination initially, but the FDA can review any such decision and can disagree with a manufacturer s determination. If the FDA disagrees with a manufacturer s determination, the FDA can require the manufacturer to cease marketing and/or recall the modified device until 510(k) clearance or a PMA is obtained.

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

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

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

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

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

- fines, injunctions and civil penalties;
- recall or seizure of our products;
- operating restrictions, partial suspension or total shutdown of production;
- refusing our request for 510(k) clearance or PMA approval of new products;

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

criminal prosecution.

International

Foreign sales of our laser-based products are subject to the regulatory requirements of the foreign country or, if applicable, the harmonized standards of the European Union. These regulatory requirements vary widely

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

Other Regulatory Requirements

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

Third Party Reimbursement

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

Employees

At December 31, 2003, we employed approximately 156 people, of which there are approximately 55 in manufacturing and quality and control, 14 in research and development, approximately 56 in sales and sales support, 15 in customer technical support and 16 in administration. Our employees are not represented by any collective bargaining agreement and we believe our employee relations are good.

Facilities

Our corporate headquarters are located at 981 Calle Amanecer, San Clemente, California, where we lease 23,000 square feet of space for manufacturing and administrative functions. The lease on this facility expires on March 31, 2006. Our wholly-owned subsidiary, BIOLASE Europe, owns a manufacturing facility totaling approximately 20,000 square feet of space in Floss, Germany. Our subsidiary currently leases half of the facility to an unrelated party and uses the remaining portion of the facility for its manufacturing operations. We believe that our facilities are sufficient for our current needs.

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PLAN OF DISTRIBUTION

The common stock offered by this prospectus is being offered by Fusion Capital Fund II, LLC, the selling stockholder. The common stock may be sold or distributed from time to time by the selling stockholder directly to one or more purchasers or through brokers, dealers, or underwriters who may act solely as agents at market prices prevailing at the time of sale, at prices related to the prevailing market prices, at negotiated prices, or at fixed prices, which may be changed. The sale of the common stock offered by this prospectus may be effected in one or more of the following methods:

- ordinary brokers' transactions;
- transactions involving cross or block trades;
- through brokers, dealers, or underwriters who may act solely as agents
- "at the market" into an existing market for the common stock;
- in other ways not involving market makers or established business markets, including direct sales to purchasers or sales effected through agents;
- in privately negotiated transactions; or
- any combination of the foregoing.

In order to comply with the securities laws of certain states, if applicable, the shares may be sold only through registered or licensed brokers or dealers. In addition, in certain states, the shares may not be sold unless they have been registered or qualified for sale in the state or an exemption from the registration or qualification requirement is available and complied with.

Brokers, dealers, underwriters, or agents participating in the distribution of the shares as agents may receive compensation in the form of commissions, discounts, or concessions from the selling stockholder and/or purchasers of the common stock for whom the broker-dealers may act as agent. The compensation paid to a particular broker-dealer may be less than or in excess of customary commissions.

Fusion Capital is an "underwriter" within the meaning of the Securities Act.

Neither we nor Fusion Capital can presently estimate the amount of compensation that any agent will receive. We know of no existing arrangements between Fusion Capital, any other stockholder, broker, dealer, underwriter, or agent relating to the sale or distribution of the shares offered by this prospectus. At the time a particular offer of shares is made, a prospectus supplement, if required, will be distributed that will set forth the names of any agents, underwriters, or dealers and any compensation from the selling stockholder, and any other required information.

We will pay all of the expenses incident to the registration, offering, and sale of the shares to the public other than commissions or discounts of underwriters, broker-dealers, or agents. We have also agreed to indemnify Fusion Capital and related persons against specified liabilities, including liabilities under the Securities Act.

Insofar as indemnification for liabilities arising under the Securities Act may be permitted to our directors, officers, and controlling persons, we have been advised that in the opinion of the SEC this indemnification is against public policy as expressed in the Securities Act and is, therefore, unenforceable.

Fusion Capital and its affiliates have agreed not to engage in any direct or indirect short selling or hedging of our common stock during the term of the common stock purchase agreement.

We have advised Fusion Capital that while it is engaged in a distribution of the shares included in this prospectus it is required to comply with Regulation M promulgated under the Securities Exchange Act of 1934, as amended. With certain exceptions, Regulation M precludes the selling stockholder, any affiliated purchasers, and any broker-dealer or other person who participates in the distribution from bidding for or purchasing, or attempting to induce any person to bid for or purchase any security which is the subject of the distribution until the entire distribution is complete. Regulation M also prohibits any bids or purchases made in order to stabilize the price of a security in

connection with the distribution of that security. All of the foregoing may affect the marketability of the shares offered hereby this prospectus.

This offering will terminate on the date that all shares offered by this prospectus have been sold by Fusion Capital.

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DESCRIPTION OF SECURITIES

Our authorized capital stock consists of 255,000,000 shares of capital stock, of which 250,000,000 shares are common stock, par value $.001 per share, 4,600,000 shares are preferred stock, par value $0.001 per share, 200,000 are Series B Convertible Preferred Stock, par value $0.05 per share, and 200,000 shares are Series C Convertible Preferred Stock, par value $0.05 per share. As of February 14, 2008, there were issued and outstanding 99,244,777 shares of common stock, options to purchase approximately 10,349,839 shares of common stock and warrants to purchase approximately 30,598,230 shares of common stock. The amount outstanding excludes the $8.5 million of common stock that may be issued to the selling stockholder.

Common Stock

Holders of our common stock are entitled to one vote for each share held in the election of directors and in all other matters to be voted on by the stockholders. There is no cumulative voting in the election of directors. Holders of common stock are entitled to receive dividends as may be declared from time to time by our board of directors out of funds legally available therefor. In the event of liquidation, dissolution or winding up of the corporation, holders of common stock are to share in all assets remaining after the payment of liabilities. Holders of common stock have no pre-emptive or conversion rights and are not subject to further calls or assessments. There are no redemption or sinking fund provisions applicable to the common stock. The rights of the holders of the common stock are subject to any rights that may be fixed for holders of preferred stock. All of the outstanding shares of common stock are fully paid and non-assessable.

Preferred Stock

Our Certificate of Incorporation authorizes the issuance of 4,600,000 shares of preferred stock with designations, rights, and preferences as may be determined from time to time by the board of directors. The board of directors is empowered, without stockholder approval, to designate and issue additional series of preferred stock with dividend, liquidation, conversion, voting or other rights, including the right to issue convertible securities with no limitations on conversion, which could adversely affect the voting power or other rights of the holders of our common stock, substantially dilute a common stockholder’s interest and depress the price of our common stock.

No shares of the Series B Convertible Preferred Stock or the Series C Convertible Preferred Stock are outstanding.

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MARKET FOR COMMON EQUITY AND RELATED STOCKHOLDER MATTERS

Our common stock is presently quoted on the OTCBB under the symbol "DORB." The table below sets forth the high and low sales prices, as provided by the American Stock Exchange and as quoted on the OTCBB, in each quarter for the period from January 1, 2006 through December 31, 2007.

	Price Range	
Period	High	Low
Fiscal Year Ended December 31, 2006:		
First Quarter	$0.69	$0.26
Second Quarter	$0.40	$0.23
Third Quarter	$0.33	$0.20
Fourth Quarter	$0.30	$0.21
Fiscal Year Ended December 31, 2007:		
First Quarter	$0.71	$0.23
Second Quarter	$0.95	$0.20
Third Quarter	$0.40	$0.26
Fourth Quarter	$0.61	$0.15

On April 18, 2006, our common stock was delisted from the American Stock Exchange and began to be quoted on the OTCBB. As of February 11, 2008, the last reported price of our common stock quoted on the OTCBB was $0.18 per share. The OTCBB price quoted reflects inter-dealer prices, without retail mark-up, mark-down or commission, and may not represent actual transactions. We have approximately 1,072 registered holders of record.

Dividend Policy

We have never declared nor paid any cash dividends, and currently intend to retain all our cash and any earnings for use in our business and, therefore, do not anticipate paying any cash dividends in the foreseeable future. Any future determination to pay cash dividends will be at the discretion of the Board of Directors and will be dependant upon our consolidated financial condition, results of operations, capital requirements and such other factors as the Board of Directors deems relevant.

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DISCLOSURE OF COMMISSION POSITION ON INDEMNIFICATION FOR SECURITIES ACT LIABILITIES

Section 102(b)(7) of the Delaware General Corporation Law allows companies to limit the personal liability of its directors to the company or its stockholders for monetary damages for breach of a fiduciary duty. Article IX of the Company's Certificate of Incorporation, as amended, provides for the limitation of personal liability of the directors of the Company as follows:

"A Director of the Corporation shall have no personal liability to the Corporation or its stockholders for monetary damages for breach of his fiduciary duty as a Director; provided, however, this Article shall not eliminate or limit the liability of a Director (i) for any breach of the Director's duty of loyalty to the Corporation or its stockholders; (ii) for acts or omissions not in good faith or which involve intentional misconduct or a knowing violation of law; (iii) for the unlawful payment of dividends or unlawful stock repurchases under Section 174 of the General Corporation Law of the State of Delaware; or (iv) for any transaction from which the Director derived an improper personal benefit. If the General Corporation Law is amended after approval by the stockholders of this Article to authorize corporate action further eliminating or limiting the personal liability of directors, then the liability of a director of the Corporation shall be eliminated or limited to the fullest extent permitted by the General Corporation Law of the State of Delaware, as so amended."

Article VIII of the Company's Bylaws, as amended and restated, provide for indemnification of directors and officers to the fullest extent permitted by the Delaware General Corporation Law.

Insofar as indemnification for liabilities arising under the Securities Act of 1933 may be permitted to directors, officers or persons controlling the registrant pursuant to the foregoing provisions, the registrant has been informed that in the opinion of the Securities and Exchange Commission such indemnification is against public policy as expressed in the Act and is therefore unenforceable.

EXPERTS

The audited consolidated financial statements of DOR BioPharma, Inc. and subsidiaries included in the Registration Statement have been audited by Sweeney, Gates & Co., an independent registered public accounting firm, for the years ended December 31, 2006 and 2005, as set forth in their report appearing herein. Such financial statements have been so included in reliance upon the reports of such firm given upon their authority as experts in accounting and auditing.

LEGAL MATTERS

The validity of the shares of our common stock offered by the selling stockholder will be passed upon by the law firm of Edwards Angell Palmer & Dodge LLP, Fort Lauderdale, Florida.

