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**UNITED STATES  
SECURITIES AND EXCHANGE COMMISSION  
Washington, D.C. 20549**

**FORM 10-K**

(Mark One)

Annual Report Pursuant to Section 13 or 15(d) of the Securities Exchange Act of 1934  
For the fiscal year ended December 31, 2001, or

Transition Report Pursuant to Section 13 or 15(d) of the Securities Exchange Act of 1934  
For the transition period from \_\_\_\_\_ to \_\_\_\_\_

Commission file number 0-21615

**BOSTON BIOMEDICA, INC.**  
(Exact name of Registrant as Specified in its Charter)

Massachusetts

(State or other Jurisdiction of  
Incorporation or Organization)

375 West Street,

West Bridgewater, Massachusetts

(Address of Principal Executive Offices)

04-2652826

(I.R.S. Employer  
Identification No.)

02379-1040

(Zip Code)

Registrant's telephone number, including area code  
(508) 580-1900

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

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

The aggregate market value of the voting common stock held by affiliates of the registrant at March 19, 2002 was \$ 18,323,000, based on the closing price of the common stock as quoted on the Nasdaq National Market on that date.

As of March 19, 2002 there were 6,752,252 shares of the registrant's common stock outstanding.

**DOCUMENTS INCORPORATED BY REFERENCE**

Portions of the registrant's proxy statement for the registrant's 2002 annual meeting of stockholders to be filed with the Securities and Exchange Commission and within 120 days after the close of the registrant's fiscal year are incorporated by reference into Part III, Items 10-13 of this Form 10-K.



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## **PART I**

### **ITEM 1. BUSINESS**

Boston Biomedica, Inc. and its wholly-owned subsidiaries (together, "the Company"), provide products and services for the detection and treatment of infectious diseases such as AIDS and Viral Hepatitis. The Company was organized in Massachusetts in 1978, and commenced significant operations in 1986. As of March 1, 2002, the Company had four business units, which are comparable to operating segments (the terms "business units" and "operating segments" are used herein interchangeably):

(1) BBI Diagnostics, an ISO 9001 certified manufacturer of quality control and other diagnostic products used to increase the accuracy of in vitro diagnostic tests;

(2) BBI Biotech Research Laboratories, the research and development arm of the Company which supplements its support for the other BBI business units with research contracts and repository services primarily for agencies of the United States government; and

(3) BBI Source Scientific, an ISO 9001 and EN 46001 certified developer and manufacturer of laboratory and medical instruments.

In addition, the Company's remaining segment is conducting research and development in the area of Pressure Cycling Technology ("PCT") with the goals of introducing new solutions for a number of healthcare issues, including: extraction of nucleic acids, inactivation of pathogens in human plasma, food safety, and genomics. The Company believes major progress has been made in year 2001 towards the goal of commercializing PCT products in year 2002; the Company is presently manufacturing prototypes of the Barocycler™ instrument and disposable PULSE™ tubes utilizing PCT technology.

In late 2000, the Company elected to exit the clinical laboratory segment of the business and accordingly, in February 2001, the Company sold the business and certain assets and liabilities of BBI Clinical Laboratories, a wholly-owned subsidiary, to a third party. The Company has substantially completed its exit from this segment of the business in the first quarter of 2002.

In July 1999, the Company announced a major reorganization and the formation of a corporate function. Pursuant to this reorganization a Senior Vice President and General Manager was appointed for each business unit, reporting to the President & Chief Operating Officer. The responsibility of the General Manager is to achieve the agreed upon goals and plan of the business unit. The primary focus of corporate is to oversee the business units and guide them according to the strategic direction of the Company.

In September 1999, the Company moved its research and development activities in PCT from leased laboratory space in Woburn, Massachusetts to its BBI Biotech facility in Gaithersburg, Maryland. This was done to allow the scientific team working on PCT to have easy and open access to the molecular and cellular biology capabilities at BBI Biotech, as well as to reduce operating costs and promote efficiencies.

In October 1999, the Company formed a new, wholly-owned subsidiary, Panacos Pharmaceuticals, Inc., ("Panacos"), a Delaware corporation. All of the Company's technology related to its drug discovery and vaccine programs, consisting primarily of patents and related sponsored research agreements, were transferred to Panacos effective January 2000. In accordance with its strategic plans, Panacos obtained additional equity financing from third party investors in November 2000 and in February 2002, in order to obtain the substantial

amount of capital required to progress to more advanced stages of drug development including human clinical trials. As of February 2002, the Company owns approximately 16% of the equity of Panacos via nonvoting shares.

The Company's strategy is to leverage its scientific capabilities in microbiology, immunology, virology, and molecular biology to (1) capitalize on both the end-user market for quality control products, especially the molecular testing market, (2) develop new products and services, (3) enhance technical leadership, (4) capitalize on complementary business operations, and (5) pursue strategic acquisitions and alliances.

## Industry Overview

*Infectious Disease Test Kits and Testing Methods.* Test kits contain in one compact package all of the materials necessary to run a test for an infectious disease. These materials include disposable diagnostic components, instructions, and reaction mixing vessels (generally 96-well plates or test tubes) that are coated with the relevant infectious disease antigens, antibodies or other materials. To perform the test, typically either a technician or a specially designed instrument mixes the solutions from the test kit with human blood specimens in a specific sequence according to the test kit instructions. The mixture must then "incubate" for up to 18 hours, during which time a series of biochemical reactions trigger signals (including color, light or radioactive count), that indicate the presence or absence and amount of specific markers of the particular disease in the specimen.

Test kits generally employ one of three methods for infectious disease testing: microbiology, immunology or molecular biology. Traditional microbiology tests use a growth medium that enables an organism, if present, to replicate and be detected visually. Immunology tests detect the antigen or antibody, which is an indicator (marker) of the pathogen (e.g., virus, bacterium, fungus or parasite). Molecular diagnostic methods, such as the polymerase chain reaction ("PCR"), test for the presence of nucleic acids (DNA or RNA) that are specific to a particular pathogen.

Most infectious disease tests currently use microbiological or immunological methods. However, molecular diagnostic methods are increasingly being used in research and clinical laboratories worldwide. The Company believes that the advent of molecular diagnostic methods complements rather than diminishes the need to test by microbiological and immunological procedures, because different test methods reveal different information about a disease state. The Company anticipates that as new test methods become more widespread, they will account for a larger portion of the Company's business.

*Quality Control for In Vitro Diagnostic Test Kits.* Customers employ quality control products in order to develop and use test kits (both infectious and non-infectious). Quality control products help ensure that test kits detect the correct analyte ("specificity"), detect it the same way every time ("reproducibility" or "precision"), and detect it at the appropriate levels ("sensitivity"). The major element of this quality control process is the continuous evaluation of test kits by the testing of carefully characterized samples that resemble the donor or patient samples routinely used with the test. Quality control is used in both the infectious and non-infectious disease markets, although currently it is not as prevalent among end-users of infectious disease test kits.

The market for quality control products consists of three main customer groups: (i) manufacturers of test kits, (ii) regulatory agencies that oversee the manufacture and use of test kits, and (iii) end-users of test kits, such as hospitals, clinical reference laboratories, plasma centers and blood banks.

## Company Products and Services

### Overview

Through its business unit BBI Diagnostics, the Company offers a broad array of "Diagnostic Products," for in vitro diagnostic use, consisting of Quality Control Panels, Accurun<sup>®</sup> Run Controls and Diagnostic Components, all used in connection with infectious disease testing. Diagnostic Products are used throughout the entire test kit life cycle, from initial research and development, through the regulatory approval process and test kit production, to training, troubleshooting and routine use by end-users. The Company's Quality Control Panels, which combine human blood specimens with comprehensive quantitative data useful for comparative analysis, help ensure that test kits are as specific, reproducible, and sensitive as possible. The Company's Accurun<sup>®</sup> Run Controls enable end-users of test kits to confirm the validity of results by monitoring test performance, thereby minimizing false negative test results and improving error detection. In addition, the Company provides Diagnostic Components, which are custom processed human plasma and serum products, to test kit manufacturers.

Through its wholly-owned subsidiary, BBI Source Scientific, Inc., ("BBI Source"), the Company designs, develops, manufactures and markets "Laboratory Instruments", primarily consisting of readers and washers and other small medical devices. These instruments are used in hospitals and clinics, and in research, environmental and food testing laboratories. Utilizing a common hardware technology platform, these instruments are used in connection with the performance of an *in-vitro* diagnostics test, including reading the test result.

BBI Biotech Research Laboratories, Inc., ("BBI Biotech"), another wholly-owned subsidiary, is the R&D "arm" of the Company, helping to develop new products and services for the other business units, including development of the Barocycler<sup>™</sup> and PULSE<sup>™</sup> tubes, and related protocols to prepare specimens. BBI Biotech seeks to obtain government grants and other research support wherever possible to help fund the cost of this R&D. In addition, BBI Biotech provides repository services for the United States government, and specialty reagents and molecular and cellular biology services for laboratories and test kit manufacturers.

### Diagnostic Products

The Company manufactures its Diagnostic Products from human plasma and serum that are obtained from nonprofit and commercial blood centers, primarily in the United States. The Company has acquired and developed an inventory of approximately 20,000 individual blood units and specimens (with volumes ranging from 1 ml to 800 ml) which provides most of the raw material for its products. Within the

Diagnostic Products class are two groups: Quality Control Products, consisting of Quality Control Panels and Accurun® Run Controls, and Diagnostic Components.

### **Quality Control Panels**

Quality Control Panels consist of blood products characterized by the presence or absence of specific disease markers and a data sheet containing comprehensive quantitative data useful for comparative analysis. These Quality Control Panels are designed for measuring overall test kit performance and laboratory proficiency, as well as for training laboratory professionals. The Company's data sheets, which contain comprehensive quantitative data useful for comparative analysis, are an integral part of its Quality Control Panels. These data sheets are created as the result of extensive testing of proposed panel components in both the Company's laboratories and at major testing laboratories on behalf of the Company in the United States, Asia and Europe, including national public health laboratories, research and clinical laboratories and regulatory agencies. These laboratories are selected based on their expertise in performing the appropriate tests on a large scale in an actual laboratory setting; this testing process provides the Company's customers with the benefit that the Quality Control Panels they purchase from the Company have undergone rigorous testing in actual clinical laboratory settings. In addition, the Company provides information on its data sheets on the reactivity of panel components in all FDA licensed test kits and all leading European test kits for the target pathogen, as well as for all other appropriate markers of this pathogen. For example, the Company's HIV panel data sheets include anti-HIV by IFA, ELISA and western blot; HIV antigen by ELISA; and HIV RNA by several molecular diagnostic procedures. The Company's data sheets require significant time and scientific expertise to prepare. The following table describes the types, usage and customers of Quality Control Panel products currently offered by the Company:

**Quality Control Panels**

<b>Product Line</b>	<b>Description</b>	<b>Use</b>	<b>Customers</b>
Seroconversion Panels	Plasma samples collected from a single individual over a specific time period showing conversion from negative to positive for markers of an infectious disease.	Compare the clinical sensitivity of competing manufacturers' test kits, enabling the user to assess the specificity and sensitivity of a test in detecting a developing antigen/antibody, or presence of pathogen nucleic acid.	Test kit manufacturers and regulators.
Performance Panels	A set of 10 to 50 serum and plasma samples collected from many different individuals and characterized for the presence or absence of a particular disease marker.	Determine test kit performance against all expected levels of reactivities in the evaluation of new, modified and improved test methods.	Test kit manufacturers and regulators.
Sensitivity Panels	Precise dilutions of human plasma or serum containing a known amount of an infectious disease marker as calibrated against international standards.	Evaluate the low-end analytical sensitivity of a test kit.	Test kit manufacturers.
Qualification Panels	Dilutions of human plasma or serum manifesting a full range of reactivities in test kits for a specific marker.	Demonstrate the consistent lot-to-lot performance of test kits, troubleshoot problems, evaluate proficiency, and train laboratory technicians.	Clinical reference laboratories, blood banks, and hospital laboratories.
OEM Panels	Custom-designed Qualification Panels for regulators and test kit manufacturers for distribution to customers or for internal use.	Train laboratory personnel on new test kits or equipment.	Custom designed with test kit manufacturers and regulators as an end-user product or for internal use.
Verification Panels	Verification Panels contain naturally occurring undiluted samples at varying titers.	Verify accuracy and ensure that reagents perform to expectation; also used to troubleshoot system problems and to document problem resolution.	Clinical reference laboratories, blood banks, hospital laboratories.

The Company first introduced Quality Control Panels in 1987. The Company currently offers a broad range of Quality Control Panels that address a variety of needs of manufacturers and regulators of test kits as well as blood banks, hospitals, clinical laboratories and other end-users. Prices for the Company's quality control seroconversion, performance and sensitivity panels range from \$450 to \$2,000 each, and its qualification, OEM, and verification panels generally range from \$100 to \$200 per panel.

Seroconversion and performance panels are comprised of unique and rare plasma specimens obtained from individuals during the short period of time when the markers for a particular disease are converting from negative to positive. As a result, the quantity of any such panel is limited, so that the Company must replace these panels as they sell out with another panel comprised of different specimens from a different individual, equally unique and rare. The Company believes that its inventory and relationships with blood centers affords it a competitive advantage in acquiring such plasma for replacement panels and developing new products to meet market demand. However, the Company cannot be certain that it will be able to continue to obtain such specimens.

Quality Control Panels currently span the immunologic markers for AIDS (i.e., HIV), Hepatitis (A, B and C), Lyme Disease and ToRCH (Toxoplasma, rubella, cytomegalovirus and herpes simplex virus).

### ***Accurun<sup>®</sup> Run Controls***

End-users of test kits use run controls to monitor test performance, in order to minimize false negative test results and improve error detection. Run controls consist of one or more specimens of known reactivity that are tested with donor or patient samples in an assay to determine whether the assay is performing within the manufacturer's specifications. Clinical laboratories generally process their patient specimens in a batch processing mode, and typically include 25 to 100 specimens to be tested in each batch (a "run"). Large laboratories may perform several runs per day, while smaller laboratories may perform only a single run each day, or sometimes only several runs per week. A clinical laboratory using a run control will place the run control product in a testing well or test tube, normally used for a specimen, and will test it in the same manner that it tests the donor or patient specimens. It will then compare the results generated to an acceptable range for the run control, determined by the user, to assess whether the results of the other, unknown specimens may be relied upon. The run control result must be within the acceptable range to be considered valid. This is often tracked visually using what is known as a Levey-Jennings chart. Depending upon a particular laboratory's quality control practices, it may use several Run Controls on each run or it may simply use a run control in a single run at the beginning and end of the day.

The Company's AccuChart<sup>™</sup> tracking and charting software, used as part of a laboratory's quality assurance program, runs on a personal computer and is designed to provide the data tracking capability needed to document laboratory performance.

The Company's Accurun<sup>®</sup> family of products is targeted at the end-users of infectious disease test kits. The Company believes that it offers the most comprehensive line of serological and nucleic acid based run controls in the industry, and that its Accurun<sup>®</sup> products, in combination with its Quality Control Panel and AccuChart products, provide an extensive line of products for quality assurance in infectious disease testing. The Company intends to continue to expand its line of Accurun<sup>®</sup> products, thereby providing its customers with the convenience and cost effectiveness of a single supplier for independent run controls.

The Company introduced its first four Accurun<sup>®</sup> Run Control products in the fourth quarter of 1993 and has since developed and released for sale an additional 52 Accurun<sup>®</sup> products. Eight products have been discontinued, for a total of 48 run controls available as of December 31, 2001. Forty-four of these products are available for clinical diagnostic purposes; the others currently are limited to research use. Current Accurun<sup>®</sup> Run Control products generally range in price from \$5 to \$60 per milliliter.