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DOR BIOPHARMA, INC. AND SUBSIDIARIES

CONSOLIDATED FINANCIAL STATEMENTS

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DOR BioPharma, Inc.
Consolidated Balance Sheet
September 30, 2007
(Unaudited)

Assets		
Current assets:		
Cash and cash equivalents	$	2,544,784
Grants receivable		173,634
Prepaid expenses		147,650
Total current assets		2,866,068
Office and laboratory equipment, net		30,701
Intangible assets, net		1,292,342
Total assets	$	4,189,111
Liabilities and shareholders' equity		
Current liabilities:		
Accounts payable	$	1,046,636
Accrued compensation		133,305
Total current liabilities		1,179,941
Shareholders' equity:		
Common stock, $.001 par value. Authorized 250,000,000		
shares; 92,997,331 issued and outstanding		92,997
Additional paid-in capital		100,614,098
Accumulated deficit		(97,697,925)
Total shareholders' equity		3,009,170
Total liabilities and shareholders' equity	$	4,189,111

The accompanying notes are an integral part of these financial statements

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DOR BioPharma, Inc.
Consolidated Statements of Operations
For the three months ended September 30,
(Unaudited)

	2007	2006
Revenues:	$ 429,445	$ 117,982
Cost of revenues	(301,672)	(70,147)
Gross profit	127,773	47,835
Operating expenses:		
Research and development	601,668	761,276
General and administrative	783,208	660,085
Total operating expenses	1,384,876	1,421,361
Loss from operations	(1,257,103)	(1,373,526)
Other income (expense):		
Interest income	10,121	10,104
Interest expense	-	(2,106)
Total other income (expense)	10,121	7,998
Net loss	$ (1,246,982)	$ (1,365,528)
Basic and diluted net loss per share	$ (0.01)	$ (0.02)
Basic and diluted weighted average common shares outstanding	92,938,838	68,533,689

The accompanying notes are an integral part of these financial statements

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DOR BioPharma, Inc.
Consolidated Statements of Operations
For the nine months ended September 30,
(Unaudited)

	2007	2006
Revenues:	$ 943,737	$ 1,644,393
Cost of revenues	(669,882)	(1,198,403)
Gross profit	273,855	445,990
Operating expenses:		
Research and development	2,611,220	3,821,255
Purchased in-process research and development	-	981,819
General and administrative	2,772,525	2,099,608
Total operating expenses	5,383,745	6,902,682
Loss from operations	(5,109,890)	(6,456,692)
Other income (expense):		
Interest income	144,062	39,282
Interest expense	(1,020)	(2,106)
Total other income (expense)	143,042	37,176
Net loss	$ (4,966,848)	$ (6,419,516)
Basic and diluted net loss per share	$ (0.06)	$ (0.10)
Basic and diluted weighted average common shares outstanding	89,389,416	62,062,667

The accompanying notes are an integral part of these financial statements

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DOR BioPharma, Inc.
Consolidated Statements of Cash Flows
For the nine months ended September 30,
(Unaudited)

	2007	2006
Operating activities:		
Net loss	$ (4,966,848)	$ (6,419,516)
Adjustments to reconcile net loss to net cash used by operating activities:		
Amortization and depreciation	84,475	148,913
Non-cash stock compensation	1,201,306	655,552
Non-cash stock purchase of in-process research and development	-	981,819
Impairment expense for intangibles	-	816,300
Change in operating assets and liabilities:		
Grants receivable	(83,701)	156,766
Prepaid expenses	(53,180)	41,926
Accounts payable	(1,064,096)	77,545
Accrued royalties	-	(60,000)
Accrued compensation	(271,389)	(48,535)
Total adjustments	(186,585)	2,770,286
Net cash used by operating activities	(5,153,433)	(3,649,230)
Investing activities:		
Acquisition of intangible assets	(294,404)	(228,668)
Purchases of equipment	(10,182)	(2,552)
Net cash used by investing activities	(304,586)	(231,220)
Financing activities:		
Net proceeds from sale of common stock	6,235,404	3,535,029
Proceeds from exercise of warrants	1,530,763	-
Proceeds from exercise of stock options	117,000	113,320
Net cash provided by financing activities	7,883,167	3,648,349
Net increase (decrease) in cash and cash equivalents	2,425,148	(232,101)
Cash and cash equivalents at beginning of period	119,636	821,702
Cash and cash equivalents at end of period	$ 2,544,784	$ 589,601
Non-cash transactions:		
Non-cash stock payment to an institutional investor	$ -	$ 220,374
Cash paid for interest	$ 1,020	$ -

The accompanying notes are an integral part of these financial statements

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DOR BioPharma, Inc.
Notes to Consolidated Financial Statements

1. Nature of Business

DOR BioPharma, Inc. ("DOR" or the "Company") is a research and development biopharmaceutical company incorporated in 1987, focused on the development of oral therapeutic products intended for areas of unmet medical need as well as therapeutic and vaccine products that are to be used as biodefense countermeasures.

On October 18, 2007, the Company received a not approvable letter from the U.S. Food and Drug Administration (the "FDA") in response to its new drug application ("NDA") for orBec® (oral beclomethasone dipropionate) for the treatment of gastrointestinal Graft-versus-Host-Disease ("GI GVHD"). The FDA also has requested nonclinical and chemistry, manufacturing & controls information as part of the not approvable letter. On October 19, 2007, we had an End of Review Conference with the FDA to further understand the letter and gain clarity as to the next steps.

DOR has also filed a Marketing Authorization Application ("MAA") with the European Medicines Evaluation Agency ("EMEA") for orBec®, which has been validated for review.

On October 1, 2007, the Company relocated its corporate offices to Ewing, New Jersey.

During the quarter ended September 30, 2007, the Company had one customer, the U.S. Federal Government. All revenues were generated from three U.S. Federal Government Grants. As of September 30, 2007, all outstanding receivables were from the U.S. Federal Government, National Institute of Allergy and Infectious Diseases ("NIAID"), a division of the National Institutes of Health ("NIH"), and the Orphan Products Division of the FDA ("Government").

2. Summary of Significant Accounting Policies

Basis of Presentation

These unaudited interim consolidated financial statements of the Company were prepared under the rules and regulations for reporting on Form 10-QSB. Accordingly, the Company omitted some information and note disclosures normally accompanying the annual financial statements. You should read these interim financial statements and notes in conjunction with the audited consolidated financial statements and their notes included in the Company's annual report on Form 10-KSB for the year ended December 31, 2006. In the Company's opinion, the consolidated financial statements include all adjustments necessary for a fair statement of the results of operations, financial position and cash flows for the interim periods. All adjustments were of a normal recurring nature. The results of operations for interim periods are not necessarily indicative of the results for the full fiscal year.

Cash and Cash Equivalents

Cash and cash equivalents include cash and highly liquid short-term investments, with an original maturity of three months or less.

Grants Receivable

Receivables consist of unbilled amounts due from grants from the U.S. Federal Government, and the NIAID. The amounts were billed in the month subsequent to quarter end. The Company considers the grants receivable to be fully collectible; accordingly, no allowance for doubtful accounts has been established. If accounts become uncollectible, they are charged to operations when that determination is made.

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Intangible Assets

Currently, the most significant estimate or judgment that DOR makes is whether to capitalize or expense patent and license costs. The Company makes this judgment based on whether the technology has alternative future uses, as defined in SFAS 2, "Accounting for Research and Development Costs". Based on this consideration, DOR capitalized all outside legal and filing costs incurred in the procurement and defense of patents.

These intangible assets are reviewed for impairment whenever events or changes in circumstances indicate that the carrying amount may not be recoverable. If the sum of the expected undiscounted cash flows is less than the carrying value of the related asset or group of assets, a loss is recognized for the difference between the fair value and the carrying value of the related asset or group of assets.

The Company capitalizes and amortizes intangibles over a period of 11 to 16 years. The Company capitalizes payments made to legal firms that are engaged in filing and protecting rights to intellectual property and rights for our current products in both the domestic and international markets. The Company believes that patent rights are its most valuable assets. Patents and patent applications are a key currency of intellectual property, especially in the early stage of product development, as their purchase and maintenance gives the Company access to key product development rights from DOR’s academic and industrial partners. These rights can also be sold or sub-licensed as part of its strategy to partner its products at each stage of development. The legal costs incurred for these patents consist of work designed to protect, preserve, maintain and perhaps extend the lives of the patents. Therefore, DOR capitalizes these costs and amortizes them over the remaining useful life of the patents. DOR capitalizes intangible assets based on alternative future use.

Impairment of Long-Lived Assets

Office and laboratory equipment and intangible assets are evaluated and reviewed for impairment at least annually or whenever events or changes in circumstances indicate that the carrying amount may not be recoverable. The Company recognizes impairment of long-lived assets in the event the net book value of such assets exceeds the estimated future undiscounted cash flows attributable to such assets or the business to which such assets relate. If the sum of the expected undiscounted cash flows is less than the carrying value of the related asset or group of assets, a loss is recognized for the difference between the fair value and the carrying value of the related asset or group of assets. Such analyses necessarily involve significant judgment.

Stock Based Compensation

The Company adopted Statement of Financial Accounting Standards (SFAS) No. 123R, “Share-Based Payment,” effective January 1, 2006, which requires companies to record compensation expense for stock options issued to employees or non-employee directors at an amount determined by the fair value of options. SFAS No. 123R is effective for annual periods beginning after December 15, 2005.

The Company has adopted SFAS No. 123R using the “modified prospective application” and therefore, financial statements from periods ending prior to January 1, 2006 have not been restated. As a result of adopting SFAS No. 123R, the Company’s net loss for the quarter ended and nine months ended September 30, 2007 was $279,340 and $529,313, respectively, higher than if it had continued to account for share-based compensation under APB No. 25.

The fair value of each option grant at the quarter ended September 30, 2007 is estimated on the date of each grant using the Black-Scholes option pricing model and amortized ratably over the option’s vesting periods. There were 2,925,000 stock options granted in the quarter ended September 30, 2007 and 3,375,000 stock options were granted during the nine months ended September 30, 2007.

The weighted average fair value of options granted with an exercise price equal to the fair market value of the stock was $0.18 and $0.27 for the quarter ended September 30, 2007 and September 30, 2006, respectively.

The fair value of options in accordance with SFAS 123 was estimated using the Black-Scholes option-pricing model and the following weighted-average assumptions: dividend yield 0%, expected life of four years, volatility of 100% and 116% in 2007 and 2006, respectively and average risk-free interest rates in 2007 and 2006 of 4.5% and 4.0%, respectively.

Stock compensation expense for options granted to non-employees has been determined in accordance with SFAS 123 and Emerging Issues Task Force ("EITF") 96-18, and represents the fair value of the consideration received, or the fair value of the equity instruments issued, whichever may be more reliably measured. For options that vest over future periods, the fair value of options granted to non-employees is amortized as the options vest.

Net Loss Per Share

In accordance with accounting principles generally accepted in the United States of America, basic and diluted net loss per share has been computed using the weighted-average number of shares of common stock outstanding during the respective periods (excluding shares that are not yet issued). The effect of stock options, and warrants are antidilutive for all periods presented.

There were options to purchase approximately 13.7 million and 12.8 million shares of the Company's common stock outstanding at September 30, 2007, and 2006, respectively.

3. Management's Plan

The Company has incurred continuing losses since its inception in 1987. At September 30, 2007, the Company had working capital of $1,687,127, and a net loss of $4,966,848. In the nine months ended September 30, 2007, the Company has raised approximately $6,500,000 through equity financing and approximately $1,647,000 in warrant and stock option exercises. Subsequent to September 2007, the Company had exercises of warrant and stock options of approximately $577,000. The Company expects to sustain additional losses over the next 12 months. The Company's ability to raise additional funding may be more difficult due to the Food and Drug Administration not approving orBec® for marketing in the United States.

Management's plan to generate positive cash flows either from operations or financing includes the following:

- The Company is exploring outlicensing opportunities for orBec® both in the US and Europe and for its BioDefense programs.
- The Company has engaged RBC Capital Markets as its advisor in exploring mergers and acquisitions and the various opportunities presented.

- The Company plans to continue seeking grant funds from governmental sources. In September 2006, the Company received two grants totaling approximately $5,500,000 to support the development of its BioDefense vaccine programs. An additional $1 million grant from the Orphan Products division of the FDA was awarded in September 2007 to its academic collaborators at the University of Texas Southwestern Medical Center to fund a supplemental trial of ricin vaccine (RiVax™) to support its ricin toxin vaccine program. Additionally, the Company's development partner, the Fred Hutchinson Cancer Research Center, has received NIH grants that support the preclinical and clinical development of orBec®/Oral BDP for the treatment of radiation injury and the prevention of GVHD.

- The Company believes that its current cash position will allow it to operate over the next 12 months. If there were no other sources of financing, reductions or discontinuation of operations of several of the Company's programs may be required. If this should occur, the Company believes it could continue to operate over the next four quarters at a reduced level and continue with its existing grant projects.

There is no assurance that the Company will be able to successfully implement its plan or will be able to generate cash flows from either operations, partnerships, or from equity financings.

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4. Intangible Assets

The following is a summary of intangible assets which consists of licenses and patents:

	Weighted Average Amortization period (years)	Cost	Accumulated Amortization	Net Book Value
September 30, 2007	10.0	$ 2,033,794	$ 714,452	$ 1,292,342
December 31, 2006	10.1	$ 1,739,391	$ 666,152	$ 1,073,239

Amortization expense was $27,000 and $45,000 for the quarters ended September 30, 2007 and 2006, respectively. Amortization expense was $75,300 and $135,000 for the nine months ended September 30, 2007 and September 30, 2006, respectively.

At September 30, 2007, based on the balance of the intangibles the annual amortization expense for each of the succeeding five years is estimated to be as follows:

Year	Amortization Amount
2007	$ 105,000
2008	105,000
2009	105,000
2010	105,000
2011	105,000

License fees and royalty payments are expensed annually.

5. Grants Receivable

In the third quarter of 2007, the Company recorded grant revenues from the three U.S. Government Grants in the amount of $429,455. For the nine months ended September 30, 2007 the Company recorded $943,737 in grant revenues. Outstanding receivables at quarter end were $173,634. This receivable has since been collected.

6. Shareholders' Equity

During the nine month period ended September 30, 2007, the Company issued 815,357 shares of common stock as payment to vendors for consulting services. An expense of $327,000 was recorded which approximated the shares' fair market value on the date of issuance. These shares of common stock were included in the Company's Form SB-2 Registration Statement filed with the SEC on March 9, 2007. Also, 6,208,287 warrants were exercised to purchase shares of common stock which provided proceeds of $1,530,763, 260,000 stock options were exercised to purchase shares of common stock which provided proceeds of $117,000, and 116,055 common stock shares were issued to employees as payment for payroll in lieu of cash in the amount of $36,250.

On February 9, 2007, the Company completed the sale of 11,680,850 shares of DOR common stock to institutional investors and certain of our officers and directors for a gross purchase price of $5,490,000 (less $259,950 in placement agent fees). The common shares purchased were priced at $0.47 per share which represented a 6% discount to the then current market price. The placement agents received warrants to purchase 560,106 shares of common stock at an

exercise price of $0.59 per share. The warrants are exercisable for a period of five years commencing on February 9, 2007. The Company filed a registration statement with the Securities and Exchange Commission which was declared effective on April 18, 2007.

The securities purchase agreement of the April 2006 private investment placement ("PIPE") stipulated that if subsequent shares were sold at a lower price per share, the investors in that transaction were entitled to receive additional shares to compensate for the difference in price. The purchase in January 2007 by Sigma-Tau of $1,000,000 of DOR's common stock at $0.246 per share created a dilutive event which triggered the issuance of additional shares. Therefore, on February 16, 2007, 995,947 shares of common stock were issued to the remaining April 2006 PIPE investors at the same price as those issued to Sigma-Tau. This transaction resulted in a charge of $308,743 to account for the difference between the original price of $0.2771 and the $0.246.

On February 21, 2007, Sigma-Tau relinquished its exclusive rights granted to it on January 3, 2007, under a letter of intent with regard to acquisition discussions. However at that time, all other terms of the letter of intent remained in effect. In consideration for entering into an exclusive letter of intent, Sigma-Tau agreed to purchase $1,000,000 of the Company's common stock at the then market price of $0.246 per share, representing 4,065,041 shares of common stock, and paid an additional $2,000,000 in cash. The $2,000,000 payment was to be considered an advance payment to be deducted from future payments due to the Company by Sigma-Tau pursuant to any future orBec® commercialization arrangement reached between the two parties.

Because no agreement was reached by March 1, 2007, the Company was obligated to return the $2 million to Sigma-Tau by May 31, 2007 (as amended by mutual consent in a letter dated May 3, 2007 and filed on Form 8-K). The Company returned the $2 million on June 1, 2007 and thus satisfied the obligation.

7. Contingencies

The October 28, 2005, letter of intent with Gastrotech Pharma A/S ("Gastrotech"), as amended on December 29, 2005, expired in accordance with its terms on January 15, 2005 without being extended or renewed. Additionally, on January 15, 2006 the Company notified Gastrotech Pharma that it would not be renewing the letter of intent. The breakup fee of $1,000,000 is only payable if a party breaches the terms of the letter of intent or terminates the letter of intent. In accordance with SFAS No. 5, the Company disclosed a potential liability in that Gastrotech advised the Company that if it were not willing to comply with the terms of the letter of intent, DOR would be in material breach of its obligations and would be obligated to pay Gastrotech the break up fee of $1,000,000. However, pursuant to SFAS No. 5, paragraph 33b, the Company has not recorded a loss provision because it does not believe there will be any monetary damages since there is no pending litigation, the Company cannot reasonably determine the amount of loss, and does not believe it has any liability to Gastrotech for allowing the letter of intent to expire. In addition, the Company has not recorded an accrual for the potential loss, because it does not believe, as described in item 8(a) and 8(b) of SFAS No. 5, that any loss has been confirmed nor has any outcome or judgment occurred. Moreover, the Company does not feel that it is probable that a liability has been incurred. Perhaps more importantly, Gastrotech has not brought any legal action against the Company. As of the date of this report, no claim or complaint has been filed by Gastrotech as to the obligation to pay a break-up fee of $1,000,000.

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8. Business Segments

The Company had two active segments for the nine months ended September 30, 2007 and 2006: BioDefense and BioTherapeutics.

	For the three months ended September 30,	
	2007	2006
Revenues		
BioDefense	$ 429,445	$ 71,881
BioTherapeutics	-	46,101
Total	$ 429,445	$ 117,982
Income (Loss) from Operations		
BioDefense	$ 25,676	$ (99,395)
BioTherapeutics	(581,363)	(624,952)
Corporate	(701,416)	(649,179)
Total	$ (1,257,103)	$ (1,373,526)
Amortization and Depreciation Expense		
BioDefense	$ 31,062	$ 38,001
BioTherapeutics	3,462	9,001
Corporate	1,525	2,002
Total	$ 36,049	$ 49,004
Identifiable Assets		
BioDefense	$ 984,287	$ 1,140,106
BioTherapeutics	511,690	377,812
Corporate	2,693,135	689,838
Total	$ 4,189,111	$ 2,207,756

	For the nine months ended September 30,	
	2007	2006
Revenues		
BioDefense	$ 943,737	$ 1,506,092
BioTherapeutics	-	138,301
Total	$ 943,737	$ 1,644,393
Income (Loss) from Operations		
BioDefense	$ (51,010)	$ (1,907,899)
BioTherapeutics	(2,276,555)	(3,468,298)
Corporate	(2,782,325)	(1,080,495)
Total	$ (5,109,890)	$ (6,456,692)
Amortization and Depreciation Expense		
BioDefense	$ 68,293	$ 112,477
BioTherapeutics	11,593	29,478
Corporate	4,587	6,955

Total	$	84,473	$	148,910

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REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

To the Board of Directors of DOR BioPharma, Inc.,

We have audited the accompanying consolidated balance sheet of DOR BioPharma, Inc. and subsidiaries at December 31, 2006 and 2005 and the related consolidated statements of operations, changes in shareholders' deficiency and cash flows for the years ended December 31, 2006 and 2005. These consolidated financial statements are the responsibility of the Company's management. Our responsibility is to express an opinion on these consolidated financial statements based on our audits.

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

In our opinion, the consolidated financial statements referred to above present fairly, in all material respects, the financial position of the Company, as of December 31, 2006 and 2005 and the results of its operations and its cash flows for the years ended December 31, 2006 and 2005, in conformity with United States generally accepted accounting principals.

/s/ Sweeney, Gates & Co.

Sweeney, Gates & Co.

Fort Lauderdale, Florida
March 1, 2007

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DOR BioPharma, Inc.
Consolidated Balance Sheet
December 31, 2006 and 2005

	2006	2005
Assets		
Current assets:		
Cash	$ 119,636	$ 821,702
Grants receivable	89,933	564,330
Prepaid expenses	94,470	138,794
Total current assets	304,039	1,524,826
Office and laboratory equipment, net	29,692	44,728
Intangible assets, net	1,073,239	1,803,020
Total assets	$ 1,406,970	$ 3,372,574
Liabilities and shareholders' (deficiency)		
Current liabilities:		
Accounts payable	$ 2,112,479	$ 1,530,900
Accrued royalties	-	60,000
Accrued compensation	-	148,601
Accrued other expenses	402,947	105,000
Total current liabilities	2,515,426	1,844,501
Shareholders' equity (deficiency):		
Common stock, $.001 par value. Authorized 250,000,000		
shares; 68,855,794 and 50,612,504, respectively issued and outstanding	68,855	50,612
Additional paid-in capital	91,553,766	86,015,192
	( )	)
Accumulated deficit	92,731,077	(84,567,731
Total shareholders' equity (deficiency)	(1,108,456)	1,528,073
Total liabilities and shareholders' equity (deficiency)	$ 1,406,970	3,372,574

The accompanying notes are an integral part of these financial statements

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DOR BioPharma, Inc.
Consolidated Statements of Operations
For the years ended December 31,

	2006	2005
Revenues	$ 2,313,020	$ 3,075,736
Cost of revenues	(1,965,074)	(2,067,034)
Gross profit	347,946	1,008,702
Operating expenses:		
Research and development	3,638,493	3,516,791
In-process research and development	981,819	-
Impairment of intangible assets	816,300	164,346
General and administrative	3,110,882	2,162,616
Total operating expenses	8,547,494	5,843,753
Loss from operations	(8,199,548)	(4,835,051)
Other income (expense):		
Interest income	41,510	78,242
Interest (expense) reversal	(5,308)	36,549
Total other income (expense)	36,202	114,791
Net loss	$ (8,163,346)	$ (4,720,260)
BasicnBasic and diluted net loss per share	$ (0.13)	$ (0.09)
Basic Basic and diluted weighted average common shares outstanding	63,759,092	49,726,249