### ***Diagnostic Components***

Diagnostic Components are processed human plasma and serum materials supplied to infectious disease test kit manufacturers and combined (often after further processing by the manufacturer) with other materials to become various reagents (fluid components) of manufacturer's test kits. The Company supplies Diagnostic Components in three product lines: Normal Human Plasma and Serum, Basematrix, and Characterized Disease State Serum and Plasma. Normal Human Plasma is the clear liquid portion of blood which contains proteins, antibodies, hormones and other substances, with the Normal Human Serum product also having the clotting factors removed. Basematrix, the Company's proprietary processed serum product that has been chemically converted from plasma, is designed to be a highly-stable, lower cost substitute for most normal human serum and plasma applications. Characterized Disease State Serum and Plasma are collected from specific blood donors pre-selected because of the presence or absence of a particular disease marker. The Company often customizes its Diagnostic Components by further processing the raw material to meet the specifications of the test kit manufacturer. The Company's Diagnostic Components range in price from \$0.25 to \$60 per milliliter.

### **Laboratory Instruments**

BBI Source, the Laboratory Instrumentation operating segment, designs, develops, manufactures and markets laboratory instruments and other small medical devices used in hospitals and clinics and in research, environmental and food testing laboratories. These instruments are generally sold on a private-label or OEM basis for other companies utilizing a common hardware technology platform. The instruments manufactured by the Company use advanced optical detection methods (luminescence, fluorescence, reflectance, photometry), robotics, fluidics, and unique software, all of which are desired by customers reselling or supplying state-of-the-art instrumentation systems to laboratories worldwide in various applications. This segment also manufactures the Barocycler<sup>™</sup> associated with the Company's planned year 2002 introduction of PCT technology based products.

Most of the Laboratory Instrumentation products currently being offered have been commercialized for a number of years and were primarily developed in conjunction with in vitro diagnostics test kit manufacturers. The Barocycler<sup>™</sup> represents the Company's first major instrument based product launch. BBI Source also seeks to attract development partners for new prototype products. Management believes that these products address important market segments in biomedical and clinical diagnostic testing and in environmental monitoring and food testing research. The BBI Source product line currently includes the following:

***MicroChem<sup>®</sup> and MicroChemII<sup>®</sup> Photometers.*** A compact, low-cost, single tube photometer designed for immunoassay and general chemistry applications, including infectious disease immuno assays, food and water safety testing.

***ChemStat<sup>®</sup> Automated Photometer.*** A high-speed, automated photometer with a sample capacity of 95 tubes and a read rate of one sample per second. This product is suited for high-volume processing of immunoassay and general chemistry.

***E/LUMINA<sup>®</sup> II Luminescence Analyzer.*** A flexible luminometer for both "flash" and "glow" luminescence methods, this automated system reads up to 114 samples and reports final results.

***EXECWASH<sup>®</sup> Washing System.*** An automated immunoassay washing system that can be quickly configured by the user to wash

different solid-phase assay formats by proprietary manifold designs. The EXEC-WASH is fully compatible with a variety of other Company products, such as the ChemStat and the E/LUMINA II Luminescence Analyzer.

**Protocol Design Software System.** A development tool for researchers and assay manufacturers, the program operates under Microsoft® Windows and serves as the master programming center for EXEC-WASH systems to create fluid handling protocols.

**Verif-EYE®.** A reflectance reader for fast, reliable results for use in research and development or process inspection and verification by rapid test kit manufacturers.

## Services

The Company seeks to focus its specialty laboratory services in the advanced biomedical research area. The Company concentrates its services in those areas of infectious disease testing which are complementary to its quality control and diagnostic products businesses.

### **Contract Research and Services**

The BBI Biotech operating segment offers a variety of research services in molecular biology, cell biology and immunology to governmental agencies, diagnostic test kit manufacturers and biomedical researchers. Molecular biology services include DNA extractions and sequencing, genotyping, DNA library construction and screening and development of custom nucleic acid amplification assays. Cell biology and immunology services include sterility testing, virus infectivity assays, cultivations of virus or bacteria from clinical specimens, preparation of viral or bacterial antigens and custom western blot assays.

The Company currently provides contract research services under several contracts and grants. These services are primarily related to infectious disease diagnostics, in support of the products and services that the Company wishes to develop. Current contracts include the following: clinical trials support for candidate HIV vaccines and HBV therapies, identification and DNA sequencing of human genes involved in neurological disorders and cancer, and development of PCR based assays. Additional assays developed over the years include PCR based assays for HIV, Parvovirus B19, Hepatitis B virus, West Nile Virus, Lyme Disease, Babesiosis, Ehrlichia and HSV.

### **Blood Processing and Repository Services**

Since 1983, BBI Biotech has provided blood processing and repository services for the National Cancer Institute ("NCI"), also a part of the National Institutes of Health ("NIH"). The repository stores over 8,000,000 specimens and processes or ships up to several thousand specimens per week in support of various NIH cancer and virus research programs. In 2001, BBI Biotech was awarded a follow on \$10.3 million NCI repository contract. In 1998, BBI Biotech received a six-year \$4.7 million repository contract (including five one-year extension options) with the National Heart, Lung and Blood Institute of the NIH. In 1999, it received a seven-year, \$9.6 million repository contract with the National Institute of Allergy and Infectious Disease. In 2000, BBI Biotech was awarded a one-year \$854,000 subcontract by New England Research Institutes, Inc. to provide repository and related specimen processing and testing services for the Hepatitis C Antiviral Long-term Treatment against Cirrhosis (HALT-C) Trial, a clinical trial funded by the National Institutes of Diabetes and Digestive and Kidney Diseases (NIDDK), an institute of the NIH. Subsequent funding has continued. BBI Biotech is currently focusing on developing a research and development program to extend the life and maintain the quality of specimens that are stored at ultra-low temperatures as well as expanding the Company's repository customer base to include more industry clients. To date all renewal options under these contracts have been approved, although the Company cannot be certain that any subsequent options will be exercised.

### **Other Services**

**Clinical Trials.** The Company from time to time conducts clinical trials for domestic and foreign test kit and device manufacturers. Manufacturers must collect data for submission to the United States FDA and other countries' regulatory agencies, and these manufacturers contract with organizations such as the Company to perform this work. By providing this service, the Company is able to maintain close contact with test kit and device manufacturers and regulators, and is able to evaluate new technologies in various stages of development. The Company believes that the reputation of its laboratory and scientific staff, its large number of Quality Control Panels, and its inventory of characterized serum and plasma specimens assist the Company in marketing its clinical trial services to its customers. The Company has performed clinical trials for a number of United States and foreign test kit and device manufacturers seeking to obtain FDA approval for their infectious disease test kits and medical devices.

**Laboratory Instrumentation Services.** BBI Source offers services to design, develop, manufacture and distribute laboratory instruments to companies seeking to market biomedical products manufactured under government-approved manufacturing practices. These services range in complexity from consulting to full system development, technology transfer, and distribution.

**After-sales Service.** BBI Source also provides after-sales service, including third party maintenance. Management believes that after-sales service provides a marketing advantage in many of the Company's markets, since many of the Company's customers do not maintain their own full service departments. The Company's service department is located at BBI Source's facility in Garden Grove, California. The Company utilizes an independent third party contractor located in Giessen, Germany, to provide a fully functional European service and support center.

## Research and Development

The Company's research and development efforts are focused on (i) the ongoing development of pressure cycling technology ("PCT") for nucleic acid extraction and pathogen inactivation, which the Company anticipates having a commercially available extraction system for sale in year 2002; (ii) the development of new and improved Quality Control Products (Panels and Accurun®) for the end-user market and the *in vitro* diagnostics market, (iii) the development of purified reagents and proteins and nucleic acid based assays; and (iv) the design and development of new laboratory instruments and mechanical and optical detection techniques, emphasizing its Verif-EYE reflectance

reader. The Company has approximately 20 full or part-time employees involved in its research and development effort associated with continuing operations as of December 31, 2001. As announced in 1998, at the time of its acquisition of BioSeq, Inc., the Company continues to invest significantly in research and development both in whole dollars and as a percentage of revenue, and expects to continue to do so for the foreseeable future. See "Management's Discussion and Analysis of Financial Condition and Results of Operations -- Results of Operations." The Company's research scientists work closely with sales, marketing, manufacturing, regulatory and finance personnel to identify and prioritize the development of new products and services. Whenever it can, the Company seeks to supplement its research and development funding with grants provided by various agencies and departments of the United States government. See also "Contract Research and Services."

**Quality Control Products.** In the area of Quality Control Products, the Company's product development activities center on the identification and characterization of materials for the manufacture of new products and the replacement of sold-out products. During 2001, the Company introduced 2 new Seroconversion, Performance, and Sensitivity Panel products, and 4 new Accurun<sup>®</sup> Run Controls. The Company is developing new Quality Control Products for use with both immunological and molecular diagnostic tests for subtypes and variants of HIV, HCV and HBV, controls for HIV drug resistant assays and a variety of controls targeted for leading instrument platforms. The Company has increased the number of Quality Control Products it offers from approximately 20 products in 1990 to more than 200 in 2001.

**Laboratory Instruments.** The Company's product development activities related to laboratory instruments are centered on development of the Barocycler<sup>™</sup> and the PULSE<sup>™</sup> tube, additional configurations of a "reflectance" reader to produce objective results from rapid *in vitro* diagnostic tests as well as an updated version of the MicroChem<sup>®</sup> (the MicroChem<sup>®</sup> II). In addition, the Company continues to work on applications for existing products to broaden their utilization.

**Pressure Cycling Technology ("PCT").** The Company owns patented technology based on PCT. PCT research is primarily focused in two areas: (1) nucleic acid extraction and purification from target pathogens in connection with sample preparation for PCR or other molecular testing; and (2) pathogen inactivation of blood plasma intended for transfusion or for further fractionation into transfusion products. Both of these areas of research have been recently funded by Phase II Small Business Innovative Research Grants, which provide \$750,000 each, over a two year period. The company is currently developing a pressure cycling system utilizing a computer controlled instrument, the Barocycler<sup>™</sup> NEP2017, and specialized PULSE<sup>™</sup> tubes which are capable of releasing biologically active nucleic acids and proteins from plant and animal tissues, as well as other organisms, such as mycobacteria, which are not easily disrupted by standard chemical methods. The pressure cycling system is expected to be available for sale in 2002.

## Sales and Marketing

The Company's sales and marketing efforts are organized by business unit consistent with the unit's business objectives, and coordinated via frequent planning with senior management. Overall, the Company employs approximately 24 people in sales, marketing, and customer service functions associated with continuing operations as of December 31, 2001. The Company's overall marketing strategy is to focus on the needs of its customers in three broad areas: (i) diagnostic products to improve the quality and accuracy of test results and kit components for the *in vitro* diagnostic industry, (ii) life science products and services in support of infectious disease researchers, and (iii) a sample preparation system planned for introduction in year 2002 based on PCT technology.

The strategy for Diagnostic Products is to focus on customer needs in the infectious disease testing market throughout the entire test kit life-cycle, from initial research and development, through the regulatory approval process and test kit production, to training, troubleshooting and routine use by end-users such as clinical laboratories, hospitals and blood banks. The end-user portion of this market is promoted under the marketing platform, known as "Total Quality System" ("TQS"). TQS is a package of Quality Control Products, including the Company's Accurun<sup>®</sup> Run Controls and AccuChart Quality Control Software, that is designed to provide test kit end-users with the products needed in an overall quality assurance program. These products enable laboratories to evaluate each of the key elements involved in the testing process: the test kit, laboratory equipment, and laboratory personnel. The Company believes that TQS effectively addresses the need for end-users to ensure the accuracy of their test results. The Company intends to continue to expand its sales and marketing activities with respect to its Accurun<sup>®</sup> line of run control products. In addition, the Company continues to expand the Accurun<sup>®</sup> product line to support the high growth nucleic acid testing market, and to capitalize on the worldwide implementation of new technology to improve the safety of blood products.

The Company's Diagnostic Products are currently sold through a combination of telephone, mail, third party distributors and direct sales efforts. Domestically, Diagnostic Products are sold through a direct sales force led by a Director of Sales and Marketing. The sales force consists of two sales group managers and 12 sales representatives. Internationally, the Company distributes its Diagnostic Products both directly and through independent distributors located in Japan, Australia, North and South America, Southeast Asia, Israel and Europe. The Company's international sales manager oversees the Company's foreign distributors. The Company's Laboratory Instruments are sold through a direct domestic and international sales force consisting of one director and one sales representative.

The Company emphasizes high quality products and services, technical knowledge, and responsiveness to customer needs in its marketing activities for both products and services. The Company educates its distributors, customers and prospective customers about its products through a series of detailed marketing brochures, technical bulletins and pamphlets, poster presentations, news releases and direct mail pieces. These materials are supplemented by occasional advertising in industry publications, technical presentations, and exhibitions at local, national and international trade shows and expositions. The Company utilizes a product information library on its web site ([www.bbii.com](http://www.bbii.com)) allowing customers, sales personnel and international distributors immediate access to detailed product information and marketing literature.

## Seasonality

Historically, the Company's results of operations have been subject to quarterly fluctuations due to a variety of factors, primarily customer purchasing patterns, (sometimes driven by end-of-year expenditures), and seasonal demand. In particular, the Company's sales of

its off-the-shelf Diagnostic Products typically have been highest in the fourth quarter and lowest in the first quarter of each fiscal year, whereas OEM product sales may peak in any quarter of the year, depending on the customer's underlying production cycle for their own product. Research Contracts are generally for large dollar amounts spread over one to five-year periods, and upon completion, frequently do not have renewal phases. As a result, these contracts can cause large fluctuations in revenue and net income. In addition to staff dedicated to internal research and development, certain of the Company's technical staff work on both Contract Research for customers and Company sponsored research and development. The allocation of certain technical staff to such projects depends on the volume of Contract Research. As a result, research and development expenditures fluctuate due to increases or decreases in contract research performed.

## Customers

The Company's customers for Diagnostic Products consist of four major groups: (1) international diagnostics and pharmaceutical manufacturing companies, such as Abbott Diagnostics, Bayer, bioMerieux, Biorad, Chiron, Dade-Behring, DiaSorin, Fujirebio, Hoffman LaRoche and Ortho Diagnostics (Johnson & Johnson); (2) regulatory agencies such as the United States FDA and CDC, the British Public Health Laboratory Service, the French Institut National de la Transfusion Sanguine, and the German Paul Ehrlich Institute, (3) national and international proficiency providers such as the College of American Pathologists and the European Union Concerted Action for Quality Control and (4) end-users of diagnostic test kits, such as hospital and independent clinical laboratories, including Quest Diagnostics, Specialty Laboratories, public health laboratories and blood banks, including the American Red Cross, Swiss Red Cross, and United Blood Services.

The Company's customers for Laboratory Instruments consist of international diagnostic and pharmaceutical manufacturing companies and are generally sold on an OEM basis, for use by hospitals, and clinical and research laboratories. In addition, Laboratory Instruments are sold directly to environmental and food testing laboratories, and wineries. Customers include Hitachi Chemical Diagnostics, Beckman/Hybritech Inc., Vicam, Edwards Life Science, Nihon Kohden, Vysis and Toray Fuji Bionics Inc.

The Company's customers for contract research include various agencies of the National Institutes of Health (NIH) such as the National Institute of Allergies and Infectious Disease ("NIAIDS"), the National Cancer Institute ("NCI"), and the National Heart Lung and Blood Institute ("NHLBI").

The Company does not have long-term contracts with its customers for Diagnostic Products, which are generally sold pursuant to purchase orders for specific purchases. Laboratory Instruments are generally sold on an OEM basis under medium-term contracts with monthly delivery dates. The Company believes that its relationships with customers are satisfactory.

The Company's Consolidated Financial Statements, including the Notes thereto, set forth in Item 8 of this report provide information relating to the Company's foreign and domestic sales.