The accompanying notes are an integral part of these financial statements

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DOR BioPharma, Inc.
Consolidated Statements of Changes in Shareholders' (Deficiency)
For the years ended December 31, 2006 and 2005

	Common Stock		Additional Paid-In capital	AccumulatedDeficit	Treasury Stock	
	Shares	Par Value			Shares	Cost
Balance, January 1, 2005	42,218,404	$42,218	$83,216,533	($79,847,471)	120,642	($427,697)
Issuance of common stock	8,396,100	8,396	3,539,897	-	-	-
Treasury stock retired	(2,000)	(2)	(426,383)	-	(120,642)	427,697
Reversal of non-cash compensation	-	-	(284,855)	-	-	-
Net loss	-	-	-	(4,720,260)	-	-
Balance, December 31, 2005	50,612,504	50,612	86,045,192	($84,567,731)	-	-
Issuance of common stock	13,429,504	13,430	3,521,570	-	-	-
Issuance of common stock for exercise of options	504,100	504	112,816	-	-	-
Issuance of common stock to vendors	506,942	507	134,171	-	-	-
Issuance of warrants to vendors	-	-	121,965	-	-	-
Issuance of common stock for an equity commitment fee	512,500	512	(512)	-	-	-

Issuance of common stock to employees	222,061	222	82,632	-	-	-
Issuance of common stock to minority shareholders	3,068,183	3,068	978,750	-	-	-
Stock option expense	-	-	557,182	-	-	-
Net loss	-	-	-	(8,163,346)	-	-
Balance, December 31, 2006	68,855,794	$68,855	$91,553,766	($92,731,077)	-	$ -

The accompanying notes are an integral part of these financial statements

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DOR BioPharma, Inc.
Consolidated Statements of Cash Flows
For the years ending December 31,

	2006	2005
Operating activities		
Net loss	$ (8,163,346)	$ (4,720,260)
Adjustments to reconcile net loss to net cash used by operating activities:		
Amortization and depreciation	137,044	194,284
Non-cash stock compensation	896,680	(284,855)
Non-cash stock purchase of in-process research and development	981,819	-
Impairment expense for intangibles	816,300	164,346
Change in operating assets and liabilities:		
Grants receivable	474,397	178,657
Prepaid expenses	44,324	(71.191)
Accounts payable	476,605	(167,039)
Accrued compensation	254,347	83,356
Accrued royalties	(60,000)	(40,000)
Total adjustments	4,021,516	49,558
Net cash used by operating activities	(4,141,830)	(4,670,702)
Investing activities:		
Purchases of office and laboratory equipment	(2,552)	(21,561)
Acquisition of intangible assets	(206,004)	(250,570)
Net cash used by investing activities	(208,556)	(272,131)
Financing activities:		
Net proceeds from issuance of common stock	3,535,000	3,548,293
Repayments of note payable	-	(115,948)
Proceeds from exercise of options	113,320	-
Net cash provided by financing activities	3,648,320	3,432,345
Net (decrease) in cash and cash equivalents	(702,066)	(1,510,488)
Cash and cash equivalents at beginning of period	821,702	2,332,190
Cash and cash equivalents at end of period	$ 119,636	$ 821,702
Supplemental disclosure of cash flow:		
Cash paid for interest	$ 3,170	$ 41,865
Non-cash transactions:		
Non-cash stock option expense (reversal)	$ -	$ (284,855)
Non-cash payment to an institutional investor	220,374	$ -

The accompanying notes are an integral part of these financial statements

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DOR BioPharma, Inc.
Notes to Consolidated Financial Statements

1. Nature of Business

Nature of Business

The Company is a biopharmaceutical company incorporated in 1987, focused on the development of biodefense vaccines and biotherapeutic products intended for areas of unmet medical need. DOR's biodefense business segment consists of converting biodefense vaccine programs from early stage development to advanced development and manufacturing. DOR's biotherapeutic business segment consists of development of orBec® and other biotherapeutics products namely OraprineTM, LPMTM-Leuprolide, and LPETM and PLPTM Systems for Delivery of Water-Insoluble Drugs.

During the year ending December 31, 2006, the Company had one customer, the U.S. Federal Government. All revenues were generated from two U.S. Federal Government Grants. As of December 31, 2006 all outstanding receivables were from the U.S. Federal Government, National Institute of Health and The Food and Drug Administration.

2. Summary of Significant Accounting Policies

Principles of Consolidation

The consolidated financial statements include DOR BioPharma Inc., and its wholly owned subsidiaries ("DOR" or the "Company"). All significant intercompany accounts and transactions have been eliminated in consolidation.

Segment Information

Operating segments are defined as components of an enterprise about which separate financial information is available that is evaluated on a regular basis by the chief operating decision maker, or decision making group, in deciding how to allocate resources to an individual segment and in assessing the performance of the segment.

Grants Receivable

Receivables consist of unbilled amounts due from grants from the U.S. Federal Government, National Institute of Health and The Food and Drug Administration. The amounts were billed in the month subsequent to year end. The Company considers the grants receivable to be fully collectible; accordingly, no allowance for doubtful accounts has been established. If accounts become uncollectible, they are charged to operations when that determination is made.

Intangible Assets

Currently, the most significant estimate or judgment that we make is whether to capitalize or expense patent and license costs. We make this judgment based on whether the technology has alternative future uses, as defined in SFAS 2, "Accounting for Research and Development Costs". Based on this consideration, we capitalized all outside legal and filing costs incurred in the procurement and defense of patents.

These intangible assets are reviewed for impairment whenever events or changes in circumstances indicate that the carrying amount may not be recoverable. If the sum of the expected undiscounted cash flows is less than the carrying value of the related asset or group of assets, a loss is recognized for the difference between the fair value and the

carrying value of the related asset or group of assets.

The Company capitalizes and amortizes intangibles over a period of 11 to 16 years. The Company capitalizes payments made to legal firms that are engaged in filing and protecting rights to intellectual property and rights for our current products in both the domestic and international markets. The Company believes that patent rights form one of its most valuable assets. Patents and patent applications are a key currency of intellectual property, especially in the early stage of product development, as their purchase and maintenance gives the Company access to key product development rights from DOR's academic and industrial partners. These rights can also be sold or sub-licensed as part of its strategy to partner its products at each stage of development. The legal costs incurred for these patents consist of work designed to protect, preserve, maintain and perhaps extend the lives of the patents. Therefore, DOR capitalizes these costs and amortizes them over the remaining useful life of the patents. DOR capitalizes intangible assets based on alternative future use.

Impairment of Long-Lived Assets

Office and laboratory equipment and intangible assets are evaluated and reviewed for impairment whenever events or changes in circumstances indicate that the carrying amount may not be recoverable. The Company recognizes impairment of long-lived assets in the event the net book value of such assets exceeds the estimated future undiscounted cash flows attributable to such assets. If the sum of the expected undiscounted cash flows is less than the carrying value of the related asset or group of assets, a loss is recognized for the difference between the fair value and the carrying value of the related asset or group of assets. Such analyses necessarily involve significant judgment.

The Company recorded impairment of intangible assets of $816,300 and $164,346 for the years ended December 31, 2006 and 2005, respectively.

Fair Value of Financial Instruments

Accounting principles generally accepted in the United States of America require that fair values be disclosed for the Company's financial instruments. The carrying amounts of the Company's financial instruments, which include grants receivable and current liabilities are considered to be representative of their respective fair values.

Revenue Recognition

All of the Company's revenues are from government grants which are based upon subcontractor costs and internal costs covered by the grant, plus a facilities and administrative rate that provides funding for overhead expenses. Revenues are recognized when expenses have been incurred by subcontractors or when DOR incurs internal expenses that are related to the grant.

Research and Development Costs

Research and Development costs are charged to expense when incurred. Research and development includes costs such as clinical trial expenses, contracted research and license agreement fees with no alternative future use, supplies and materials, salaries and employee benefits, equipment depreciation and allocation of various corporate costs. Purchased in-process research and development expense (IPR&D) represents the value assigned or paid for acquired research and development for which there is no alternative future use as of the date of acquisition.

Stock Based Compensation

The Company adopted Statement of Financial Accounting Standards (SFAS) No. 123R, "Share-Based Payment," effective January 1, 2006, which requires companies to record compensation expense for stock options issued to employees or non-employee directors at an amount determined by the fair value of options. SFAS No. 123R is effective for annual periods beginning after December 15, 2005.

The Company has adopted SFAS No. 123R using the "modified prospective application" and therefore, financial statements from periods ending prior to January 1, 2006 have not been restated. As a result of adopting SFAS No. 123R, the Company's net loss for the year ended December 31, 2006 was $557,182, higher than if it had continued to account for share-based compensation under APB No. 25. Basic and diluted earnings per share for the year ended December 31, 2006 would have changed by $0.01 if the Company had not adopted SFAS No. 123R.

The fair value of each option grant at the year ended December 31, 2006 is estimated on the date of each grant using the Black-Scholes option pricing model and amortized ratably over the option's vesting periods. 4,360,000 stock options were granted for the year ended December 31, 2006.

Pro forma information, assuming the Company had accounted for its employee and director stock options granted under the fair value method prescribed by SFAS No. 123R for the year ended December 31, 2005 is presented below:

Net loss as reported	$ (4,720,260)
Add stock-based employee compensation expense related to stock options determined under fair value method	(393,226)
Amounts (credited) charged to income	(284,855)
Pro forma net loss according to SFAS 123	$ (5,398,341)

Net loss per share:	
As reported, basic and diluted	$ (0 .09)
Pro forma, basic and diluted	$ (0 .11)

The weighted average fair value of options granted with an exercise price equal to the fair market value of the stock was $0.30 and $0.48 for 2006 and 2005, respectively.

The fair value of options in accordance with SFAS 123 was estimated using the Black-Scholes option-pricing model and the following weighted-average assumptions: dividend yield 0%, expected life of four years, volatility of 105% and 121% in 2006 and 2005, respectively and average risk-free interest rates of 4.76% and 3.75% in 2006 and 2005, respectively.

Stock compensation expense for options granted to non-employees has been determined in accordance with SFAS 123 and Emerging Issues Task Force (“EITF”) 96-18, and represents the fair value of the consideration received, or the fair value of the equity instruments issued, whichever may be more reliably measured. For options that vest over future periods, the fair value of options granted to non-employees is amortized as the options vest.

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Income Taxes

The Company files a consolidated federal income tax return and utilizes the asset and liability method of accounting for income taxes. Under this method, deferred tax assets and liabilities are recognized for the future tax consequences attributable to differences between the financial statement carrying amounts of existing assets and liabilities and their respective tax bases. A valuation allowance is established when it is more likely than not that all or a portion of a deferred tax asset will not be realized. A review of all available positive and negative evidence is considered, including the Company's current and past performance, the market environment in which the Company operates, the utilization of past tax credits, length of carryback and carryforward periods. Deferred tax assets and liabilities are measured utilizing tax rates expected to apply to taxable income in the years in which those temporary differences are expected to be recovered or settled. No current or deferred income taxes have been provided through December 31, 2006 because of the net operating losses incurred by the Company since its inception.

Net Loss Per Share

In accordance with accounting principles generally accepted in the United States of America, basic and diluted net loss per share has been computed using the weighted-average number of shares of common stock outstanding during the respective periods (excluding shares that are not yet issued). The effect of stock options, and warrants are antidilutive for all periods presented.

Use of Estimates and Assumptions

The preparation of financial statements in conformity with accounting principles generally accepted in the United States requires management to make estimates and assumptions that affect the reported amounts in the financial statements and accompanying notes. Actual results could differ from those estimates.

New Accounting Pronouncements

In May 2005, the FASB issued SFAS No. 154, "Accounting Changes and Error Corrections" which provides guidance on the accounting for and reporting of accounting changes and correction of errors. This statement changes the requirements for the accounting for and reporting of a change in accounting principle and applies to all voluntary changes in accounting principle. It also applies to changes required by an accounting pronouncement in the unusual instance that the pronouncement does not include specific transition provisions.

In September 2006, the FASB issued SFAS No. 157, "Fair Value Measurements" ("SFAS No. 157") which defines fair value, establishes a framework for measuring fair value and expands disclosure about fair value measurements. SFAS No. 157 is effective for fiscal years beginning after November 15, 2007. The Company will adopt SFAS No. 157 on January 1, 2008, as required, and is currently evaluating the impact of such adoption on its financial statements.

In June 2006, the FASB issued FASB Interpretation No. 48, "Accounting for Uncertainty in Income Taxes" ("FIN 48"), which is an interpretation of SFAS No. 109, "Accounting for Income Taxes." FIN 48 prescribes a recognition threshold and a measurement attribute for the financial statement recognition and measurement of tax positions taken or expected to be taken in a tax return. For those benefits to be recognized, a tax position must be more-likely-than-not to be sustained upon examination by taxing authorities. The amount recognized is measured as the largest amount of benefit that is greater than 50 percent likely of being realized upon ultimate settlement. The Company will adopt the provisions of FIN 48 effective January 1, 2007, and is currently evaluating the impact of such adoption on its financial statements.

In February 2007, the FASB issued SFAS 159, "The Fair Value Option for Financial Assets and Financial Liabilities" ("SFAS 159"). SFAS 159 permits entities to choose to measure many financial assets and financial liabilities at fair

value. Unrealized gains and losses on items for which the fair value option has been elected are reported in earnings. SFAS 159 is effective for fiscal years beginning after November 15, 2007. The Company is currently assessing the impact of SFAS 159 on its consolidated financial position and results of operations.

3. Management's Plan

The Company has incurred continuing losses since its inception in 1987. At December 31, 2006, the Company had negative working capital of $ 2,211,387, and a net loss of $ 8,163,346. Subsequent to year end the Company has raised approximately $ 6,500,000 through equity financing. The Company expects to sustain additional losses over the next 12 months. The Company's ability to raise additional funding may be compromised should the Food and Drug Administration deny approval of orBec® for sale in the United States.

Management's plan to generate positive cash flows either from operations or financing includes the following:

- The Company is exploring outlicensing opportunities for orBec® both in the US and Europe and for its BioDefense programs.

- The Company plans to continue seeking grant funds from governmental sources. In September 2006, the Company received two grants totaling approximately $5,300,000 to support the development of its BioDefense vaccine programs.

- The Company believes that its current cash position will allow it to operate over the next 12 months. However, several factors could affect this with the outcome of the NDA and MAA filings. Therefore, if there were no other sources of financing and it is not able to utilize the funding from the investment banking organization, reductions or discontinued operations of several of the Company's programs may be required. If this should occur, the Company believes it could continue to operate over the next eight quarters at a reduced level and only continue with the existing grant projects.

There is no assurance that the Company will be able to successfully implement its plan or will be able to generate cash flows from either operations, partnerships, or from equity financings.

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4. Office and Laboratory Equipment

Office and laboratory equipment are stated at cost. Depreciation is computed on a straight-line basis over five years. Office and laboratory equipment consisted of the following at December 31, 2006:

Office equipment	$ 117,660
Laboratory equipment	23,212
Total	140,872
Accumulated depreciation	(111,180)
	$ 29,692

Depreciation expense was $17,593 and $25,443 for the years ended December 31, 2006 and 2005.

5. Intangible Assets

The following is a summary of intangible assets which consists of licenses and patents:

	Weighted Average Amortization period (years)	Cost	Accumulated Amortization	Net Book Value
December 31, 2006	10.1	$ 1,739,391	$ 666,152	$ 1,073,239
December 31, 2005	10.2	$ 2,605,472	$ 802,452	$ 1,803,020

Amortization expense was $119,451 in 2006 compared to $168,841 for 2005.

Based on the balance of licenses and patents at December 31, 2006, the annual amortization expense for each of the succeeding five years is estimated to be as follows:

Year	Amortization Amount
2007	$ 106,000
2008	106,000
2009	106,000
2010	106,000
2011	106,000

License fees and royalty payments in connection with the below agreements are expensed annually.

In July 2003, the Company entered into an exclusive license agreement with the University of Texas South Western (UTSW) for administering the ricin vaccine via the intramuscular route for initial license fees of 250,000 shares valued at $200,000 of DOR common stock and $200,000 in cash. Subsequently, the Company negotiated the remaining intranasal and oral rights to the ricin vaccine for $50,000 in annual license fees in subsequent years. On March 1, 2005, the Company signed a sponsored research agreement with UTSW extending through March 31, 2007 for $190,000 which will grant the Company certain rights to intellectual property.

In October 2003, the Company executed an exclusive license agreement with the University of Texas System (UTMB) for the use of luminally-active steroids, including beclomethasone dipropionate (BDP) in the treatment of irritable bowel syndrome. Pursuant to this agreement, the Company paid UTMB a license fee of $10,000 and also agreed to pay an additional $10,000 license fee expense each year. The Company also agreed to pay past and future

patent maintenance costs. The cost for 2006 and 2005 were $14,012 and $12,728, respectively. The Company acquired a sublicense agreement and may receive payments on this sublicense in the event of the sublicensee reaching certain milestones.

In July 2006, the Company signed a sponsored research agreement for $37,500 with Thomas Jefferson University (TJU). In 2005, the Company signed a sponsored research agreement for $150,000. In May 2003, the Company signed a license agreement with TJU for the licensure of detoxified botulinum toxin for use as a vaccine. The Company paid TJU $30,000 in cash and issued 141,305 shares of common stock valued at $130,000. The Company also agreed to reimburse TJU for past and future patent maintenance. The patent maintenance expense for 2006 and 2005 was $35,665 and $157,293, respectively. The patent costs are capitalized. The Company is also responsible for a license maintenance fee of $10,000 in 2005 and $15,000 in 2006 and each year thereafter. These costs are expensed as incurred. The Company must also pay TJU $200,000, upon the first filing of any New Drug Application (“NDA”) with the United States Food and Drug Administration (“FDA”) and $400,000 upon first approval of an NDA relating to the first licensed product by FDA.

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6. Shareholders' Equity

Preferred Stock

The Company has 5 million authorized shares of preferred stock, none are issued or outstanding.

Common Stock

On May 10, 2006, the Company completed a merger pursuant to which Enteron Pharmaceutical, Inc. ("Enteron"), the common stock of which the Company held 88.13% prior to the merger, was merged into a wholly-owned subsidiary of the Company. Pursuant to this transaction, the Company issued 3,068,183 shares of common stock to the Enteron minority shareholders in exchange for all of the outstanding common stock of Enteron that the Company did not already own. This transaction was accounted for as a purchase, and accordingly the Company recorded an in-process research and development expense of $981,819. The common stock was recorded at the shares' fair market value on the date of the merger.

On April 10, 2006, the Company completed the sale of 13,099,964 shares of common stock to institutional and other accredited investors for a purchase price, net of expenses, of $3,410,032. The investors also received warrants to purchase 13,099,964 shares of common stock at an exercise price of $0.45 per share. The warrants are exercisable for a period of three years commencing on April 10, 2006. The Company filed a registration statement with the Securities and Exchange Commission and it was declared effective on May 25, 2006.

On January 17, 2006, the Company entered into a common stock purchase agreement with Fusion Capital Fund II, LLC. The Fusion facility allowed them to purchase on each trading day $20,000 of DOR common stock up to an aggregate of $6,000,000 million over approximately a 15-month period. As part of this agreement DOR issued Fusion 512,500 shares of common stock as a commitment fee, the non-cash payment for this was $220,374 valued at the shares' fair market value. During 2006 Fusion purchased 329,540 common shares for $ 124,968. The Company does not intend to use the Fusion facility.

In February 2005, the Company sold 8,396,100 shares of common stock at $0.45 per share for proceeds, net of expenses, of $3,548,293 in a private placement to institutional investors. Investors also received warrants to purchase 6,297,075 shares of common stock at an exercise price of $0.505 per share. These warrants expire on August 8, 2010 and are callable when the price reaches $1.52 for 20 consecutive days. The placement agent was paid cash of $188,912, and warrants to purchase 629,708 shares of the Company's common stock exercisable by August 8, 2010 at $0.625. The warrants are callable when the price reaches $1.88 for 20 consecutive days.

In 2005, the Company retired 120,640 shares of treasury stock.

Stock Compensation to Employees and Non-employees

During the year ended December 31, 2006, the Company issued 506,942 shares of common stock as payment to vendors for consulting services. An expense of $134,679 was recorded which approximated the shares' fair market value on the date of issuance. Additionally, the Company issued 193,413 shares of common stock as part of severance payments to terminated employees and 28,648 shares of common stock to employees. An expense of $75,979 and $6,875, respectively was recorded, which approximated the shares' fair market value on the date of issuance. These shares of common stock issued were covered by the Company's Form S-8 Registration Statement filed with the SEC on December 30, 2005. Also, 504,100 stock options 1995 Omnibus Option Plan were exercised to purchase shares of common stock which provided proceeds of $113,320.

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7. Stock Option Plans and Warrants

The 2005 Equity Incentive Plan is divided into four separate equity programs: 1) the Discretionary Option Grant Program, under which eligible persons may, at the discretion of the Plan Administrator, be granted options to purchase shares of common stock, 2) the Salary Investment Option Grant Program, under which eligible employees may elect to have a portion of their base salary invested each year in options to purchase shares of common stock, 3) the Automatic Option Grant Program, under which eligible nonemployee Board members will automatically receive options at periodic intervals to purchase shares of common stock, and 4) the Director Fee Option Grant Program, under which non-employee Board members may elect to have all, or any portion, of their annual retainer fee otherwise payable in cash applied to a special option grant. In addition under the plan the Board may elect to pay certain consultants, directors, and employees in common stock. The 2006 column in the table below only accounts for transactions occurring as part of the 2005 Equity Incentive Plan.