During the fiscal years 2001, 2000, and 1999, sales (from continuing operations) to the Company's three largest customers accounted for an aggregate of approximately 30%, 20% and 24%, respectively, of the Company's net sales, although the customers were not identical in each period. During the fiscal years 2001, 2000, and 1999, the combined revenues from all branches of the National Institutes of Health, a United States Government agency, accounted for approximately 31%, 30% and 23%, respectively, of total consolidated revenues from continuing operations of the Company. While these contracts contain standard terms and conditions relative to audits and/or termination, in whole or in part, without prior notice at the Government's convenience the Company has never had any contracts terminated and has no knowledge of any actions pending. While the Company believes that the loss of any one of these customers would have an adverse effect on the Company's results, this risk is partially mitigated by the diversity of its customer base within the *in vitro* diagnostics industry and the different diseases and instrument platforms on which they focus.

## Manufacturing and Operations

The Company manufactures and assembles Diagnostic Products at its facility in West Bridgewater, Massachusetts. Raw materials (primarily plasma and serum) are acquired from a variety of vendors and through a program of donor recruitment, screening, management, and plasma/serum collection and characterization. Laboratory instruments are manufactured and assembled at the Company's facility in Garden Grove, California. All important raw materials and components acquired come from a variety of local and/or national suppliers and distributors who have multiple sources of supply. Both of these facilities are ISO 9001 certified.

The Company operates its research and development laboratory (including PCT) in Gaithersburg, Maryland and a repository facility in Frederick, Maryland. See "Item 2 -- PROPERTIES."

## Competition

The market for the Company's products and services is highly competitive. Many of the Company's competitors are larger than the Company and have greater financial, research, manufacturing, and marketing resources. Important competitive factors for the Company's products include product quality, price, ease of use, customer service and reputation. In a broader sense, industry competition is based upon scientific and technical capability, proprietary know-how, access to adequate capital, the ability to develop and market products and processes, the ability to attract and retain qualified personnel, and the availability of patent protection. To the extent that the Company's products and services do not reflect technological advances, the Company's ability to compete in its current and future markets could be adversely affected.

In the area of Quality Control Products, the Company competes in the United States with NABI (formerly North American Biologicals, Inc.) in run controls and quality control panel products, with Acrometrix, Ambion, Bio-Rad Laboratories, Inc., Blackhawk Biosystems Inc. and MAS in run controls, and with a number of smaller, privately-held companies in quality control panels. In Europe, in addition to the above, the Dutch Red Cross offers several run control and panel products. The Company believes that all of these competitors currently offer a less diverse line of panel and run control products than the Company, although the Company cannot be certain



that these companies will not expand their product lines.

In the Diagnostic Components area, the Company competes with integrated plasma collection and processing companies such as Serologicals, Inc. and NABI, as well as smaller, independent plasma collection centers and brokers of plasma products. In the Diagnostic Components area, the Company competes on the basis of quality, breadth of product line, technical expertise and reputation.

The laboratory instrument manufacturing industry is diverse and highly competitive. The Company believes its technology base, reputation for reliability, systems integration and service capabilities provide it with a competitive advantage over its competitors which include: Dynatech Corp, Kollman Manufacturing Company, Inc., Bio-Tek Instruments Inc., Relat Inc. (part of Colorado Medtech, Inc.), APW, and Plexus (SeaMed), as well as numerous, smaller companies, such as Awareness Technology Inc.

BBI Biotech competes primarily with BioReliance Corporation and several universities for research and development contracts and with ATTC, Cryonix, Corielle and McKesson Bioservices, Inc., for repository services.

### **Intellectual Property**

The Company holds as trade secrets current technology used to prepare Basematrix and other blood-based products. None of the Company's Diagnostic Components has been patented. The Company relies primarily on a combination of trade secrets and non-disclosure and confidentiality agreements to establish and protect its proprietary rights in these products and related technology. The Company cannot be certain that others will not independently develop or otherwise acquire the same, similar or more advanced trade secrets and know-how.

BBI Source has also relied on trade secrets and proprietary know-how for its Laboratory Instruments which it protects in part by entering into confidentiality agreements with persons or parties deemed appropriate by management. In addition, the Company currently has six issued United States patents, covering significant aspects of the Company's core instrument technology and techniques, as well as several electronic and mechanical designs employed in the Company's products. These patents expire between 2006 and 2013.

The Company has eight patents issued and several pending patent applications for its Pressure Cycling Technology. Several of these have been followed up with foreign applications, and the Company expects to file additional foreign applications in the future relating to Pressure Cycling Technology. These patents expire between 2015 and 2019.

The Company has no reason to believe that its products and proprietary methods infringe the proprietary rights of any other party. However, the Company cannot be certain that other parties will not assert infringement claims in the future.

BBI<sup>®</sup>, Accurun<sup>®</sup>, MicroChem<sup>®</sup>, MicroChemII<sup>®</sup>, Chemstat<sup>®</sup>, EXECWASH<sup>®</sup> and Verif-EYE<sup>®</sup> are registered trademarks of the Company. The Company's registered trademarks currently have expiration dates ranging from 2004 to 2008 and the Company may renew such registrations prior to expiration.

### **Government Regulation**

The manufacture and distribution of medical devices, including products manufactured by the Company that are intended for *in vitro* diagnostic use, are subject to extensive government regulation in the United States and in other countries.

In the United States, the Food, Drug, and Cosmetic Act ("FDCA") prohibits the marketing of most *in vitro* diagnostic products until they have been cleared or approved by the FDA, a process that is time-consuming, expensive, and uncertain. *In vitro* diagnostic products must be the subject of either a premarket notification clearance (a "510(k)") or an approved premarket approval application ("PMA"). With respect to devices reviewed through the 510(k) process, a company may not market a device for diagnostic use until an order is issued by the FDA finding the product to be substantially equivalent to an existing FDA cleared, and marketed device. A 510(k) submission may involve the presentation of a substantial volume of data, including clinical data, and may require a substantial period of review. With respect to devices reviewed through the PMA process, a company may not market a device until the FDA has approved a PMA application, which must be supported by extensive data, including preclinical and clinical trial data, literature, and manufacturing information to prove the safety and effectiveness of the device.

The Company's Accurun<sup>®</sup> Run Controls, when marketed for blood donor screening or diagnostic use, have been classified by the FDA as medical devices that until 1998 required clearance under the 510(k) process. In 1998, new rules took effect that exempted unassayed controls intended for use in diagnostic testing from the requirement for a 510(k) submission. BBI may now label these products "For *In Vitro* Diagnostic Use" if they are validated according to the Company's protocols and manufactured according to cGMP (current Good Manufacturing Practices, which is FDA guidance for manufacturing processes for medical devices). The FDA still requires 510(k) clearance for assayed controls, and controls intended for use in blood screening. The FDA could, in addition, require that some products be reviewed through the PMA process, which generally involves a longer review period and the submission of more information to FDA. The Company cannot be certain that it will obtain regulatory approvals on a timely basis, if at all. Failure to obtain regulatory approvals in a timely fashion or at all could have a material adverse effect on the Company.

As of March 1, 2002, a total of 15 products in the Accurun 1<sup>®</sup> line and 29 single analyte Accurun<sup>®</sup> Run controls have either received 510(k) clearance or have been validated according to the Company's protocols and are manufactured according to cGMP. Certain of the Company's Accurun<sup>®</sup> Run Controls are currently marketed "for research use only." The labeling of these products limits their use to research. It is possible, however, that some purchasers of these products may use them for diagnostic purposes despite the Company's intended use. In these circumstances, the FDA could allege that these products should have been cleared or approved by the FDA, or validated prior to marketing, and initiate enforcement action against the Company, which could have a material adverse effect on the Company. The FDA has issued a Draft Policy Compliance Guideline, which, if it takes effect as currently issued, will strictly limit the sale of products labeled "for research use only." The Company is monitoring this situation, and will adapt its policies as required.

BBI Source generally obtains 510(k) and CE approval for all laboratory instrumentation designed and manufactured in its Garden Grove, CA facility.

The Company is registered as a medical device manufacturer with the FDA for its Diagnostic Products and Laboratory Instruments and files changes/listings of its products semi-annually. The Company's facilities in West Bridgewater, Massachusetts for Diagnostic Products and Garden Grove, California for Laboratory Instruments are FDA Good Manufacturing Practices (FDA/GMP) facilities. The Company must maintain high standards of quality in manufacturing, testing and documentation, and implement strict cGMP/QSR requirement guidelines governing reagent and instrument manufacturing.

Once cleared or approved, medical devices are subject to pervasive and continuing regulation by the FDA, including, but not limited to cGMP/QSR requirements, regulations governing testing, control, and documentation and reporting of adverse experiences with the use of the device. The FDA monitors ongoing compliance with cGMP/QSR requirements and other applicable regulatory requirements by conducting periodic inspections. FDA regulations require FDA clearance or approval for certain changes if they do or could affect the safety and effectiveness of the device, including, for example, new indications for use, labeling changes or changes in design or manufacturing methods. In addition, both before and after clearance or approval, medical devices are subject to certain export and import requirements under the FDCA. Product labeling and promotional activities are subject to scrutiny by the FDA and, in certain instances, by the Federal Trade Commission. Products may be promoted by the Company only for their approved use. Failure to comply with these and other regulatory requirements can result, among other consequences, in failure to obtain pre-market approvals, withdrawal of approvals, total or partial suspension of product distribution, injunctions, civil penalties, recall or seizures of products and criminal prosecution.

The Company believes that its Quality Control Panels are not regulated by the FDA because they are not intended for diagnostic purposes. The Company believes that its Diagnostic Components, which are components of *in vitro* diagnostic products, may be subject to certain regulatory requirements under the FDCA and other laws administered by the FDA, but do not require that the Company obtain a pre-market approval or clearance. The Company cannot be certain, however, that the FDA would agree or that the FDA will not adopt a different interpretation of the FDCA or other laws it administers, which could have a material adverse effect on the Company.

The Company's Diagnostic Products and Laboratory Instruments business units are both ISO9001 certified, with registration by TUV Rheinland for the Diagnostic Products unit and British Standard Institute for the Laboratory Instruments unit. The Laboratory Instrument group is also certified to EN46001, a set of supplementary requirements applicable to their products.

Laws and regulations affecting some of the Company's products are in effect in many of the countries in which the Company markets or intends to market its products. These requirements vary from country to country. Member states of the European Economic Area (which is composed of members of the European Union and the European Free Trade Association) are in the process of adopting various product and service "Directives" to address essential health, safety, and environmental requirements associated with the products and services. These "Directives" cover both quality system requirements (ISO Series 9000 Standards and the EN46001 Requirements) and product and marketing related requirements. In addition, some jurisdictions have requirements related to marketing of the Company's products. The Company cannot be certain that it will be able to obtain any regulatory approvals required to market its products on a timely basis, or at all. Delays in receipt of, or failure to receive such approvals, or the failure to comply with regulatory requirements in these countries or states could lead to compliance action, which could have a material adverse effect on the Company's business, financial condition, or results of operations.

The Company's service-related business (clinical trials, repository operations, contract research and instrumentation services) is subject to other national and local requirements. The Company's facilities are subject to review, inspection, licensure or accreditation by some states, national professional organizations, and other national regulatory agencies. Studies to evaluate the safety or effectiveness of FDA regulated products (primarily human and animal drugs or biologics) must also be conducted in conformance with relevant FDA requirements, including Good Laboratory Practice ("GLP") and Good Manufacturing Practice ("GMP") regulations, investigational new drug or device regulations, Institutional Review Board ("IRB") regulations and informed consent regulations.

The Company currently holds permits issued by Centers for Disease Control and Prevention (Importation of Etiological Agents or Vectors of Human Diseases), the US Department of Agriculture (Importation and Transportation of Controlled Materials and Organisms and Vectors) and the Maryland State and US Nuclear Regulatory Commission (*in vitro* testing with by-product material under general license, covering the use of certain radioimmunoassay test methods and Radioactive Materials).

The Company is also subject to government regulation under the Clean Water Act, the Toxic Substances Control Act, the Resource Conservation and Recovery Act, the Atomic Energy Act, and other national, state and local restrictions relating to the use and disposal of biohazardous, radioactive and other hazardous substances and wastes. The Company is an exempt small quantity generator of hazardous waste and has a US Environmental Protection Agency identification number. The Company is also registered with the US Nuclear Regulatory Commission for use of certain radioactive materials. The Company is also subject to various state regulatory requirements governing the handling of and disposal of biohazardous, radioactive and hazardous wastes. The Company has never been a party to any environmental proceeding.

Internationally, some of the Company's products are subject to additional regulatory requirements, which vary significantly from country to country. Each country in which the Company's products and services are offered must be evaluated independently to determine the country's particular requirements. In foreign countries, the Company's distributors are generally responsible for obtaining any required government consents.

## **Employees**

As of December 31, 2001 the Company employed 202 persons, all of whom were located in the United States. Of these, 98 persons were employed by the West Bridgewater, Massachusetts company, 3 (part time) by the New Britain, Connecticut company (a discontinued operation), 78 at its two Maryland facilities, and 23 by the Garden Grove, California company. None of the Company's employees is covered by a collective bargaining agreement. The Company believes that it has a satisfactory relationship with its employees.

## Executive Officers of the Registrant

The following table sets forth the names, ages and positions of the executive officers of the Company as of December 31, 2001:

<u>Name</u>	<u>Age</u>	<u>Position</u>
Richard T. Schumacher	51	Chief Executive Officer and Chairman of the Board
Kevin W. Quinlan	51	President and Chief Operating Officer, Treasurer and Director
Patricia E. Garrett, Ph.D.	58	Senior Vice President - Strategic Programs
Mark M. Manak, Ph.D.	50	Senior Vice President and General Manager of BBI Biotech
David F. Petersen	55	Senior Vice President and General Manager of BBI Source
Kathleen W. Benjamin	45	Vice President, Human Resources
Richard D'Allessandro	55	Vice President, Information Technology

*Mr. Schumacher*, the Founder of the Company, has been the Chief Executive Officer and Chairman since 1992 and served as President from 1986 to August 1999. Mr. Schumacher served as the Director of Infectious Disease Services for Clinical Science Laboratory, a New England-based medical reference laboratory, from 1986 to 1988. From 1972 to 1985, Mr. Schumacher was employed by the Center for Blood Research, a nonprofit medical research institute associated with Harvard Medical School. Mr. Schumacher received a B.S. in zoology from the University of New Hampshire.

*Mr. Quinlan*, a Director of the Company since 1986, has served as President and Chief Operating Officer since August 1999 and Treasurer since June 2001. From January 1993 to August 1999, he served as Senior Vice President, Finance, Chief Financial Officer and Treasurer. From 1990 to December 1992, he was the Chief Financial Officer of ParcTec, Inc. a New York-based leasing company. Mr. Quinlan served as Vice President and Assistant Treasurer of American Finance Group, Inc. from 1981 to 1989 and was employed by Coopers & Lybrand from 1975 to 1980. Mr. Quinlan is a certified public accountant and received a M.S. in accounting from Northeastern University and a B.S. in economics from the University of New Hampshire.

*Dr. Garrett* is presently Senior Vice President – Strategic Programs, and served as Senior Vice President and General Manager of BBI Clinical Laboratories from 1999 through 2001. From 1988 to 1999, she served as Senior Vice President, Regulatory Affairs & Strategic Programs. From 1980 to 1987, Dr. Garrett served as the Technical Director of the Chemistry Laboratory, Department of Laboratory Medicine at the Lahey Clinic Medical Center. Dr. Garrett earned her Ph.D. from the University of Colorado and was a postdoctoral research associate at Harvard University, Oregon State University, Massachusetts Institute of Technology and the University of British Columbia.