December 31,	2006	2005
Shares available for grant at beginning of year	7,000,000	(1,979,339)
Increase in shares available	-	10,000,000
Options granted	(4,360,000)	(3,500,000)
Options forfeited or expired	1,325,000	2,479,339
Common stock payment for services	(728,968)	-
Shares available for grant at end of year	3,236,032	7,000,000

In 2006, 504,100 options were exercised that were covered under the 1995 plan.

In 2004, the Company granted options to employees and directors that were conditional upon stockholder approval of an amendment to the 1995 Omnibus Option Plan. Accordingly, a measurement date did not exist at the approval date. The Company recorded an expense of approximately $285,000. This expense was reversed in 2005.

Option activity for the years ended December 31, 2006 and 2005 was as follows:

	Options	Weighted Average Options Exercise Price
Balance at January 1, 2005	11,979,339	$ 0.64
Granted	500,000	0.41
Forfeited	(2,465,000)	0.83
Balance at December 31, 2005	10,014,339	0.59
Granted	4,360,000	0.30
Forfeited	(2,230,900)	0.83
Exercised	(504,100)	-
Balance at December 31, 2006	11,639,339	$ 0.59

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The weighted-average exercise price, by price range, for outstanding options at December 31, 2006 was:

Price Range	Weighted Average Remaining Contractual Life in Years	Outstanding Options	Exercisable Options
$0.20-$0.50	7.99	9,335,000	6,565,763
$0.51-$1.00	6.47	1,662,839	1,662,839
$1.01-$6.00	3.59	641,500	641,500
Total	7.53	11,639,339	8,870,102

From time to time, the Company grants warrants to consultants and grants warrants to purchase common stock in connection with private placements.

Warrant activity for the years ended December 31, 2006 and 2005 was as follows:

	Warrants	Weighted Average Warrant Exercise Price
Balance at January 1, 2005	15,692,718	$ 1.24
Granted	6,926,783	0.52
Expired	(452,383)	5.91
Balance at December 31, 2005	22,167,118	0.92
Granted	14,961,672	0.25
Balance at December 31, 2006	37,128,790	$ 0.65

500,000 warrants to purchase common stock were issued to vendors in the amount of $121,965.

The weighted-average exercise price, by price range, for outstanding warrants at December 31, 2006 was:

Price Range	Weighted Average Remaining Contractual Life in Years	Outstanding Warrants	Exercisable Warrants
$0.24-$0.75	2.54	24,541,175	24,541,175
$0.76-$1.50	1.81	10,141,733	10,141,733
$1.51-$8.50	1.29	2,445,882	2,445,882
Total	2.26	37,128,790	37,128,790

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8. Income Taxes

Deferred tax assets as of December 31, 2006 were as follows:

Deferred tax assets:	
Net operating loss carryforwards	$25,000,000
Orphan drug and research and development credit carryforwards	3,000,000
Other	3,000,000
Total	31,000,000
Valuation allowance	(31,000,000)
Net deferred tax assets	$ -

At December 31, 2006, the Company had net operating loss carryforwards of approximately $67,000,000 for Federal and state tax purposes, which are currently expiring each year until 2025.

The net change in the valuation allowance for the year ended December 31, 2006 and 2005, was an increase of approximately $5,000,000 and $2,000,000, respectively, resulting primarily from net operating losses generated. Based on ownership changes that have and may occur, future utilization of the net operating loss carryforwards may be limited.

The following is the approximate amount of the Company’s net operating losses that expire over the next five years:

2007	$ 981,000
2008	910,000
2009	1,328,000
2010	1,711,000
2011	870,000

Reconciliations of the difference between income tax benefit computed at the federal and state statutory tax rates and the provision for income tax benefit for the years ended December 31, 2006 and 2005 was as follows:

	2006	2005
Income tax loss at federal statutory rate	(34.00)%	(34.00)%
State taxes, net of federal benefit	(3.63)	(3.63)
Permanent differences, principally purchased in-process research and development	3.30	-
Valuation allowance	34.33	37.63
Provision for income taxes (benefit)	- %	- %

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9. Risks and Uncertainties

The Company is subject to risks common to companies in the biotechnology industry, including, but not limited to, litigation, product liability, development of new technological innovations, dependence on key personnel, protections of proprietary technology, and compliance with FDA regulations.

During the year ended December 31, 2006, the Company had one vendor that constituted approximately 28% of the outstanding payables.

At December 31, 2006 and 2005, the Company had deposits in financial institutions that exceeded the amount covered by the Federal Deposit Insurance Company. The excess amounts at December 31, 2006 and 2005 were $19,636 and $721,702, respectively.

10. Contingencies

On October 26, 2006, the Company received a summons in a civil case from Michael T. Sember, the Company's former Chief Executive Officer. The complaint claims that the Company breached the employment agreement entered into with Mr. Sember on December 7, 2004, specifically in the payment of his bonus. The Company has paid his severance and accrued vacation according to the terms of his employment agreement. Under the terms of this agreement, and as of August 2006, the Company began paying Mr. Sember $150,000 in severance and $28,383 in vacation over the subsequent six months from the date of his termination in the normal payroll cycles. The Company denies the merit of the claim as it is contrary to what is specifically stated in the agreement. On August 25, 2006, Mr. Sember was terminated without Just Cause (as such term is defined in the agreement). The Company's position is that, upon termination of Mr. Sember without Just Cause, he was to be paid six months severance, any unpaid bonuses, and any vacation accrued but not taken. The complaint contends that a minimum annual bonus of $100,000 was due. In addition, Mr. Sember is also seeking costs and attorney's fees incurred for this action. The Company denies that it owes Mr. Sember any bonus and will vigorously defend against Mr. Sember's claim that he is entitled to a bonus of $100,000. The Company has not recorded this contingency.

The October 28, 2005 letter of intent with Gastrotech, as amended on December 29, 2005, expired in accordance with its terms on January 15, 2005 without being extended or renewed. Additionally, on January 15, 2006 the Company notified Gastrotech Pharma that it would not be renewing the letter of intent. The breakup fee of $1,000,000 is only payable if a party breaches the terms of the letter of intent or terminates the letter of intent. In accordance with SFAS No. 5, the Company disclosed a potential liability in that Gastrotech advised the Company that if it were not willing to comply with the terms of the letter of intent, DOR would be in material breach of its obligations and would be obligated to pay Gastrotech the break up fee of $1,000,000. However, pursuant to SFAS No. 5, paragraph 33b, the Company has not recorded a loss provision because it does not believe there will be any monetary damages since there is no pending litigation, the Company cannot reasonably determine the amount of loss, and does not believe it has any liability to Gastrotech for allowing the letter of intent to expire. In addition, the Company has not recorded an accrual for the potential loss, because it does not believe as described in item 8(a) and 8(b) of SFAS No. 5 that any loss has not been confirmed, nor has any outcome or judgment occurred. Moreover, the Company does not feel that it is probable that a liability has been incurred. Perhaps more importantly, Gastrotech has not brought any legal action against the Comp may. No potential loss is estimatable at this time. As of the date of this report, no claim or complaint has been filed by Gastrotech Pharma A/S ("Gastrotech") as to the obligation to pay a break-up fee of $1,000,000. The Company's position is that it does not owe Gastrotech any break-up fee pursuant to not renewing its letter of intent to acquire Gastrotech.

11. Subsequent Events

On February 21, 2007, Sigma-Tau Pharmaceuticals, Inc. (“Sigma-Tau”) relinquished its exclusive rights granted to it on January 3, 2007, under a letter of intent with regard to acquisition discussions. However, all other terms of the letter of intent remained in effect, and the Company and Sigma-Tau are engaged in discussions for a European collaboration relating to orBec®. In consideration for entering into an exclusive letter of intent, Sigma-Tau agreed to purchase $1,000,000 of the Company’s common stock at the market price of $0.246 per share, representing 4,065,041 shares of common stock, and has paid an additional $2,000,000 in cash. The $2,000,000 payment was to be considered an advance payment to be deducted from future payments due to the Company by Sigma-Tau pursuant to any future orBec® commercialization arrangement reached between the two parties. Because of this transaction’s dilutive nature, all prior investors in the April 2006 private placement had their warrants repriced to $0.246. Additionally, certain shareholders who still held shares of the Company’s common stock were issued additional shares of the Company’s common stock. Because no agreement was reached by March 1, 2007, the Company is obligated to return the $2 million to Sigma-Tau by April 30, 2007. If the Company does not repay Sigma Tau by May 31, 2007, interest will accrue at a rate of 6% compounded annually and Sigma Tau will have the option, at its sole discretion of converting the accrued amount into common stock at a price per share equal to 80% of the market price at the time the payment is made.

On February 9, 2007, the Company completed the sale of 11,680,850 shares of DOR common stock to institutional and other accredited investors for a purchase price of $5,490,000.

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12. Business Segments

The Company had two active segments for the year ended December 31, 2006 and 2005: BioDefense and BioTherapeutics. Summary data:

	December 31, 2006	2005
Net Revenues		
BioDefense	$ 2,173,128	$ 2,896,878
BioTherapeutics	139,892	178,858
Total	$ 2,313,020	$ 3,075,736
Loss from Operations		
BioDefense	$ (1,943,732)	$ (847,830)
BioTherapeutics	(5,061,664)	(1,665,812)
Corporate	(1,164,152)	(2,321,409)
Total	$ (8,199,548)	$ (4,835,051)
Identifiable Assets		
BioDefense	$ 849,295	$ 2,189,216
BioTherapeutics	343,876	420,250
Corporate	213,799	763,108
Total	$ 1,406,970	$ 3,372,574
Amortization and Depreciation Expense		
BioDefense	$ 103,855	$ 63,212
BioTherapeutics	24,395	118,351
Corporate	8,794	12,721
Total	$ 137,044	$ 194,284

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PART II
INFORMATION NOT REQUIRED IN PROSPECTUS

ITEM 13. Other Expenses of Issuance and Distribution.

The following table sets forth the estimated costs and expenses of the Registrant in connection with the offering described in the registration statement.

SEC registration fee	$180
Legal fees and expenses	$20,000
Accounting fees and expenses	$2,000
Miscellaneous	$1,000
TOTAL	$23,180

ITEM 14. Indemnification of Directors and Officers.

Section 102(b)(7) of the Delaware General Corporation Law grants the Registrant the power to limit the personal liability of its directors to the Registrant or its stockholders for monetary damages for breach of a fiduciary duty. Article X of the Registrant’s Certificate of Incorporation, as amended, provides for the limitation of personal liability of the directors of the Registrant as follows:

"A Director of the Corporation shall have no personal liability to the corporation or its stockholders for monetary damages for breach of his fiduciary duty as a Director; provided, however, this Article shall not eliminate or limit the liability of a Director (i) for any breach of the Director’s duty of loyalty to the Corporation or its stockholders; (ii) for acts or omissions not in good faith or which involve intentional misconduct or a knowing violation of law; (iii) for the unlawful payment of dividends or unlawful stock repurchases under Section 174 of the General Corporation Law of the State of Delaware; or (iv) for any transaction from which the Director derived an improper personal benefit. If the General Corporation Law is amended after approval by the stockholders of this Article to authorize corporate action further eliminating or limiting the personal liability of directors, then the liability of a director of the Corporation shall be eliminated or limited to the fullest extent permitted by the General Corporation Law of the State of Delaware, as so amended."