*Dr. Manak* has served as Senior Vice President and General Manager of BBI Biotech since August 1999. From 1992 to 1999 he served as Senior Vice President, Research and Development. From 1980 to 1992, he served as Director of Molecular Biology and Director of Contracts and Services of Biotech Research Laboratories. Dr. Manak received his Ph.D. in biochemistry from the University of Connecticut and completed postdoctoral research work in biochemistry/virology at Johns Hopkins University.

*Mr. Petersen* has served as Senior Vice President and General Manager of BBI Source since August 1999. From May 1998 to August 1999, he was Vice President, BBI Source Scientific. Mr. Petersen has 25 years of experience in operations management and materials planning including 10 years as Senior Director of Operations for Source Scientific. Before joining Source Scientific in 1988, he was the Manager of Manufacturing for Matrix Instruments from 1985 to 1988 and previously was Manager of Production and Inventory Control for Farr Company, Inc. from 1977 to 1985. He is certified in production and inventory management (CPIM) by the American Production and Inventory Control Society (APICS). He is also an Assistant Professor at California State University Dominguez Hills, where he instructs upper division courses in manufacturing techniques and material resource planning. He holds a B.S. in business management from the University of LaVerne in LaVerne, California.

*Ms. Benjamin* has served as Vice President, Human Resources since January 1999. Prior to her promotion to Vice President, Ms. Benjamin served as Director of Human Resources and Investor Relations from 1997 to 1999. Prior to joining the Company in 1997 she was employed by Shields Health Care Group, a provider of Magnetic Resonance Imaging and radiation oncology, serving as their Director of Operations from 1992 to 1997. Prior to this time she was an educator. Ms. Benjamin received her B.S., from the College of Life Sciences and Agriculture at the University of New Hampshire.

*Mr. D'Allessandro* has served as Vice President, Information Technology since January 1999. Mr. D'Allessandro joined the Company in 1993 as Director, Management Information Systems and served in that capacity until his promotion to Vice President. Mr. D'Allessandro has 30 years of experience in data processing/information systems technology, with a focus on manufacturing and biotechnology organizations. Mr. D'Allessandro is APICS certified and received his B.S. in Management Information Systems from Northeastern University.

Officers are nominated by the Chief Executive Officer and elected by the Board of Directors.

## ITEM 2. PROPERTIES.

The Company owns its corporate offices and diagnostic products manufacturing facility for its BBI Diagnostics operating segment, which is located in a two-story, 32,000 square foot building in West Bridgewater, Massachusetts. The Company has been renovating and expanding this facility during recent years, and believes that upon completion of renovations, its facility in West Bridgewater MA will be sufficient to meet its needs for several years. This building is subject to a 10 year mortgage. Monthly payments on this mortgage is based on a 20 year amortization schedule with a balloon payment representing the remaining balance due in full on March 10, 2010. As of February 2002, the Company leases 27,000 square feet of space in Garden Grove, California where its BBI Source business unit manufactures laboratory instruments; this lease expires on January 31, 2005. The Company leases laboratory facilities in Gaithersburg and Frederick, Maryland. The BBI Biotech segment's Gaithersburg facility contains 36,500 square feet of custom built laboratory and office space, and is

occupied under a ten-year lease that is due to expire on October 31, 2007. The Frederick facility contains 36,000 square feet of repository space under a seven-year lease that is due to expire on November 30, 2006.

BBI Clinical Laboratories, a discontinued operation, operated from a 15,000 square foot facility in New Britain CT pursuant to a lease which expires in July 2005. The buyer of the business and certain assets and liabilities of BBICL reimbursed the Company for essentially all rental-related costs of this facility during the period February 21, 2001 through December 31, 2001.

### ITEM 3. LEGAL PROCEEDINGS.

In August 1999, the Company sold 500,000 warrants to purchase the Company's stock to Paradigm Group, LLC, a private investment company. In February 2000, the Company received notice that Paradigm Group, LLC exercised all of their warrants to purchase the Company's common stock. The holders of the warrants were required to pay the exercise price when the registration of the underlying shares became effective which was in December 2000. In August 2000, the Company received a summons and complaint from Paradigm Group, LLC naming the Company as a defendant. The suit, filed in the Circuit Court of Cook County, Illinois, alleged breach of contract claims and fraud against the Company in connection with the sale by the Company to the Paradigm Group, LLC of the above warrants, the exercise of those warrants by Paradigm Group, LLC and a delay in the registration of those shares with the U. S. Securities and Exchange Commission. In December 2000, Paradigm Group, LLC withdrew this lawsuit. In the fourth quarter of 2000, the Company expensed approximately \$265,000 of costs related to these warrants and the registration of the underlying shares. On June 15, 2001 the Company and Paradigm Group, LLC entered into an agreement to permanently settle their disputes. Under the terms of the agreement, Paradigm Group, LLC rescinded their exercise of the common stock purchase warrants, which have since expired, and the Company retained the 500,000 shares associated with their exercise. These shares were included in the total shares outstanding as well as in the calculation of earnings (loss) per share from February 17, 2000 (the date of exercise) through June 15, 2001 (the date of the agreement). As of September 30, 2001 these shares were cancelled by the Company.

### ITEM 4. SUBMISSION OF MATTERS TO A VOTE OF SECURITY HOLDERS.

No matter was submitted during the fourth quarter of fiscal 2001 to a vote of security holders of the Company.

## PART II

### ITEM 5. MARKET FOR REGISTRANT'S COMMON EQUITY AND RELATED STOCKHOLDER MATTERS.

The Company completed an initial public offering of its Common Stock, \$.01 par value, (the "Common Stock") on October 31, 1996. The Common Stock is listed on the Nasdaq National Market under the symbol "BBII".

The following table sets forth the high and low price, by quarter, during the two most recent fiscal years:

<u>Fiscal Year Ended December 31, 2000</u>	<u>High</u>	<u>Low</u>
First Quarter	\$ 16.97	\$ 2.25
Second Quarter	7.50	3.38
Third Quarter	7.13	2.63
Fourth Quarter	4.63	1.50
<u>Fiscal Year Ended December 31, 2001</u>	<u>High</u>	<u>Low</u>
First Quarter	\$ 3.00	\$ 0.75
Second Quarter	3.84	1.50
Third Quarter	4.31	1.30
Fourth Quarter	3.24	2.25

As of March 19, 2002, there were 20,000,000 shares of Common Stock authorized of which 6,752,252 shares were issued and outstanding, held of record by approximately 3,800 stockholders. See also Note 12 of Notes to Consolidated Financial Statements included in Part 2, Item 8 hereunder.

The Company has not declared or paid any dividends on its Common Stock. In accordance with the terms of the Company's mortgage with a bank, payment of dividends on Common Stock is not permitted. The Company plans to reinvest future profits to expand its business.

### Recent Sales of Unregistered Securities

In December 2001, the Company sold 600,000 shares of common stock of the Company for an aggregate purchase price of \$1,500,000 in a private placement to five accredited investors. The shares were issued in the first quarter of fiscal 2002 and therefore were not included in the total shares outstanding as well as in the calculation of earnings (loss) per share for the year ended December 31, 2001. The issuance of the shares was effected without registration under the Securities Act of 1933, as amended, in reliance upon the exemption from registration contained in Rule 506 of Regulation D promulgated under the Securities Act.

### ITEM 6. SELECTED FINANCIAL DATA (In thousands, except per share data)

The statement of income data for each of the fiscal years in the five-year period ended December 31, 2001, and the balance sheet data

as of December 31, 2001, 2000, 1999, 1998, and 1997, have been derived from the consolidated financial statements of the Company. This data should be read in conjunction with Item 8--Consolidated Financial Statements and Supplementary Data, and Item 7--Management's Discussion and Analysis of Financial Condition and Results of Operations appearing elsewhere herein.

<b>Consolidated Statement of Income Data:</b>	<b>Year Ended December 31,</b>				
	<b>2001</b>	<b>2000</b>	<b>1999</b>	<b>1998 (1)</b>	<b>1997 (2)</b>
<b>REVENUE:</b>					
Products	\$ 13,093	\$ 12,387	\$ 14,057	\$ 13,075	\$ 11,711
Services	8,733	7,083	5,741	6,190	4,844
Total revenue	21,826	19,470	19,798	19,265	16,555
<b>COSTS AND EXPENSES:</b>					
Cost of products	6,338	7,270	7,267	7,180	5,774
Cost of services	6,783	5,581	4,568	4,289	3,624
Research and development	2,303	2,444	3,132	2,297	1,311
Acquired research and development (3)	-	-	-	4,231	-
Selling and marketing	2,916	2,660	2,831	2,883	2,306
General and administrative	3,977	4,919	3,451	3,334	2,447
Impairment of intangible asset (4)	-	1,464	-	-	-
Total operating costs and expenses	22,317	24,338	21,249	24,214	15,462
(Loss) income from continuing operations	(491)	(4,868)	(1,451)	(4,949)	1,093
Interest (expense) income, net (5)	(380)	(1,594)	(413)	(48)	287
(Loss) income from continuing operations before income taxes	(871)	(6,462)	(1,864)	(4,997)	1,380
(Provision for) benefit from income taxes (6)	(16)	(1,152)	744	614	(510)
(Loss) income from continuing operations before cumulative effect of change in accounting principle	(887)	(7,614)	(1,120)	(4,383)	870
Cumulative effect of change in accounting principle (5)	-	(190)	-	-	-
(Loss) income from continuing operations	(887)	(7,804)	(1,120)	(4,383)	870
Income (loss) from discontinued operations	4,334	(197)	306	(6)	135
Net income (loss)	\$ 3,447	\$ (8,001)	\$ (814)	\$ (4,389)	\$ 1,005
(Loss) income per share from continuing operations, basic	\$ (0.14)	\$ (1.43)	\$ (0.24)	\$ (0.94)	\$ 0.20
(Loss) income per share from continuing operations, diluted	(0.14)	(1.43)	(0.24)	(0.94)	0.18
Net (loss) income per share, basic	0.56	(1.46)	(0.17)	(0.94)	0.23
Net (loss) income per share, diluted	\$ 0.56	\$ (1.46)	\$ (0.17)	\$ (0.94)	\$ 0.21
Number of shares used to calculate net (loss) income per share					
Basic	6,204	5,465	4,670	4,655	4,438
Diluted	6,204	5,465	4,670	4,655	4,780

<b>Consolidated Balance Sheet Data:</b>	<b>December 31,</b>				
	<b>2001</b>	<b>2000</b>	<b>1999</b>	<b>1998</b>	<b>1997</b>
Working capital	\$ 9,407	\$ 3,596	\$ 8,615	\$ 8,231	\$ 8,935
Net assets from discontinued operations	-	1,238	1,978	1,346	1,180
Total assets	21,414	22,549	24,934	23,038	22,882
Long term debt, less current maturities	2,403	5,287	7,146	3,977	-
Total stockholders' equity	13,440	7,750	13,646	14,069	18,067
Dividends	-	-	-	-	-

- (1) Effective September 30, 1998, the Company acquired all classes of stock of BioSeq, Inc., a development stage company with no revenue, for a total purchase price of \$4,226.
- (2) Effective July 1, 1997, the Company acquired the business and net assets of Source Scientific, Inc. for \$1,994 which increased 1997 revenue by \$2,608.
- (3) Consists of \$3,381 of in-process research and development related to the BioSeq acquisition, and a charge of \$850 related to the purchase of licensed technology from BioSeq in the first quarter of 1998.
- (4) Includes a \$1,464 write-down of goodwill associated with the acquisition of BBI Source Scientific.
- (5) Includes \$840 of interest expense in 2000 associated with the beneficial conversion feature of the Company's 3% Senior Subordinated Convertible Debentures. \$190 of this amount is recorded as a cumulative effect of change in accounting principle in 2000.
- (6) Includes \$1,135 in 2000 for establishment of a full valuation allowance on the Company's deferred tax assets.

## **ITEM 7. MANAGEMENT'S DISCUSSION AND ANALYSIS OF FINANCIAL CONDITION AND RESULTS OF OPERATIONS.**

### **OVERVIEW**

The Company generates revenue from products and services provided primarily to the in vitro diagnostic infectious disease industry. As discussed in Note 6 to the Consolidated Financial Statements, the Company currently has four operating segments: "Diagnostics," "Biotech," "Laboratory Instrumentation" and "Pressure Cycling Technology, ("PCT")". Two of these, "Diagnostics" and "Laboratory Instrumentation" primarily manufacture products. Within Diagnostics there are three major product lines: Quality Control Panels, Accurun(R)Run Controls, and Diagnostic Components. The remaining two segments generate primarily service revenue and consist of "Biotech", and "PCT" (research and development). Within Biotech there are four major product lines: Contract Research, Repository

Services, Specialty Reagents and Research Services. Revenue in the "PCT" segment consists of both private and National Institutes of Health ("NIH") funded support for the research activities associated with our pressure cycling technology. There was also NIH funding in 2000 for the Company's former drug discovery operations which were spun-off as an independent company in November 2000. See Note 6 of Notes to Financial Statements for a further discussion of the activities of these segments and Note 2 of Notes to Financial Statements relative to the Company's discontinued clinical laboratory operations.

Effective January 2000, all of the Company's technology related to its drug discovery and vaccine programs, consisting primarily of patents and related sponsored research agreements, were transferred to Panacos Pharmaceuticals, Inc. ("Panacos"), a wholly-owned subsidiary that the Company formed in October 1999. In November 2000 and in February 2002, Panacos sold equity to third party investors, reducing the Company's ownership to approximately 16% which is held in non-voting preferred stock. As a result, the Company no longer consolidates the results of Panacos. As of November 14, 2000 the Company's investment in Panacos was zero and the Company is no longer required to fund Panacos's operations. Therefore no further losses of Panacos will be recorded by the Company. The Company believes that this will position Panacos to progress to more advanced stages of drug development including clinical trials, while at the same time allowing management to focus more time on the Company's core business.

In December 2000, the Company made a decision to exit the clinical laboratory testing services segment and in February 2001, BBI Clinical Laboratories, Inc. ("BBICL"), a wholly-owned subsidiary of the Company, sold the business and certain assets and liabilities to a third party for an adjusted purchase price of \$8,958,000. The escrow account was terminated in December 2001 by mutual agreement between the buyer and the Company, resulting of approximately \$358,000 being received by the Company from the escrow account. The Company has retained certain other assets and liabilities of BBICL, primarily property, plant and equipment, together with the facility lease subsequent to the closing date, which the Company is attempting to sublease. The Company has written down all of the retained assets not otherwise redistributed to other business units to their estimated net realizable value. The Company recorded an after-tax gain of \$4,334,000 in 2001. The remaining estimate of closing costs included an estimate of costs associated with disposing of all remaining assets and retiring all existing liabilities including a facility lease. The Company will utilize in year 2001 certain prior period net operating loss carryforwards, previously reserved for by the Company, to partially offset the tax effect of this gain. In accordance with a transition services agreement, the Company operated the business in a normal fashion from the date of closing to December 2001, during which substantially all costs associated with operation of the business subsequent to the closing date were borne by the purchaser.

## ***PRODUCTS***

The economics and cost structures of the segments have certain differences. The Diagnostics segment has historically been the largest and most profitable segment, both in absolute dollars and in operating profit margin, as it operates primarily in a commercial environment with fewer competitors and relatively short product development cycles. The Laboratory Instrumentation segment had been in decline for several years prior to its acquisition in mid 1997, and management is working to turn around this business. It also operates in a highly competitive, low margin business: contract manufacturing of instruments and medical devices. At the current low annual revenue level of less than \$2.5 million, it operates significantly under capacity with high fixed overhead costs, and should therefore significantly benefit from relatively small revenue increases.