Article VIII of the Registrant's Bylaws, as amended and restated, provide for indemnification of directors and officers to the fullest extent permitted by Section 145 of the Delaware General Corporation Law.

The Registrant has a directors’ and officers’ liability insurance policy.

The above discussion is qualified in its entirety by reference to the Registrant’s Certificate of Incorporation and Bylaws.

ITEM 15. Recent Sales of Unregistered Securities.

During February 2005, the Registrant completed a private placement in which it issued (i) 8,396,100 shares of common stock at $0.45 per share and (ii) warrants exercisable for 6,247,075 shares of its common stock at an exercise price of $0.505 per share, resulting in net proceeds of approximately $3.5 million. The warrants have a five-year term. Also, as part of the compensation received for its assistance in the private placement, the placement agent received warrants to purchase an aggregate of 629,708 shares of the Registrant's common stock at an exercise price of $0.625 per share. The shares of common stock and warrants were offered in transactions exempt from registration under the Securities Act in reliance upon Rule 506 of Regulation D under Section 4(2) of the Securities Act, as transactions not involving a public offering.

In January 2006, the Registrant entered into a common stock purchase agreement with Fusion Capital Fund II, LLC ("Fusion Capital"). Fusion Capital agreed to purchase on each trading day $20,000 of common stock up to a total of $6,000,000 over approximately a 15-month period. The Registrant may elect to sell less common stock to Fusion Capital than the daily amount and may increase the daily amount as the market price of the stock increases. The purchase price of the shares of common stock will be equal to a price based upon the market price of the common stock at date of purchase without any fixed discount to the market price. Fusion Capital does not have the right to purchase shares of common stock in the event that the price of the common stock is less than $0.12. The Registrant has the right to sell $20,000 per trading day under the agreement with Fusion Capital unless the stock price equals or exceeds $0.40, in which case the daily amount may be increased under certain conditions as the price of the Registrant's common stock price increases.

Under the terms of a Securities Purchase Agreement dated as of April 6, 2006 among the Registrant and the institutional and other accredited investors named therein, the Registrant issued 13,099,964 shares of its common stock to the investors, for aggregate gross proceeds of $3,630,000, and warrants, exercisable for three years, to purchase an aggregate of 13,099,964 shares of the Registrant's common stock at an exercise price of $0.45 per share. Such securities were issued pursuant to an exemption provided by Section 4(2) of the Securities Act of 1933, as amended, and Rule 506 of Regulation D promulgated thereunder.

On January 3, 2007, the Registrant completed a private placement in which it issued 4,065,041 shares of common stock at $0.246 per share, resulting in net proceeds of $1 million. The shares of common stock were issued in transactions exempt from registration under the Securities Act, in reliance upon Rule 506 of Regulation D under Section 4(2) of the Securities Act, as transactions not involving a public offering.

Under the terms of a Securities Purchase Agreement dated as of February 9, 2007 among the Registrant and institutional investors and certain of it's officers and directors named therein, the Registrant issued 11,680,850 shares of its common stock to the investors, for aggregate gross proceeds of $5,490,000. Also, as part of the compensation received for its assistance in the private placement, the placement agent received $259,950 cash and warrants to purchase an aggregate of 560,106 shares of the Registrant's common stock at an exercise price of $0.59 per share. Such securities were issued pursuant to an exemption provided by Section 4(2) of the Securities Act of 1933, as amended, and Rule 506 of Regulation D promulgated thereunder.

On February 14, 2008, the Registrant entered into a common stock purchase agreement with Fusion Capital. Pursuant to the terms of the agreement, the Registrant may require Fusion Capital to purchase between $80,000 and $1 Million of common stock depending on certain conditions, up to a total of $8,500,000 over approximately a 25-month period. The Registrant may elect to sell more common stock to Fusion Capital than the three day amount as the market price of the stock increases. The purchase price of the shares of common stock will be equal to a price based upon the current or past market price of the common stock. The Registrant does not have the right to require Fusion Capital to purchase shares of common stock in the event that the price of the common stock is less than $0.10 per share. The Registrant has the right to sell $80,000 per every third trading day under the agreement with Fusion Capital unless the stock price equals or exceeds $0.15, in which case the amount may be increased under certain conditions as the price of the Registrant's common stock price increases. Such securities would be issued pursuant to an exemption provided by Section 4(2) of the Securities Act of 1933, as amended, and Rule 506 of Regulation D promulgated thereunder.

Pursuant to the agreement, the Registrant issued to Fusion Capital 1,275,000 shares of common stock as a partial commitment fee, and 2,777,778 common shares and a four year warrant to purchase 1,388,889 shares of common stock for $0.22 per share, for an aggregate price of $500,000. Such securities were issued pursuant to an exemption provided by Section 4(2) of the Securities Act of 1933, as amended, and Rule 506 of Regulation D promulgated thereunder.

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ITEM 16. Exhibits.

2.1 Agreement and Plan of Merger, dated May 10, 2006 by and among the Company, Corporate Technology Development, Inc., Enteron Pharmaceuticals, Inc. and CTD Acquisition, Inc (incorporated by reference to Exhibit 2.1 included in our Registration Statement on Form SB-2 (File No. 333-133975) filed on May 10, 2006).

3.1 Amended and Restated Certificate of Incorporation (incorporated by reference to Exhibit 3.1 included in our Quarterly Report on Form 10-QSB, as amended, for the fiscal quarter ended September 30, 2003).

3.2 Certificate of Amendment to Amended and Restated Certificate of Incorporation (incorporated by reference to Exhibit 4.2 included in our Registration Statement on Form S-8 (File No. 333-130801) filed on December 30, 2005).

3.3 Certificate of Amendment to Amended and Restated Certificate of Incorporation (incorporated by reference to Annex A to our Proxy Statement filed December 12, 2006).

3.4 By-laws (incorporated by reference to Exhibit 3.1 included in our Quarterly Report on Form 10-QSB, as amended, for the fiscal quarter ended June 30, 2003).

3.5 Certificate of Designations of Series A Junior Participating Preferred Stock (incorporated by reference to Exhibit 3.1 included in our current report on Form 8-K filed on June 22, 2007).

4.1 Form of Investor Warrant issued to each investor dated as of April 12, 2000 (incorporated by reference to Exhibit 4.4 included in our Registration Statement on Form S-3 (File No. 333- 36950), as amended on December 29, 2000).

4.2 Finder Warrant issued to Paramount Capital, Inc. dated as of April 12, 2000 (incorporated by reference to Exhibit 4.5 included in our Registration Statement on Form S-3 (File No. 333- 36950), as amended on December 29, 2000).

4.3 Warrant issued to Aries Fund dated as of May 19, 1997 (incorporated by reference to Exhibit 4.6 included in our Registration Statement on Form S-3 (File No. 333-36950), as amended on December 29, 2000).

4.4 Warrant issued to Aries Domestic Fund, L.P. dated as of May 19, 1997 (incorporated by reference to Exhibit 4.7 included in our Registration Statement on Form S-3 (File No. 333- 36950), as amended on December 29, 2000).

4.5 Warrant issued to Paramount Capital, Inc. dated as of October 16, 1997 (incorporated by reference to Exhibit 4(i)(c) included in our Quarterly Report on Form 10-QSB, as amended, for the fiscal quarter ended September 30, 1997).

4.6 Warrant issued to Paramount Capital, Inc. dated as of October 16, 1997 (incorporated by reference to Exhibit 4(i)(d) included in our Quarterly Report on Form 10-QSB, as amended, for the fiscal quarter ended September 30, 1997).

4.7 Warrant issued to Élan International Services, Ltd. Dated January 21, 1998 (incorporated by reference to Exhibit 4.4 included in our Annual Report on Form 10-KSB, as amended, for the fiscal year ended December 31, 1997).

4.8 Form of Warrant to be issued to CTD warrant holders (incorporated by reference to Exhibit 4.12 include in our Registration Statement on Form S-4 filed on October 2, 2001).

4.9 Form of Warrant issued to each investor in the December 2002 private placement (incorporated by reference to Exhibit 4.9 included in our Annual Report on Form 10-KSB, as amended, for the fiscal year ended December 31, 2003).

4.10 Form of Warrant issued to each investor in the September 2003 private placement (incorporated by reference to Exhibit 99.4 included in our current report on Form 8-K filed on July 18, 2003).

4.11 Form of Warrant issued to each investor in the March 2004 private placement (incorporated by reference to Exhibit 99.4 included in our current report on Form 8-K filed on March 4, 2004).

4.12 Form of Warrant issued to each investor in the February 2005 private placement (incorporated by reference to Exhibit 10.2 included in our current report on Form 8-K filed on February 3, 2005).

4.13 Form of Warrant issued to each investor in the April 2006 private placement (incorporated by reference to Exhibit 10.2 included in our current report on Form 8-K filed on April 7, 2006).

4.14 Form of Warrant issued to finders in connection with the February 2007 private placement. (incorporated by reference to Exhibit 4.14 included in our registration statement on Form SB-2 filed on April 16, 2007).

4.15 Rights Agreement dated June 22, 2007, between the Company and American Stock Transfer & Trust Company, as Rights Agent (incorporated by reference to Exhibit 4.1 included in our current report on Form 8-K filed on June 22, 2007).

4.16 Form of Right Certificate (incorporated by reference to Exhibit 4.2 included in our current report on Form 8-K filed on June 22, 2007).

4.17 Warrant dated February 14, 2008, issued to Fusion Capital Fund II, LLC.*

5.1 Opinion of Edwards Angell Palmer & Dodge LLP.*

10.1 Amended and Restated 1995 Omnibus Incentive Plan (incorporated by reference to Exhibit 10.1 included in our Quarterly Report on Form 10-QSB, as amended, for the fiscal quarter ended September 30, 2003).

10.2 Form of Affiliate Agreement dated as of August 15, 2001 by and between the Company and the affiliates of CTD (incorporated by reference to Exhibit 10.3 included in our current report on Form 8-K filed on December 14, 2001).

10.3 Noncompetition and Nonsolicitation Agreement entered into by and among the Company, CTD and Steve H. Kanzer dated as of November 29, 2001 (incorporated by reference to Exhibit 10.30 included in our Annual Report on Form 10-KSB as amended for the fiscal year ended December 31, 2002).

10.4 Termination of the Endorex Newco joint venture between the Company, Élan Corporation, Élan International Services, and Elan Pharmaceutical Investments dated December 12, 2002 (incorporated by reference to Exhibit 10.37 included in our Annual Report on Form 10-KSB as amended for the fiscal year ended December 31, 2002).

10.5 Option Agreement with General Alexander M. Haig Jr. (incorporated by reference to Exhibit 10.39 included in our Annual Report on Form 10-KSB as amended for the fiscal year ended December 31, 2002).

10.6 Separation agreement and General Release between the Company and Ralph Ellison dated July 9, 2004 (incorporated by reference to Exhibit 10.7 included in our Annual Report on Form 10-KSB, as amended, for the fiscal year ended December 31, 2004).