## ***SERVICES***

BBI Biotech has been project oriented with a high proportion of its revenue generated from government contracts (for both research and service activities) and assisting the other segments in their new product and service development. It has the highest level of inter-segment activity, and is structured around project tracking of direct costs plus overhead, general and administrative costs and a low percentage fee. Its financial goal has been to breakeven, (prior to the allocation of corporate overhead) while contributing to the development of future products and services for the Company. The "PCT" segment's R&D operation does not currently have any product or service revenue, but expects to launch its first products in 2002. Revenue to date consists of both private and public (NIH) funding of segment research. Most of the expenditures by this segment are for R&D expenses, patent costs and general management expenses. . The Company continues to seek funding from both private and public sources to minimize the impact of their development costs on the Company's overall operating results. Panacos Pharmaceuticals obtained independent third party equity financing in November 2000 thus terminating the Company's responsibility going forward to fund future research and development activities of Panacos. In February 2002, Panacos raised \$5 million in additional equity thereby diluting the Company's interest in non-voting preferred shares of Panacos to 16%.

## ***QUARTERLY FLUCTUATIONS***

Historically, the Company's results of operations have been subject to quarterly fluctuations due to a variety of factors, primarily customer purchasing patterns, driven by end-of-year expenditures. In particular, in the Diagnostics segment, the Company's sales of its off-the-shelf Quality Control Products and Diagnostic Components typically have been highest in the fourth quarter and lowest in the first quarter of each fiscal year, whereas OEM product sales may peak in any quarter of the year, depending on the production cycle of a given project. In the Company's Biotech segment, research contracts are generally for large dollar amounts spread over one to five year periods, and upon completion, frequently do not have renewal phases. As a result these contracts can cause large fluctuations in revenue and net income. In addition to staff dedicated to internal research and development, certain of the Company's technical staff work on both contract research for customers and Company sponsored research and development. The allocation of certain technical staff to such projects depends on the volume of Contract Research. As a result, research and development expenditures fluctuate due to increases or decreases in contract research performed. Neither the Laboratory Instrumentation segment nor the PCT segment is subject to material seasonal variations.

## ***RESEARCH AND DEVELOPMENT***

With the acquisition of BioSeq, Inc and its pressure cycling technology in September 1998 as well as the hiring of a Vice President for the Drug Discovery and Development program (which evolved into Panacos Pharmaceuticals, Inc. in 2000), the Company has expended significant amounts for ongoing research and development spending on new technologies in PCT and Panacos (2000 only). In the past three

years, the Company's BioSeq research subsidiary has incurred approximately \$3.2M of research and development expenses substantially related to development of a unique instrument and disposable specimen processing tube in conjunction with PCT. The Company has received eight patents for this technology and intends to have commercial products, using this technology, available for sale in year 2002. In addition to ongoing development of new Accurun Products the Company has also incurred development costs on reagent purification projects. Research and development expenses incurred in year 2000 also include approximately \$600,000 related to Panacos Pharmaceuticals drug discovery and development program.

### **EXPORT SALES**

The Company does not have any foreign operations. However, the Company does have significant export sales in Europe, the Pacific Rim countries and Canada to agents under distribution agreements, as well as directly to test kit manufacturers. All sales are denominated in US dollars. Export sales for the years ended December 31, 2001, 2000, and 1999 were \$3.4 million, \$4.2 million, and \$4.0 million, respectively. The Company expects that export sales will continue to be a significant source of revenue and gross profit.

### **RESULTS OF OPERATIONS**

The following table sets forth for the periods indicated the percentage of total revenue represented by certain items reflected in the Company's consolidated statements of operations:

	<u>Year Ended December 31,</u>		
	<u>2001</u>	<u>2000</u>	<u>1999</u>
Revenue:			
Products	60.0 %	63.6 %	71.0 %
Services	40.0	36.4	29.0
Total revenue	<u>100.0</u>	<u>100.0</u>	<u>100.0</u>
Gross profit	39.9	34.0	40.2
Operating expenses:			
Research and development	10.6	12.6	15.8
Selling and marketing	13.4	13.7	14.3
General and administrative	18.2	25.3	17.4
Impairment of intangible asset	-	7.5	-
Total operating expenses	<u>42.1</u>	<u>59.1</u>	<u>47.5</u>
Operating loss from continuing operations	(2.3)	(25.0)	(7.3)
Interest expense, net	(1.7)	(8.2)	(2.1)
Loss before income taxes and cumulative effect of change in accounting principle	(4.0)	(33.2)	(9.4)
(Provision for) benefit from income taxes	(0.1)	(5.9)	3.8
Cumulative effect of change in accounting principle	-	(1.0)	-
Income (loss) from discontinued operations	<u>19.9</u>	<u>(1.0)</u>	<u>1.5</u>
Net income (loss)	<u>15.8</u>	<u>(41.1)</u>	<u>(4.1)</u>
Product gross profit	51.6 %	41.3 %	48.3 %
Services gross profit	29.9 %	21.2 %	20.4 %

### **YEARS ENDED DECEMBER 31, 2001 AND 2000**

#### Revenue

Total revenue from continuing operations increased 12.1%, or \$2,356,000, to \$21,826,000 in 2001 from \$19,470,000 in 2000. The increase in revenue was the result of an increase in product revenue of 5.7%, or \$705,000 to \$13,093,000 in 2001 from \$12,387,000 in 2000, coupled with an increase in service revenue of 23.3%, or \$1,651,000, to \$8,733,000 in 2001 from \$7,082,000 in 2000.

Product Revenue. The product revenue increase was primarily attributable to increased sales of basematrix and characterized specimens to IVD test kit manufacturers and continued strong domestic sales of Accurun controls in the Diagnostics segment.

Service Revenue. The Biotech segment experienced a significant increase in repository and research services revenue. In addition, service revenue recognized in year 2000 also included \$161,000 of funding received by Panacos for drug discovery activities; as noted above, the Company no longer consolidates the results of operations of Panacos.

#### Gross Profit

Overall gross profit increased 31.5%, or \$2,087,000, to \$8,705,000 in 2001 from \$6,619,000 for year 2000. Product gross profit increased 32.0%, or \$1,637,000, to \$6,755,000 in 2001 from \$5,118,000 for 2000; product gross margin increased to 51.6% in 2001 from 41.3% in 2000. Services gross profit increased \$449,000 to \$1,950,000 in 2001 from \$1,501,000 for 2000 and service gross margin increased to 29.9% in 2001 from 21.2% in 2000.

Product Gross Margin. The increase in product gross margin at the Diagnostics segment, was derived from increased sales of higher margin catalog products coupled with a higher level of sales. This was coupled with a gross margin increase at the Laboratory

Instrumentation segment driven by the cost reduction plan implemented in September 2000. In year 2000, the Company recorded charges for inventory valuation at both of these segments, thereby lowering gross margins.

Service Gross Margin. The increase in service gross margin was due to an increase in higher margin commercial services as well as increased repository revenue, both performed at the Biotech segment.

#### Research and Development

Research and development expenditures decreased 5.7%, or \$141,000, to \$2,303,000 in 2001 from \$2,444,000 in 2000. The year 2000 included \$600,000 of research and development expenses associated with Panacos, the results of which are no longer included in the Company's results of operation as discussed above. Exclusive of funding to Panacos in 2000, research and development expenses increased \$459,000 in 2001 most of which was driven by higher research and development spending on the Company's PCT program activities.

#### Selling and Marketing

Selling and marketing expenses increased by 9.6%, or \$256,000, to \$2,916,000 in 2001 from \$2,660,000 in 2000. This increase was a result of filling several sales and marketing positions in the latter part of 2000 as well as increased travel and promotion costs at the Diagnostic segment.

#### General and Administrative

General and administrative costs declined 19.2%, or \$942,000, to \$3,977,000 in 2001 from \$4,919,000 in 2000. This decrease was primarily a result of several factors. First, there were headcount reductions at Corporate, and the Diagnostics and Laboratory Instrumentation segments in the latter part of year 2000 and into year 2001. Second, there was a significantly lower level of professional fees in 2001 compared to 2000, when the Company explored several strategic and financing options; also in 2001, the Company reversed \$80,000 of expenses previously accrued in year 2000, based on the June 2001 legal settlement reached with Paradigm Group, LLC, as discussed further in the accompanying footnotes to the financial statements. Finally, a portion of the decline was associated with the September 2000 write down of goodwill at the Laboratory Instrumentation segment, thereby reducing amortization expense in year 2001 by \$115,000 compared to the year 2000.

#### Impairment of Intangible Asset

As part of an ongoing strategic review process, the Company's Board of Directors met in late September 2000 to review the progress of its Laboratory Instrumentation segment, and that segment's prospects for the future to determine if any impairment of the segment's goodwill had occurred. Based on information presented at that meeting and subsequent analyses showing lower revenue expectations, management approved a cost reduction plan including a headcount reduction, salary freeze, and sublease of excess manufacturing space. Using the lower revenue projections associated with this plan, the Laboratory Instrumentation segment's undiscounted future cash flows were projected to be less than the carrying value of that segment's goodwill. In accordance with the provisions of "Statement of Financial Accounting Standards No. 121 - - Accounting for the Impairment of Long-Lived Assets and for Long-Lived Assets to Be Disposed Of," this segment's goodwill was written down by approximately \$1,464,000 in the third quarter of 2000.

#### Operating Income (Loss)

Operating loss from continuing operations decreased to \$491,000 in 2001 versus \$4,868,000 in 2000. The Diagnostics segment's operating income increased to \$1,674,000 in 2001 from \$1,015,000 in 2000, due to an increase in product revenue coupled with an increase in product gross margin, partially offset by an increased absorption of corporate overhead by this segment as explained further hereunder. The Laboratory Instrumentation segment had an operating loss of \$(460,000) for 2001 versus a loss for 2000 of \$(2,819,000); year 2000 results of operation include a charge of \$1,464,000 taken in the third quarter of 2000 related to impairment of intangible assets as discussed further above, whereas year 2001 operating results reflect the impact of the September 2000 cost reduction plan. The PCT segment had an operating loss of \$(1,493,000) in 2001 as compared to an operating loss of \$(1,298,000) in year 2000; also in year 2000, Panacos incurred a \$1,027,000 pre-tax operating loss; the Company no longer consolidates the results of operation of Panacos subsequent to November 2000 as previously discussed. Effective January 2001, the Company adjusted its allocation of corporate overhead based upon a revised corporate structure effective in 2001. The present corporate structure reflects the Company's implementation, in the latter part of 2000, of a cost reduction plan at the Laboratory Instrumentation segment, the Company's spin-off of Panacos as an independent company, and the Company's decision to exit the Clinical Laboratory testing business. The latter item is reflected as discontinued operations in the accompanying financial statements. In accordance with generally accepted accounting principles, the Company ceased allocating corporate overhead to the Clinical Laboratory testing business for all periods presented. This adjustment results in the Diagnostics unit absorbing a large portion of corporate overhead, which in prior years would have been allocated to Panacos and the Clinical Laboratory testing business.

#### Interest Expense/Cumulative Change in Accounting Principle

Interest expense decreased from \$1,617,000 in 2000 to \$438,000 in 2001. The large portion of the decrease is associated with reduced interest expense incurred in 2001 on the Company's line of credit, which was outstanding for all of 2000 but was repaid and terminated by the Company in February 2001 as discussed further in the section "Discontinued Operations" hereunder. Additional interest expense was incurred in the year 2001 associated with the Company obtaining a \$2,447,000 (net) mortgage on its West Bridgewater MA facility in April 2000.

In year 2000, the Company incurred a charge of \$898,000 (including \$190,223 for the cumulative effect of change in accounting principle, see Note 7 of Notes to Consolidated Financial Statements). In the first quarter of 2001, the Company redeemed the remaining \$2,040,000 (face value) of outstanding 3% Senior Subordinated Convertible Debentures (the "Debentures") plus accrued interest and a premium of \$190,000 (which was charged to interest expense). The pro-rata portion of unamortized original issue discount, debt issuance and warrant related costs associated with the redeemed Debentures, amounting to approximately \$377,000, is included in the loss on



extinguishment of the Debentures. Substantially offsetting this loss is the Company's reversal of approximately \$528,000 of interest expense in year 2001, previously recorded in 2000, associated with the amortization of the Debentures beneficial conversion feature.

#### Income Taxes

In the third quarter of 2000, the Company established a full valuation allowance for its deferred tax assets in accordance with Statement of Financial Accounting Standards No. 109 and in consideration of three consecutive years of losses; accordingly, the Company has not subsequently recognized an income tax benefit associated with the loss from continuing operations in either year 2000 nor 2001 as these tax assets have been fully reserved for. The Company has recorded approximately \$16,000 of state tax expense in year 2001.

#### Loss from Continuing Operations

Loss from continuing operations decreased to \$(887,000) for the year ended December 31, 2001 from \$(7,804,000) for year 2000, as a result of the items discussed above.

#### Discontinued Operations

On February 20, 2001, the Company sold the business and certain assets and liabilities of its wholly-owned subsidiary BBICL to a third party for an adjusted purchase price of \$8,958,000. The escrow account was terminated in December 2001 by mutual agreement between the buyer and the Company, resulting in approximately \$358,000 being received by the Company from the escrow account. The Company has retained certain other assets and liabilities of BBICL, primarily property, plant and equipment, together with the facility lease subsequent to the closing date, which the Company is attempting to sublease. The Company has written down all of the retained assets not otherwise redistributed to other business units to their estimated net realizable value.

The Company has recorded a gain of \$4,334,000 net of taxes of \$969,000 in 2001. The Company expects to utilize prior period net operating loss carryforwards, previously reserved for by the Company, to partially offset the tax effect of this gain. Additionally, the Company has taken a tax benefit of approximately \$364,000 related to stock option exercises that was not previously recorded as the Company was in a loss position. This tax benefit was recorded as a credit to additional paid-in capital in 2001.

The Company has recorded its estimate of remaining short and long term accrued liabilities to exit the Clinical Laboratory testing business, totaling approximately \$1,687,000 as of December 31, 2001. The major components of this accrual are estimated income taxes (\$420,000), severance and other employee related costs (\$75,000), estimated lease exit and facility related costs (\$750,000) and potential health care claims and other related potential audit adjustments (\$318,000), with the remainder for other miscellaneous costs associated with exiting this business segment.

Revenues from discontinued operations, net of intercompany eliminations, were \$973,000 for the period from January 1, 2001 to February 20, 2001 and \$8,367,000 for the year ended December 31, 2000. Operating (losses) from discontinued operations were \$(136,000) for the year ended December 31, 2001 and \$(197,000) for the year ended December 31, 2000. In summary, income (loss) from discontinued operations was \$4,334,000 for the year ended December 31, 2001 and \$(197,000) for the year ended December 31, 2000.

In accordance with a transition services agreement, the Company operated the business in a normal fashion during the period February 20, 2001 through December 2001. All of the revenues generated by, and substantially all costs associated with operating the business subsequent to the closing date of the transaction are the responsibility of the purchaser. A portion of the proceeds from this sale were used to redeem all outstanding Debentures and to retire the Company's line of credit in the first quarter of 2001.

#### Summary

In summary, the Company had net income of \$3,448,000 for the year ended December 31, 2001 as compared to a net loss of \$(8,001,000) for the year ended December 31, 2000. This improvement was driven by four factors: first and foremost, the gain recognized on the sale of the Company's clinical laboratory business; secondly, a significantly reduced operating loss in 2001 compared to 2000 as all business units posted improved operating results, and Panacos (which incurred a pretax loss of \$1,027,000 in 2000) no longer being consolidated in 2001; thirdly, the impairment of intangible assets at the Laboratory Instrumentation segment recorded in 2000, which increased the loss for 2000; and fourthly, higher interest expense in 2000 due to the higher debt carried prior to the repayments that occurred after the sale of the clinical laboratory business.

The earnings per share computation for 2001 reflects both the issuance of 801,325 additional shares of common stock in the first quarter of 2001, as certain holders of the Debentures exercised their rights to convert \$1,210,000 of such Debentures into shares of the Company's common stock, and the issuance of 178,877 additional shares of common stock associated with the exercise of stock options, warrants and purchases made pursuant to the employee stock purchase plan. In addition, on June 15, 2001, the Company and Paradigm Group, LLC entered into an agreement to permanently settle their disputes. Under the terms of the agreement, Paradigm Group, LLC rescinded their exercise of the common stock purchase warrants, which have since expired, and the Company retained the 500,000 shares associated with their exercise. These shares were included in the total shares outstanding as well as in the calculation of earnings (loss) per share from February 17, 2000 (the date of exercise) through June 15, 2001 (the date of the agreement). As of September 30, these shares were cancelled by the Company. In December 2001, an additional 600,000 shares of common stock were subscribed to and paid for by a group of investors for \$1,500,000. These shares were issued in the first quarter of 2002 and therefore were not included in the total shares outstanding as well as in the calculation of earnings (loss) per share for the year ended December 31, 2001.

#### **YEARS ENDED DECEMBER 31, 2000 AND 1999**

#### Revenue

Total revenue from continuing operations decreased 1.7%, or \$328,000, to \$19,470,000 in 2000 from \$19,798,000 in 1999. The

decrease in revenue was the result of a decrease in product revenue of 11.9% or \$1,670,000 to \$12,387,000 in 2000 from \$14,057,000 in 1999, partially offset by an increase in service revenue of 23.4% or \$1,341,000 to \$7,083,000 in 2000 from \$5,742,000 in 1999.

Product Revenue. The product revenue decrease was primarily attributable to a \$1,078,000 decrease in the Diagnostics segment and a \$625,000 decrease in the Laboratory Instrumentation segment. The Diagnostics decrease was the result of a reduced level of sales of its OEM and Seroconversion panels, and Basematrix as the consolidation within the in vitro diagnostic industry has negatively affected demand for these products. These decreases were partially offset by increases in Accurun(R) and Characterized Disease State blood product sales. The Laboratory Instrumentation segment revenue decreased due to a lower level of contract manufacturing due to the timing of an order from a large customer and another customer experiencing financial difficulty causing them to place their order on hold. The Company believes the negative effects of industry consolidation are mostly behind it and that there are growth opportunities within both its existing business as well as providing products for rapid test and chip based technologies.

Service Revenue. The increase in service revenue was primarily attributable to increases of \$104,000 from the Diagnostics segment, \$850,000 from the Biotech segment and \$161,000 in the Panacos segment. The growth in Diagnostics was related to increased service work for in-vitro Diagnostic manufacturers including plasma inactivations. The Biotech segment's growth was due to new government contracts for both its repository and research services. The Panacos and PCT segments' growth was a result of funding received from both the NIH and the Consortium for Plasma Science, which partially defrayed the cost of pressure cycling technology development and certain other drug discovery activities associated with Panacos.

#### Gross Profit

Overall gross profit decreased 16.9%, or \$1,344,000, to \$6,619,000 in the year ended December 31, 2000 from \$7,963,000 for 1999. Product gross profit decreased 24.6%, or \$1,671,000, to \$5,118,000 in 2000 from \$6,789,000 for 1999 and product gross margin decreased to 41.3% in 2000, from 48.3% in 1999. Services gross profit increased \$327,000 to \$1,501,000 in 2000 from \$1,174,000 for 1999 and service gross margin increased to 21.2% in 2000, from 20.4% in 1999.

Product Gross Margin. The decrease in product gross margin was due substantially to a 12.3% decrease in the gross margin of the Laboratory Instrumentation operating segment. This decrease was due to a lower level of sales activity, resulting in underutilized capacity and excess overhead costs. In addition, the Company adjusted the inventory valuations for both this segment and the Diagnostic segment in year 2000.

Service Gross Margin. The increase in service gross margin was due to small increases in both the Diagnostics and the Panacos and PCT segments, which were partially offset by a lower service gross margin from the Biotech segment due to an increase in low margin government contracts.

#### Research and Development

Research and development expenditures decreased 22.0%, or \$688,000, to \$2,444,000 in 2000 as compared to \$3,132,000 in 1999. The Company continued to emphasize development efforts within the PCT and Panacos business segments, the latter being included during the period January 1, 2000 to November 14, 2000 as discussed further hereunder. Research and development expenditures at these segments were approximately flat. However there was a decrease in spending at the Laboratory Instrumentation segment as the PlateMate program was discontinued in September 1999. In addition, there was a decrease in spending at Biotech in order to meet contract schedules.

#### Selling and Marketing

Selling and marketing expenses decreased by 6.0%, or \$171,000, to \$2,660,000 in 2000 from \$2,831,000 in 1999. This decrease was a result of a slight reduction in promotion and travel costs, and vacancies in several key positions at the Diagnostics and Laboratory Instrumentation segments. Some of these positions were filled early in the third quarter of 2000.

#### General and Administrative

General and administrative costs increased 42.6%, or \$1,468,000, to \$4,919,000 for 2000 from \$3,451,000 in 1999. This increase was primarily the result of an increase in professional consulting services associated with the Company's various financing and strategic transactions and options in 2000. Additionally, \$448,000 of general and administrative personnel related expenses incurred in 1999 were capitalized as part of the ERP system implementation in accordance with applicable accounting standards. The Company completed the project in November 1999; therefore, no additional costs were capitalized in 2000.

#### Impairment of Intangible Asset

As part of an ongoing strategic review process, the Company's Board of Directors met in September 2000 to review the progress of its Laboratory Instrumentation segment, and that segment's prospects for the future to determine if any impairment of the segment's goodwill had occurred. Based on information presented at that meeting and subsequent analyses showing lower revenue expectations, management approved a cost reduction plan including a headcount reduction, salary freeze, and sublease of excess manufacturing space. Using the lower revenue projections associated with this plan, the Laboratory Instrumentation segment's undiscounted future cash flows were projected to be less than the carrying value of that segment's goodwill. In accordance with the provisions of both "Accounting Principles Board Opinion No. 17 - Intangible Assets" and "Statement of Financial Accounting Standards No. 121 - Accounting for the Impairment of Long-Lived Assets and for Long-Lived Assets to Be Disposed Of," this segment's goodwill was written down by approximately \$1,464,000 in the third quarter of fiscal year 2000.

#### Operating Loss

Consolidated loss from continuing operations increased to \$4,868,000 in 2000 versus a \$1,451,000 loss in 1999. The Diagnostics segment's operating income decreased to \$1,015,000 in 2000 from \$2,436,000 in 1999 as a result of decreased revenue and the beneficial

effect on 1999's operating income of capitalizing certain employee salaries associated with the ERP System implementation. The Biotech segment's operating loss decreased to \$398,000 in 2000 from \$482,000 in 1999, due to increased revenue from government contracts. The Laboratory Instrumentation segment had an operating loss of \$2,819,000 for 2000 versus a loss for 1999 of \$1,163,000. The year 2000 loss includes a write-down of approximately 80% of their goodwill as of the previous balance sheet date. Excluding this, the Laboratory Instrumentation segment had an operating loss of \$1,355,000 for 2000 as a result of continued low levels of revenue. At the end of the third quarter of 2000, management approved a cost reduction plan in the Laboratory Instrumentation segment including a headcount reduction, salary freeze, and sublease of excess manufacturing space. The operating loss of the PCT and Panacos segments combined increased to \$2,325,000 in 2000 from \$2,006,000 in 1999 due to planned research and development and patent related costs. The Company continued to invest heavily in the areas of pressure cycling technology and the drug discovery program, through its subsidiary BBI BioSeq and its investment in Panacos Pharmaceuticals.

The Company's ownership of Panacos was reduced to 30.5% in the fourth quarter of 2000 as a result of Panacos obtaining additional equity financing from new investors. Accordingly, the Company terminated consolidation accounting subsequent to November 14, 2000. The Company had recorded Panacos's pre-tax operating losses for the period January 1, 2000 to November 14, 2000 in the amount of approximately \$1,027,000.

#### Interest Expense/Cumulative Change in Accounting Principle

Interest expense increased from \$420,000 in 1999 to \$1,617,000 in 2000. Throughout the year 2000, the Company carried a higher average debt balance and interest rate on its line of credit than in 1999. Additional interest expense was incurred in 2000 associated with the Company obtaining a new \$2,447,000 mortgage on its West Bridgewater MA facility, effective April 2000. In addition, the Company incurred a charge of \$898,000 (including \$190,223 for the cumulative effect of change in accounting principle, see Note 7 of Notes to Consolidated Financial Statements) due to amortization of the beneficial conversion feature, warrant costs and original issue discount/debt issuance costs associated with the Company's August 2000 issuance of \$3,250,000 3% Senior Subordinated Convertible Debentures.

#### Income Taxes

In 2000 the Company established a full valuation allowance for its deferred tax assets in accordance with Statement of Financial Accounting Standards No. 109 and in consideration of three consecutive years of losses. In 1999 the Company recorded an income tax benefit at a combined rate of 38%.

#### Loss from Continuing Operations

Loss from continuing operations increased to \$7,614,000 for the year ended December 31, 2000 from \$1,120,000 for the year ended December 31, 1999, as a result of the items discussed above.

#### Discontinued Operations

The Clinical Laboratory Services segment, a discontinued operation, had an operating loss of \$197,000 in 2000 versus income of \$306,000 for 1999 due to both a lower volume of molecular testing as several customers began performing these tests in-house in 2000, and competitive pricing pressure in molecular testing, resulting in lower gross margin.

#### Summary

The Company had a net loss of \$8,001,000 in 2000 as compared to a net loss of \$814,000 in 1999 as a result of the operating loss, interest expense associated with the August 2000 issuance of \$3,250,000 of debentures, the impairment of an intangible asset at the laboratory instrument segment, and the establishment of a full valuation allowance for deferred tax assets as described above.

### **LIQUIDITY AND FINANCIAL CONDITION**

As of December 31, 2001, the Company had existing cash balances of approximately \$2,858,000 compared with \$1,782,000 at December 31, 2000. The Company's working capital position increased to \$9,407,000 as of December 31, 2001 from \$3,596,000 as of December 31, 2000. These improvements in both ending cash and working capital position were the result of utilizing proceeds generated by the sale of the clinical laboratory business in February 2001 (as discussed above) thereby enabling the Company to pay off a substantial portion of its debt, as further discussed below.

Net cash used in operations for the year ended December 31, 2001 was \$56,000 as compared to \$2,796,000 during the year ended December 31, 2000. The improvement in cash used in operations during 2001 is primarily associated with the decreased loss from continuing operations and the collection of an income tax refund in the first quarter of 2001.

Net cash used in investing activities was \$381,000 in 2001 versus \$1,025,000 in the comparable prior year period. During 2000, the Company's BBI Biotech segment invested \$580,000 to build-out its new repository facility in Frederick, Maryland. In addition, significant investments were made for laboratory and manufacturing equipment. The decrease of cash used for investing was due to a decision by management to control capital expenditures.

Cash used in financing activities was \$6,110,000 in 2001 versus cash provided of \$4,783,000 for the year 2000. In 2001, the Company used proceeds from the sale of the business and certain assets of BBICL to pay off in full the remaining \$5,762,635 balance on its line of credit and retire all remaining Debentures. Partially offsetting this in 2001, the Company received proceeds totaling \$425,000 associated with the exercise of stock options and warrants, which have resulted in 178,877 new shares of common stock being issued. In December 2001, an additional 600,000 shares of common stock were subscribed to and paid for by a group of investors for \$1,498,000, net of issuance costs. These shares were issued in the first quarter of 2002 and therefore were not included in the total shares outstanding as well as in the calculation of earnings (loss) per share for the year ended December 31, 2001. Cash provided by financing in 2000 consisted

of approximately \$1,264,000 of cash received from the exercise of stock options and warrants, net proceeds from a \$2,447,000 mortgage on its West Bridgewater, MA facility in April 2000 and net proceeds of \$2,871,000 related to the issuance of 3% Senior Subordinated Convertible Debentures. This was partially offset by \$1,383,000 of repayments on the Company's line of credit.

As of December 31, 2001, the Company had entered into a one year loan of \$525,000 to its Chief Executive Officer ("CEO"), renewable at the Company's option, and collateralized by 90,000 of his shares of Boston Biomedica common stock. Interest on the loan was payable monthly at the annual rate of 7%. The loan is shown on the balance sheet as a decrease to stockholders equity. In January 2002, the loan was repaid in full. The loan was replaced by the Company's pledge of a \$1,000,000 interest bearing deposit at a financial institution to provide additional security for loans in the aggregate amount of \$2,418,000 from the financial institution to an entity controlled by the CEO. The loans are personally guaranteed by the CEO. The Company's pledge is secured by a junior interest in the collateral provided by the CEO to the financial institution. Such collateral includes all of his real property and common stock holdings in Boston Biomedica, Inc. The original loan and subsequent pledge of \$1,000,000 were made to assist the CEO in refinancing indebtedness related to, among other things, his divorce settlement and to enable him to avoid the need to sell his common stock holdings in Boston Biomedica, Inc. on the open market to satisfy his debts. The Company's Board of Directors and, with respect to the decision to pledge the \$1,000,000 cash collateral, a special committee of the independent directors, evaluated a number of alternatives and concluded that the original loan to the CEO and the subsequent pledge were the best alternative and in the best interests of the Company's stockholders because it would, among other things, avoid selling pressure on the Company's common stock and relieve the financial pressures on the CEO that could otherwise divert his attention from the Company.

In April 2000, the Company borrowed \$2,447,000 (net of issuance costs) under a mortgage agreement on its West Bridgewater, MA facility. The Company used these funds to reduce the outstanding balance on its line-of-credit. The mortgage is due on March 31, 2010. During the first five years the note carries an interest rate of 9.75%; after five years the rate charged will be 0.75% greater than the bank base rate then in effect. Under this mortgage agreement the Company is subject to certain financial covenants. The Company has satisfactorily met the conditions of these covenants for the year 2001. Payments due on this mortgage are based on a 20 year amortization schedule with a balloon payment representing the remaining balance due in full on March 10, 2010.

In August 1999, the Company sold 500,000 warrants to purchase the Company's stock to Paradigm Group, a private investment company. The private placement consisted of 400,000 common stock purchase warrants with an exercise price of \$4.25 and 100,000 common stock purchase warrants with an exercise price of \$5.25. Paradigm Group paid the Company \$50,000 for the warrants. In addition, National Securities received 40,000 common stock purchase warrants with an exercise price of \$4.25, 10,000 common stock purchase warrants with an exercise price of \$5.25, and 25,000 common stock purchase warrants with an exercise price of \$8.00, as transaction fee. In February 2000, the Company received notice that Paradigm Group, LLC exercised all of their warrants to purchase the Company's common stock. The holders of the warrants were required to pay the exercise price when the registration of the underlying shares became effective which was in December 2000. In August 2000, the Company received a summons and complaint from Paradigm Group, LLC naming the Company as a defendant. The suit, filed in the Circuit Court of Cook County, Illinois, alleged breach of contract claims and fraud against the Company in connection with the sale by the Company to the Paradigm Group, LLC of the above warrants, the exercise of those warrants by Paradigm Group, LLC and a delay in the registration of those shares with the U. S. Securities and Exchange Commission. In December 2000, Paradigm Group, LLC withdrew this lawsuit. In the fourth quarter of 2000, the Company expensed approximately \$265,000 of costs related to these warrants and the registration of the underlying shares. On June 15, 2001 the Company and Paradigm Group, LLC entered into an agreement to permanently settle their disputes. Under the terms of the agreement, Paradigm Group, LLC rescinded their exercise of the common stock purchase warrants, which have since expired, and the Company retained the 500,000 shares associated with their exercise. These shares were included in the total shares outstanding as well as in the calculation of earnings (loss) per share from February 17, 2000 (the date of exercise) through June 15, 2001 (the date of the agreement). As of September 30, 2001, these shares were cancelled by the Company.