10.7 License Agreement between the Company and the University of Texas Southwestern Medical Center (incorporated by reference to Exhibit 10.8 included in our Annual Report on Form 10-KSB, as amended, for the fiscal year ended December 31, 2004).

10.8 License Agreement between the Company and Thomas Jefferson University (incorporated by reference to Exhibit 10.9 included in our Annual Report on Form 10-KSB, as amended, for the fiscal year ended December 31, 2004).

10.9 License Agreement between the Company and the University of Texas Medical Branch (incorporated by reference to Exhibit 10.10 included in our Annual Report on Form 10-KSB, as amended, for the fiscal year ended December 31, 2004).

10.10 Consulting Agreement between the Company and Lance Simpson of Thomas Jefferson University. (incorporated by reference to Exhibit 10.43 included in our Annual Report on Form 10-KSB as amended for the fiscal year ended December 31, 2002).

10.11 Form of Subscription Agreement between the Company and each investor dated July 18, 2003 (incorporated by reference to Exhibit 99.3 included in our current report on Form 8-K filed on July 18, 2003).

10.12 Form of Securities Purchase Agreement between the Company and each investor dated March 4, 2004 (incorporated by reference to Exhibit 99.3 included in our current report on Form 8-K filed on March 4, 2004).

10.13 Employment agreement between the Company and Mike Sember dated December 7, 2004 (incorporated by reference to Exhibit 10.16 included in our Annual Report on Form 10-KSB, as amended, for the fiscal year ended December 31, 2004).

10.14 Employment agreement between the Company and Evan Myrianthopoulos dated December 7, 2004 (incorporated by reference to Exhibit 10.17 included in our

Annual Report on Form 10-KSB, as amended, for the fiscal year ended December 31, 2004).

10.15 Employment agreement between the Company and James Clavijo dated February 18, 2005 (incorporated by reference to Exhibit 10.18 included in our Annual Report on Form 10-KSB, as amended, for the fiscal year ended December 31, 2004).

10.16 Form of Securities Purchase Agreement between the Company and each investor dated February 1, 2005 (incorporated by reference to Exhibit 10.1 included in our current report on Form 8-K filed on February 3, 2005).

10.17 Amendment No. 1 dated February 17, 2005 to the Securities Purchase Agreement between the Company and each investor dated February 1, 2005 (incorporated by reference to Exhibit 10.20 included in our Annual Report on Form 10-KSB, as amended, for the fiscal year ended December 31, 2004).

10.18 Form Registration Rights agreement between the Company and each investor dated February 1, 2005 (incorporated by reference to Exhibit 10.3 included in our current report on Form 8-K filed on February 3, 2005).

10.19 2005 Equity Incentive Plan (incorporated by reference to Appendix D to our Proxy Statement filed December 12, 2005).

10.20 Form S-8 Registration of Stock Options Plan dated December 30, 2005 (incorporated by reference to our registration statement on Form S-8 filed on December 30, 2005).

10.21 Form of Securities Purchase Agreement between the Company and each investor dated January 17, 2006 (incorporated by reference to Exhibit 10.1 included in our current report on Form 8-K filed on January 20, 2006)

10.22 Form of Registration Rights agreement between the Company and each investor dated January 17, 2006 (incorporated by reference to Exhibit 4.1 included in our current report on Form 8-K filed on January 20, 2006).

10.23 Securities Purchase Agreement dated as of April 6, 2006 among the Company and the investors named therein (incorporated by reference to Exhibit 10.1 included in our current report on Form 8-K filed on April 7, 2006).

10.24 Registration Rights Agreement dated as of April 6, 2006 among the Company and the investors named therein (incorporated by reference to Exhibit 10.3 included in our current report on Form 8-K filed on April 7, 2006).

10.25 Employment Agreement, dated as of August 29, 2006, between Christopher J. Schaber, Ph.D., and the Company (incorporated by reference to Exhibit 10.1 included in our current report on Form 8-K filed on August 30, 2006).

10.26 Letter of Intent dated January 3, 2007 by and between DOR BioPharma, Inc. and Sigma-Tau Pharmaceuticals, Inc (incorporated by reference to Exhibit 10.1 included in our current report on Form 8-K filed on January 4, 2007).

10.27

January 17, 2007 letter from Cell Therapeutics, Inc. to DOR BioPharma, Inc (incorporated by reference to Exhibit 10.1 included in our current report on Form 8-K filed on January 19, 2007).

10.28 Securities Purchase Agreement dated February 7, 2007 by and among the Company and the investors named therein (incorporated by reference to Exhibit 10.1 included in our current report on Form 8-K filed on February 12, 2007).

10.29 Registration Rights Agreement dated February 7, 2007 by among the Company and the investors named therein (incorporated by reference to Exhibit 10.2 included in our current report on Form 8-K filed on February 12, 2007).

10.30 Letter from Sigma-Tau Pharmaceuticals, Inc. dated February 21, 2007 (incorporated by reference to Exhibit 10.1 included in our current report on Form 8-K filed on February 23, 2007).

10.31 Letter dated May 3, 2007 between the Company and Sigma-Tau Pharmaceuticals, Inc. (incorporated by reference to Exhibit 10.1 included in our current report on Form 8-K filed on May 4, 2007).

10.32 Employment Agreement dated December 27, 2007, between Christopher J. Schaber, PhD and the Company (incorporated by reference to Exhibit 10.1 included in our current report on Form 8-K filed on December 28, 2007).

10.33 Employment Agreement dated December 27, 2007, between Evan Myrianthopoulos and the Company (incorporated by reference to Exhibit 10.2 included in our current report on Form 8-K filed on December 28, 2007).

10.34 Employment Agreement dated December 27, 2007, between James Clavijo, CPA and the Company (incorporated by reference to Exhibit 10.3 included in our current report on Form 8-K filed on December 28, 2007).

10.35 Common Stock Purchase Agreement dated February 14, 2008, between the Company and Fusion Capital Fund II, LLC.*

10.36 Registration Rights Agreement dated February 14, 2008, between the Company and Fusion Capital Fund II, LLC.*

23.1 Consent of Sweeney, Gates & Co., independent registered public accounting firm.*

23.2 Consent of Edwards Angell Palmer & Dodge LLC (contained in the opinion filed as Exhibit 5.1 hereto).*

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* Filed herewith.

ITEM 17. Undertakings.

(a) The undersigned Registrant hereby undertakes as follows:

1.

File, during any period in which it offers or sells securities, a post-effective amendment to this registration statement to:

i. Include any prospectus required by section 10(a)(3) of the Securities Act;

ii. Reflect in the prospectus any facts or events which, individually or together, represent a fundamental change in the information in the registration statement; and Notwithstanding the forgoing, any increase or decrease in volume of securities offered (if the total dollar value of securities offered would not exceed that which was registered) and any deviation From the low or high end of the estimated maximum offering range may be reflected in the form of prospects filed with the Commission pursuant to Rule 424(b) if, in the aggregate, the changes in the volume and price represent no more than a 20% change in the maximum aggregate offering price set forth in the "Calculation of Registration Fee" table in the effective registration statement.

iii. Include any additional or changed material information on the plan of distribution.

2. For determining liability under the Securities Act, treat each post-effective amendment as a new registration statement of the securities offered, and the offering of the securities at that time to be the initial bona fide offering.

3. File a post-effective amendment to remove from registration any of the securities that remain unsold at the end of the offering.

4. For determining liability of the undersigned small business issuer under the Securities Act to any purchaser in the initial distribution of the securities, the undersigned small business issuer undertakes that in a primary offering of securities of the undersigned small business issuer pursuant to this registration statement, regardless of the underwriting method used to sell the securities to the purchaser, if the securities are offered or sold to such purchaser by means of any of the following communications, the undersigned small business issuer will be a seller to the purchaser and will be considered to offer or sell such securities to such purchaser:

i. Any preliminary prospectus or prospectus of the undersigned small business issuer relating to the offering required to be filed pursuant to Rule 424;

ii. Any free writing prospectus relating to the offering prepared by or on behalf of the undersigned small business issuer or used or referred to by the undersigned small business issuer;

iii. The portion of any other free writing prospectus relating to the offering containing material information about the undersigned small business issuer or its securities provided by or on behalf of the undersigned small business issuer; and

iv. Any other communication that is an offer in the offering made by the undersigned small business issuer to the purchaser.

(b) Insofar as indemnification for liabilities arising under the Securities Act of 1933 (the "Act") may be permitted to directors, officers and controlling persons of the small business issuer pursuant to the foregoing provisions, or otherwise, the small business issuer has been advised that in the opinion of the Securities and Exchange Commission such indemnification is against public policy as expressed in the Act and is, therefore, unenforceable.

In the event that a claim for indemnification against such liabilities (other than the payment by the small business issuer of expenses incurred or paid by a director, officer or controlling person of the small business issuer in the successful defense of any action, suit or proceeding) is asserted by such director, officer or controlling person in connection with the securities being registered, the small business issuer will, unless in the opinion of its counsel the matter has been settled by controlling precedent, submit to a court of appropriate jurisdiction the question whether such indemnification by it is against public policy as expressed in the Securities Act and will be governed by the final adjudication of such issue.

SIGNATURES

Pursuant to the requirements of the Securities Act of 1933, the registrant certifies that it has reasonable grounds to believe that it meets all of the requirements for filing on Form S-1 and has duly caused this registration statement to be signed on its behalf by the undersigned, thereunto duly authorized, in the City of Ewing, State of New Jersey, on the 14th day of February 2008.

DOR BIOPHARMA, INC.

By: / s/ Christopher J. Schaber
Christopher J. Schaber
President and Chief Executive Officer

POWER OF ATTORNEY

KNOW ALL MEN BY THESE PRESENTS, that each person whose signature appears below constitutes and appoints Christopher J. Schaber and Evan Myrianthopoulos, and each of them, his true and lawful attorneys-in-fact and agents, with full power of substitution and resubstitution, for him and in his name, place and stead in any and all capacities, to sign any or all amendments to this Registration Statement on Form S-1 (including post-effective amendments), and to file the same, with all exhibits thereto, and other documents in connection therewith with the Securities and Exchange Commission, granting unto said attorneys-in-fact and agents full power and authority to do and perform each and every act and thing requisite and necessary to be done in and about the premises, as fully and to all intents and purposes as he might or could do in person, hereby ratifying and confirming that said attorneys-in-fact and agents, or their substitute or substitutes, may lawfully do or cause to be done by virtue hereof.

Pursuant to the requirements of the Securities Act of 1933, this Registration Statement has been signed by the following persons in the capacities and on the dates indicated.

Signature	Title	Date
/s/ Christopher J. Schaber Christopher J. Schaber	Director, President and Chief Executive Officer (Principal Executive Officer)	February 14, 2008
/s/ Evan Myrianthopoulos Evan Myrianthopoulos	Director, Chief Financial Officer (Principal Financial and Accounting Officer)	February 14, 2008
/s/ James S. Kuo James S. Kuo	Chairman of the Board	February 14, 2008
/s/ Cyrille F. Buhrman Cyrille F. Buhrman	Director	February 14, 2008