The Company believes that its cash and working capital resources (exclusive of the \$1,000,000 pledge and loan guarantee discussed above), coupled with internally generated funds from operations, will be sufficient to fund operations and anticipated capital expenditures for the next year. The Company continually evaluates financing options, as well as other strategic alternatives, in order to maximize shareholder value.

## CONTRACTUAL OBLIGATIONS

The following is a summary of the Company's contractual obligations as of December 31, 2001

Contractual Obligations	Payments Due by Period				
	Total	Less than 1 year	1-3 years	3-5 years	After 5 years
Mortgage payments*	\$4,137,000	\$287,000	\$575,000	\$575,000	\$2,700,000
Capital Lease Obligations	76,000	43,000	26,000	7,000	-
Real Estate Leases	5,467,000	1,090,000	2,329,000	1,778,000	270,000
Minimum future royalty payments	100,000	50,000	50,000	-	-
Obligations relating to Discontinued Operations	1,687,000	1,148,000	417,000	122,000	-
<b>Total Contractual Cash Obligations</b>	<b>\$11,467,000</b>	<b>\$2,618,000</b>	<b>\$3,397,000</b>	<b>\$2,482,000</b>	<b>\$2,970,000</b>

\* Monthly payments on this mortgage include principal and interest and are based on a 20-year amortization schedule with a balloon payment representing the remaining balance due in full on March 10, 2010.

In January 2002, the Company made a \$1,000,000 pledge and loan guarantee of certain indebtedness of a entity controlled by an officer/director via a deposit of equal amount in an interest bearing account with a lending institution. A description of this transaction is noted above.

### **RECENT ACCOUNTING PRONOUNCEMENTS**

In late 2000 and early 2001, the Financial Accounting Standards Board Emerging Issues Task Force (“EITF”) reached consensus on a number of revisions to EITF Issue No. 98-5 “Accounting for Convertible Securities with Beneficial Conversions Features or Contingently Adjustable Conversion Ratios.” The Securities and Exchange Commission’s (“SEC”) Observer to the EITF indicated the SEC’s preference that the revision relative to the computation of a beneficial conversion features associated with convertible securities be applied to all securities issued after May 20, 1999. The Company therefore applied this adjusted calculation to the beneficial conversion feature associated with its August 2000 issuance of \$3,250,000 of 3% Senior Subordinated Convertible Debentures and accordingly, the Company has included the effects of the revisions, as indicated by the SEC staff member. Approximately \$190,000 of this revised computation is reflected as the cumulative effect of a change in accounting principle in the accompanying financial statements for the year ended December 31, 2000.

In September 2000, the FASB issued SFAS No. 140 “Accounting for Transfers and Servicing of Financial Assets and Extinguishments of Liabilities—a replacement of FASB Statement No. 125”. SFAS No. 140 revises the standards for accounting for securitizations and other transfers of financial assets and collateral and requires certain disclosures, but it carries over most of SFAS No. 125’s provisions without reconsideration. This Statement is effective for transfers and servicing of financial assets and extinguishments of liabilities occurring after March 31, 2001. This Statement is effective for recognition and reclassification of collateral and for disclosures relating to securitization transactions and collateral for fiscal years ending after December 15, 2000. The Company does not believe the adoption of SFAS No. 140 has had a material effect on its financial statements.

In March 2000, the FASB issued FASB Interpretation No. 44, “Accounting for Certain Transactions Involving Stock Compensation,” (an Interpretation of Accounting Principles Bulletin Opinion No. 25 (“APB 25”)) (“FIN 44”). FIN 44 provides guidance on the application of APB 25, particularly as it relates to options. The effective date of FIN 44 was July 1, 2000, and the Company has adopted FIN 44 as of that date. The application of FIN 44 has not had a material effect on the Company’s financial statements.

Statement of Financial Accounting Standards No. 141, “Business Combinations” (SFAS 141), is effective for all business combinations initiated after June 30, 2001. The new standard requires companies to record business combinations using the purchase method of accounting. The Company has not done a business combination since the issuance of SFAS 141.

Statement of Financial Accounting Standards No. 142, “Goodwill and Other Intangible Assets” (SFAS 142), is effective for the Company beginning January 1, 2002. SFAS 142 requires, among other things, the cessation of the amortization of goodwill. In addition, the standard includes provisions for the reclassification of certain existing recognized intangibles as goodwill, reassessment of the useful lives of existing recognized intangibles, reclassification of certain intangibles out of previously reported goodwill and the identification of reporting units for purposes of assessing potential future impairments of goodwill. SFAS 142 also requires companies to complete a transitional goodwill impairment test six months from the date of adoption. The Company is assessing the impact of this new statement on its consolidated financial position and results of operations but does not believe its adoption will have a material effect on the Company’s financial statements.

Statement of Financial Accounting Standards No. 143, “Accounting for Asset Retirement Obligations” (SFAS 143), is effective January 1, 2003. SFAS 143 addresses the financial accounting and reporting for obligations and retirement costs related to the retirement of tangible long-lived assets. We do not expect that the adoption of SFAS 143 will have a significant impact on our financial statements.

Statement of Financial Accounting Standards No. 144, “Accounting for the Impairment or Disposal of Long-Lived Assets” (SFAS 144), is effective January 1, 2002. SFAS 144 supersedes FASB Statement No. 121, “Accounting for the Impairment of Long-Lived Assets and for Long-Lived Assets to Be Disposed Of,” and the accounting and reporting provisions relating to the disposal of long-lived assets. We do not expect that the adoption of SFAS 144 will have a significant impact on our financial statements.

### **CRITICAL ACCOUNTING POLICIES AND ESTIMATES**

To prepare the financial statements in conformity with generally accepted accounting principles, management is required to make significant estimates and assumptions that affect the reported amounts of assets and liabilities and disclosure of contingent assets and liabilities at the date of the financial statements and the reported amounts of revenues and expenses during the reporting period. In particular, the Company records reserves for estimates regarding the collectability of accounts receivable, the value and realizability of intangible assets, deferred tax assets, the net realizable value of its inventory, as well as an estimate for remaining liabilities associated with discontinued operations. On an on-going basis, we evaluate our estimates, including those related to collectability of accounts receivable, inventories, intangible assets, deferred tax assets, and contingencies and litigation. We base our estimates on historical experience and on various other assumptions that are believed to be reasonable under the circumstances, the results of which form the basis for making judgments about the carrying values of assets and liabilities that are not readily apparent from other sources. Actual results could differ from the estimates and assumptions used by management.

Product revenue is recognized upon shipment of the products or, for specific orders at the request of the customer, on a bill and hold basis after completion of manufacture. All bill and hold transactions meet specified revenue recognition criteria which include normal billing, credit and payment terms, firm commitment and transfer to the customers of all risks and rewards of ownership. Total revenue related to bill and hold transactions was approximately \$610,000, \$562,000, and \$1,998,000, for the years ended December 31, 2001, 2000, and 1999, respectively. During the fiscal years 2001, 2000, and 1999, the combined revenues from all branches of the National Institutes of Health, a United States Government agency, accounted for approximately 31%, 30% and 23%, respectively, of total consolidated revenues from continuing operations of the Company. Additional future revenues originating from various branches of the National Institutes of Health is subject to possible future changes in government funding levels.

The Company reviews inventory for estimated obsolescence or unmarketable inventory and adjusts for the difference between the cost of inventory and the estimated net realizable value based upon assumptions about future demand and market conditions. If actual market conditions are less favorable than those projected by management, additional inventory adjustments may be required.

Intangible assets primarily relate to the value of acquired patents associated with the PCT technology. The cost of these acquired patents is amortized on a straight-line basis over the estimated life of the patent which is generally four to sixteen years. Intangible assets are reviewed for impairment whenever events or changes in circumstances indicate that the carrying amount of an asset may not be recoverable.

#### **FORWARD - LOOKING INFORMATION**

The Annual Report on Form 10-K contains forward-looking statements concerning the Company's financial performance and business operations. The Company wishes to caution readers of this Annual Report on Form 10-K that actual results might differ materially from those projected in the forward-looking statements contained herein.

Factors which might cause actual results to differ materially from those projected in the forward-looking statements contained herein include the following: due to operational, scientific or technical difficulties in the implementation of its strategies and changes in customer demand, the Company's sales to IVD test kit manufacturers and sales of ACCURUN and other quality control products may not continue to be as strong as in 2001; the Company may not be successful in developing Pressure Cycling Technology into commercially viable products and services, including those in the areas of sample preparation and inactivation, or such activities that may longer than currently expected; Pressure Cycling Technology may also not be adaptable to any other commercially viable applications; certain Pressure Cycling Technology applications may not fall within the claims of the Company's eight issued U.S. patents; individuals and groups utilizing Pressure Cycling Technology may not be required to license such technology from the Company; the Company's inability to develop the end-user market for quality control products; the Company's inability to integrate the business of Source Scientific, Inc. into the Company's business and to grow the sales of Source Scientific, Inc. to the extent anticipated; the uncertainty of the renewal and full funding of contracts with National Institutes of Health (NIH); the Company's inability to obtain an adequate supply of the unique and rare specimens of plasma and serum necessary for certain of its products; the potential for significant reductions in purchases by any of the Company's major customers; and if expenses are higher than anticipated, or if revenues are lower than anticipated, the Company will require additional capital sooner than expected and there can be no assurance that the Company will be able to obtain additional capital on acceptable terms. Certain of these and other factors which might cause actual results to differ materially from those projected are more fully set forth under the caption "Risk Factors" in the Company's most recent Registration Statements on Form S-3 (SEC File No.'s 333-94379 and 333-46426).

#### **ITEM 7A. QUANTITATIVE AND QUALITATIVE DISCLOSURES ABOUT MARKET RISK**

The Company is subject to interest rate risk in connection with its long-term debt. The aggregate hypothetical loss in earnings for one year of those financial instruments held by the Company at December 31, 2001 that are subject to interest rate risk resulting from a hypothetical increase in interest rates of 10 percent is less than \$100,000, after-tax. The hypothetical loss was determined by calculating the aggregate impact of a 10 percent increase in the interest rate of each variable rate financial instrument held by the Company at December 31, 2001, that is subject to interest rate risk. Fixed rate financial instruments were not evaluated, as the Company believes the risk exposure is not material.

The Company is exposed to concentrations of credit risk in cash and cash equivalents and trade receivables. Cash and cash equivalents are placed with major financial institutions with high quality credit ratings. Trade receivables credit risk exposure is significant as the Company derives a significant portion of its revenues from a small number of customers however, this risk is mitigated by the dispersion across different industries and geographies in which the customers operate; in addition to this, approximately 31% of 2001 consolidated revenue was from all branches of the National Institutes of Health, a U.S. Government agency. The Company is exposed to credit-related risks associated with its trade accounts receivable denominated in U.S. Dollars but receivable from foreign customers.

#### **ITEM 8. FINANCIAL STATEMENTS AND SUPPLEMENTARY DATA**

### **BOSTON BIOMEDICA, INC. AND SUBSIDIARIES CONSOLIDATED BALANCE SHEETS**

	December 31,	
	2001	2000
<u>ASSETS</u>		
CURRENT ASSETS:		
Cash and cash equivalents	\$ 2,857,916	\$ 1,782,100
Accounts receivable, less allowances of \$125,617 in 2001 and \$88,981 in 2000	4,073,513	3,881,943
Inventories	6,763,144	6,465,548
Prepaid expenses and other current assets	176,275	236,731
Income taxes receivable	-	212,762
Total current assets	<u>13,870,848</u>	<u>12,579,084</u>
Property and equipment, net	6,533,671	7,459,283
OTHER ASSETS:		
Intangible assets, net	854,864	933,793
Debt issuance costs	-	203,523
Other long-term assets	154,871	135,578
Net assets from discontinued operations (Note 2)	-	1,237,535
	<u>1,009,735</u>	<u>2,510,429</u>
TOTAL ASSETS	<u>\$ 21,414,254</u>	<u>\$ 22,548,796</u>
<u>LIABILITIES AND STOCKHOLDERS' EQUITY</u>		
CURRENT LIABILITIES:		
Accounts payable	\$ 1,666,771	\$ 1,232,697
Accrued employee compensation	907,426	836,804
Other accrued expenses	607,004	974,606
Net liabilities from discontinued operations (Note 2)	1,148,222	-
Current maturities of long term debt	82,053	5,840,172
Deferred revenue and other current liabilities	52,398	99,074
Total current liabilities	<u>4,463,874</u>	<u>8,983,353</u>
LONG-TERM LIABILITIES:		
Long term debt, less current maturities	2,402,837	2,420,449
3% Senior Subordinated Convertible Debentures	-	2,818,375
Net liabilities from discontinued operations (Note 2)	538,325	-
Other liabilities	568,906	577,044
COMMITMENTS AND CONTINGENCIES (Note 10)		
STOCKHOLDERS' EQUITY:		
Common stock, \$.01 par value; 20,000,000 shares authorized, 6,132,718 and 5,652,516 issued and outstanding at December 31, 2001 and 2000, respectively	61,327	56,525
Additional paid-in capital	20,170,492	18,904,862
Accumulated deficit	(7,764,075)	(11,211,812)
Prepaid Common Stock Subscription, net of issuance costs	1,497,568	-
Loan to officer/director (Note 13)	(525,000)	-
Total stockholders' equity	<u>13,440,312</u>	<u>7,749,575</u>
TOTAL LIABILITIES & STOCKHOLDERS' EQUITY	<u>\$ 21,414,254</u>	<u>\$ 22,548,796</u>

The accompanying notes are an integral part of the Consolidated Financial Statements

**BOSTON BIOMEDICA, INC. AND SUBSIDIARIES**  
**CONSOLIDATED STATEMENTS OF INCOME**

	Years Ended December 31,		
	2001	2000	1999
<b>REVENUE:</b>			
Products	\$ 13,092,771	\$ 12,387,416	\$ 14,056,657
Services	8,733,336	7,082,538	5,741,690
Total revenue	<u>21,826,107</u>	<u>19,469,954</u>	<u>19,798,347</u>
<b>COSTS AND EXPENSES:</b>			
Cost of products	6,337,437	7,269,817	7,267,273
Cost of services	6,783,329	5,581,636	4,567,863
Research and development	2,303,350	2,443,779	3,131,590
Selling and marketing	2,916,013	2,659,935	2,831,293
General and administrative	3,976,568	4,918,899	3,450,879
Impairment of intangible asset	-	1,464,220	-
Total operating costs and expenses	<u>22,316,697</u>	<u>24,338,286</u>	<u>21,248,898</u>
Operating loss from continuing operations	(490,590)	(4,868,332)	(1,450,551)
Interest income	57,515	23,598	6,146
Interest expense, including beneficial conversion feature (Note 7)	<u>(438,008)</u>	<u>(1,617,311)</u>	<u>(419,980)</u>
Loss from continuing operations before income taxes and cumulative effect of change in accounting principle	(871,083)	(6,462,045)	(1,864,385)
(Provision for) benefit from income taxes	<u>(15,678)</u>	<u>(1,151,940)</u>	<u>744,093</u>
Loss from continuing operations before cumulative effect of change in accounting principle	(886,761)	(7,613,985)	(1,120,292)
Cumulative effect of change in accounting principle (Note 7)	-	<u>(190,223)</u>	-
Loss from continuing operations	\$ (886,761)	\$ (7,804,208)	\$ (1,120,292)
Discontinued operations (Note 2)			
Income (loss) from discontinued operations of Clinical Laboratory segment (less income taxes of \$969,000, \$0 and \$245,121 in 2001, 2000 and 1999, respectively)	<u>4,334,498</u>	<u>(196,751)</u>	<u>306,180</u>
Net income (loss)	<u>\$ 3,447,737</u>	<u>\$ (8,000,959)</u>	<u>\$ (814,112)</u>
Loss from continuing operations per share, basic & diluted	\$ (0.14)	\$ (1.43)	\$ (0.24)
Income (loss) per share from discontinued operations, basic & diluted	\$ 0.70	\$ (0.03)	\$ 0.07
Net income (loss) per share, basic & diluted	\$ 0.56	\$ (1.46)	\$ (0.17)
Number of shares used to calculate net income (loss) per share basic and diluted	6,204,384	5,465,358	4,669,717

The accompanying notes are an integral part of the Consolidated Financial Statements

**BOSTON BIOMEDICA, INC. AND SUBSIDIARIES**  
**CONSOLIDATED STATEMENTS OF CHANGES IN STOCKHOLDERS' EQUITY**  
**FOR THE YEARS ENDED DECEMBER 31, 2001, 2000 AND 1999**



	Common Stock		Additional Paid-In Capital	Receivable for Exercised Warrants	Prepaid Common Stock Subscription	Loan to Officer/Director	Retained Earnings (Deficit)	Total Stockholders' Equity
	Shares	\$ .01 Par Value						
BALANCE, December 31, 1998	4,667,816	\$ 46,679	\$ 16,418,716				\$ (2,396,741)	\$ 14,068,654
Common stock issued	53,300	533	147,905					148,438
Stock warrants issued, net of issuance costs			206,011					206,011
Stock options and warrants exercised	52,249	522	36,610					37,132
Net loss							(814,112)	(814,112)
BALANCE, December 31, 1999	4,773,365	47,734	16,809,242				(3,210,853)	13,646,123
Common stock issued in connection with Employee Stock Purchase Plan	8,458	84	26,264					26,348
Stock warrants issued			1,000					1,000
Stock options and other warrants exercised	370,693	3,707	906,304					910,011
Exercise of Paradigm warrants	500,000	5,000	1,954,979	\$ (2,225,000)				(265,021)
Reserve for exercise of Paradigm warrants			(1,959,979)	2,225,000				265,021
Stock warrants issued and beneficial conversion feature in connection with 3% Senior Subordinated Convertible Debentures			1,167,052					1,167,052
Net loss							(8,000,959)	(8,000,959)
BALANCE, December 31, 2000	5,652,516	56,525	18,904,862	-			(11,211,812)	7,749,575
Common stock issued in connection with Employee Stock Purchase Plan	15,292	153	26,210					26,363
Conversion of 3% Senior Subordinated Convertible Debentures	801,325	8,013	970,876					978,889
Beneficial conversion feature in connection with 3% Senior Subordinated Convertible Debentures			(527,519)					(527,519)
Stock based compensation			30,000					30,000
Stock options and other warrants exercised	163,585	1,636	397,063					398,699
Cancellation of Exercise of Paradigm warrants	(500,000)	(5,000)	5,000					-
Tax benefit of stock options exercised			364,000					364,000
Loan to Officer / Director						\$ (525,000)		(525,000)
Prepaid Common Stock Subscription, net					\$ 1,497,568			1,497,568
Net Income							3,447,737	3,447,737
BALANCE, December 31, 2001	6,132,718	\$ 61,327	\$ 20,170,492	\$ -	\$ 1,497,568	\$ (525,000)	\$ (7,764,075)	\$ 13,440,312

The accompanying notes are an integral part of the Consolidated Financial Statements

**BOSTON BIOMEDICA, INC. AND SUBSIDIARIES  
CONSOLIDATED STATEMENTS OF CASH FLOWS**

	Years Ended December 31,		
	2001	2000	1999
<b>CASH FLOWS FROM OPERATING ACTIVITIES:</b>			
Net income (loss)	\$ 3,447,737	\$ (8,000,959)	\$ (814,112)
Less income (loss) from discontinued operations	4,334,498	(196,751)	306,180
Loss from continuing operations	(886,761)	(7,804,208)	(1,120,292)
Adjustments to reconcile net (loss) income to net cash (used in) provided by operating activities:			
Depreciation and amortization	1,415,253	1,609,454	1,338,789
Non-cash interest expense on convertible debentures	(508,906)	707,704	-
Stock based compensation	30,000	-	-
Cumulative effect of change in accounting principle	-	190,223	-
Impairment of intangible assets	-	1,464,220	-
Provision for doubtful accounts	55,808	2,064	-
Deferred income tax valuation allowance	-	1,155,325	(447,420)
Loss on disposal of property and equipment	-	4,721	35,672
Changes in operating assets and liabilities:			
Accounts receivable	(247,378)	469,943	237,548
Inventories	(297,596)	(3,855)	(73,672)
Prepaid expenses and other current assets	60,456	48,316	141,608
Receivable for income taxes	212,762	(212,762)	-
Other long-term assets	(19,294)	11,910	(2,224)
Accounts payable	434,074	(554,880)	29,150
Accrued compensation	70,622	3,571	(124,042)
Other accrued expenses	(367,602)	(101,408)	395,260
Deferred revenue	22,237	23,897	(690,760)
Deferred rent and other liabilities	(29,262)	190,078	(320,243)
Net cash used in operating activities	(55,587)	(2,795,687)	(600,626)
<b>CASH FLOWS FROM INVESTING ACTIVITIES:</b>			
Payments for additions to property and equipment	(416,202)	(1,025,460)	(2,456,521)
Proceeds from sale of property and equipment	35,509	-	-
Net cash used in investing activities	(380,693)	(1,025,460)	(2,456,521)
<b>CASH FLOWS FROM FINANCING ACTIVITIES:</b>			
Proceeds from mortgage, net of issuance costs	-	2,446,573	-
(Repayments) Proceeds from issuance of convertible debentures, net of issuance cost:	(1,663,352)	2,531,023	-
Proceeds from issuance of warrants	-	327,643	206,011
Proceeds from issuance of common stock	425,062	936,359	185,570
Proceeds from prepaid common stock subscription, net of issuance costs	1,497,568	-	-
Loan to officer/director	(525,000)	-	-
(Repayments) Borrowings on line of credit	(5,762,635)	(1,383,016)	3,168,300
Repayments of long-term debt	(82,127)	(75,462)	-
Net cash provided (used) by financing activities	(6,110,484)	4,783,120	3,559,881
<b>(DECREASE) INCREASE IN CASH AND CASH EQUIVALENTS:</b>			
Change in cash and cash equivalents provided by discontinued operations	7,622,580	543,959	(326,480)
Cash and cash equivalents, beginning of year	1,782,100	276,168	99,914
Cash and cash equivalents, end of year	\$ 2,857,916	\$ 1,782,100	\$ 276,168
<b>SUPPLEMENTAL INFORMATION:</b>			
Income taxes paid	\$ 29,801	\$ 85,119	\$ 33,391
Interest paid	370,149	416,557	414,297
<b>NON-CASH ACTIVITIES:</b>			
Capital lease obligations incurred	\$ 21,242	\$ 95,577	\$ -
Conversion of Debentures to equity	978,889	-	-

The accompanying notes are an integral part of the Consolidated Financial Statements

## BOSTON BIOMEDICA, INC. AND SUBSIDIARIES NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

### (1) Business and Significant Accounting Policies

Boston Biomedica, Inc. (“BBI”) and Subsidiaries (together, the “Company”) provide infectious disease diagnostic products, laboratory instrumentation, contract research and specialty infectious disease testing services to the *in-vitro* diagnostic industry, government agencies, blood banks, hospitals and other health care providers worldwide as of December 31, 2001. The Company also invests in new technologies related to infectious diseases. The Company is subject to risks common to companies in the biotechnology, medical device and diagnostic industries, including but not limited to, development by the Company or its competitors of new technological innovations, dependence on key personnel, protection of proprietary technology, and compliance with governmental regulations.

Significant accounting policies followed in the preparation of these consolidated financial statements are as follows:

#### (i) Principles of Consolidation

The consolidated financial statements include the accounts of BBI and its wholly-owned subsidiaries, BBI Biotech Research Laboratories, Inc. ("BBI Biotech"), BBI Source Scientific, Inc. ("BBI Source"), and BBI BioSeq, Inc. ("BBI BioSeq"). BBI consists primarily of the Diagnostic Products segment as well as the executive corporate office. In January 2000, the Company incorporated Panacos Pharmaceuticals, Inc., ("Panacos"). All of the Company's technology related to its drug discovery and vaccine programs, consisting of primarily patents and related sponsored agreements, were transferred to Panacos effective January 2000. Panacos was accounted for as a consolidated subsidiary of the Company during the period January 1, 2000 to November 14, 2000, subsequent to which Panacos obtained independent third party funding and the Company ceased consolidation of Panacos as a wholly-owned subsidiary. As of November 14, 2000 the Company's investment in Panacos was zero and the Company is no longer required to fund Panacos's operations. Therefore no further losses of Panacos will be recorded by the Company. As of February 2002, the Company holds a 16% interest in non-voting preferred shares of Panacos. All significant intercompany accounts and transactions have been eliminated in the consolidation.

In February 2001, the Company sold the business and certain assets and liabilities of BBI Clinical Laboratories, Inc. ("BBICL") to a third party in conjunction with its decision to exit the clinical laboratory business segment. Accordingly, the accompanying financial statements present BBICL's net assets and results of operations as discontinued operations.

***(ii) Use of Estimates***

To prepare the financial statements in conformity with generally accepted accounting principles, management is required to make significant estimates and assumptions that affect the reported amounts of assets and liabilities and disclosure of contingent assets and liabilities at the date of the financial statements and the reported amounts of revenues and expenses during the reporting period. In particular, the Company records reserves for estimates regarding the collectability of accounts receivable, the value and realizability of intangible assets, deferred tax assets, the net realizable value of its inventory, as well as an estimate for remaining liabilities associated with discontinued operations.

Actual results could differ from the estimates and assumptions used by management.

***(iii) Revenue Recognition***

Product revenue is recognized upon shipment of the products or, for specific orders at the request of the customer, on a bill and hold basis after completion of manufacture. All bill and hold transactions meet specified revenue recognition criteria which include normal billing, credit and payment terms, firm commitment and transfer to the customers of all risks and rewards of ownership. Total revenue related to bill and hold transactions was approximately \$610,000, \$562,000, and \$1,998,000, for the years ended December 31, 2001, 2000, and 1999, respectively.

Services are recognized as revenue upon completion of tests for laboratory services. Revenue from service contracts and research and development contracts for the Company's laboratory instrumentation business is recognized as the service and research and development activities are performed under the terms of the contracts.

Revenue under long-term contracts, generally lasting from one to five years, including funded research and development contracts, is recorded when costs to perform such research and development activities are incurred. Billings under long-term contracts are generally at cost plus a predetermined profit. Billings occur as costs associated with time and materials are incurred. Customers are obligated to pay for such services, when billed, and payments are non-refundable. On occasion certain customers make advance payments that are deferred until revenue recognition is appropriate. The Company does not believe there are any material collectability issues associated with these receivables.

Total revenue related to long-term contracts was approximately \$5,062,000, \$5,082,000, and \$4,457,000, for the years ended December 31, 2001, 2000, and 1999, respectively. Total contract costs associated with these agreements were approximately \$4,911,000, \$5,540,000, and \$4,323,000, for the years ended December 2001, 2000 and 1999, respectively. Included in the revenue recognized under long-term contracts are certain unbilled receivables representing additional indirect costs, which are allowed under the terms of the respective contracts. Unbilled receivables were less than \$50,000 for all years presented.

In December 1999, the Staff of the Securities and Exchange Commission issued Staff Accounting Bulletin No. 101, "Revenue Recognition in Financial Statements" ("SAB 101"). This SAB summarizes certain of the Staff's views in applying generally accepted accounting principles, in the United States, to revenue recognition in financial statements. SAB 101 was effective for the Company's fiscal year ended December 31, 2000. The adoption of this standard by the Company did not have a material impact on the accompanying financial statements.

***(iv) Cash and cash equivalents***

The Company's policy is to invest available cash in short-term, investment grade, interest bearing obligations, including money market funds, municipal notes, and bank and corporate debt instruments. Securities purchased with initial maturities of three months or less are valued at cost plus accrued interest, which approximates fair market value, and classified as cash equivalents.

***(v) Research and Development Costs***

Research and development costs, which are comprised of costs incurred in performing research and development activities including wages and associated employee benefits, facilities and overhead costs, are expensed as incurred.

***(vi) Inventories***

Inventories are stated at the lower of cost (first-in, first-out) or net realizable value and include material, labor and manufacturing overhead.

***(vii) Property and Equipment***

Property and equipment are stated at cost. For financial reporting purposes, depreciation is recognized using the straight-line method, allocating the cost of the assets over their estimated useful lives ranging from five to ten years for certain manufacturing and laboratory equipment, from three to five years for management information systems and office equipment, three years for automobiles and thirty years for the building. Leasehold improvements are amortized over the shorter of the life of the improvement or the remaining life of the leases, which range from four to ten years. Upon retirement or sale, the cost and related accumulated depreciation of the asset are removed from the accounting records. Any resulting gain or loss is credited or charged to income.

***(viii) Intangible Assets***

The Company has classified as intangible assets, costs associated with the fair value of certain assets of the businesses acquired. These intangible assets, which primarily include patents, licenses, and intellectual property rights, are being amortized on a straight-line basis over four to sixteen years.

***(ix) Impairment of Long-Lived Assets***

The Company evaluates the potential impairment of its long-lived assets whenever events or changes in circumstances indicate that the carrying amount of an asset may not be recoverable. At the occurrence of a certain event or change in circumstances, the Company evaluates the potential impairment of an asset based on estimated future undiscounted cash flows. In the event impairment exists, the Company will measure the amount of such impairment based on the present value of estimated future cash flows using a discount rate commensurate with the risks involved. Upon the occurrence of a material circumstance, such as the failure of certain technology to demonstrate promise that it may gain commercial acceptance or the failure of a business segment to achieve certain performance objectives, management reassesses the value of associated assets and if appropriate at that time, will recognize an impairment charge. (See Note 5.)

***(x) Income Taxes***

The Company utilizes the liability method of accounting for income taxes. Under this method, deferred taxes arise from temporary differences between the financial statement and tax bases of assets and liabilities using enacted tax rates in effect in the years in which the differences are expected to reverse. A valuation allowance is provided for net deferred tax assets if, based on the weighted available evidence, it is more likely than not that some or all of the deferred tax assets will not be realized. Tax credits are recognized when realized using the flow through method of accounting. In the year ended December 31, 2000, the Company established a full valuation allowance for all of its deferred tax assets based on applicable accounting standards and in consideration of incurring three consecutive years of losses (see Note 10).

***(xi) Concentration of Credit Risk***

Financial instruments, which potentially subject the Company to concentrations of credit risk, are principally cash and cash equivalents, and accounts receivable. The Company places its cash and cash equivalents with high credit quality financial institutions. The Company limits credit risk in cash equivalents by investing only in short-term, investment grade securities including money market funds restricted to such securities. Concentration of credit risk with respect to accounts receivable is limited to certain customers to whom the Company makes substantial sales (see Note 6). The Company does not require collateral from its customers. To reduce risk, the Company routinely assesses the financial strength of its customers and, as a consequence, believes that its trade accounts receivable credit risk exposure is limited.

***(xii) Deferred Revenue***

Deferred revenue consists of payments received from customers in advance of services performed.

***(xiii) Computation of Earnings (Loss) per Share***

Basic earnings (loss) per share is computed by dividing income (loss) available to common shareholders by the weighted average number of common shares outstanding. Diluted earnings (loss) per share is computed by dividing income (loss) available to common shareholders by the weighted average common shares outstanding plus additional common shares that would have been outstanding if dilutive potential common shares had been issued. For purposes of this calculation, stock options are considered common stock equivalents in periods in which they have a dilutive effect. Options and warrants that are antidilutive are excluded from the calculation.

Potentially dilutive securities having a net effect of 9,531, 2,500, and 68,023 common shares were not included in the computation of diluted loss per share because to do so would have been antidilutive for the years ended December 31, 2001, 2000 and 1999, respectively.

***(xiv) Segment Reporting***

SFAS No. 131, "Disclosures about Segments of an Enterprise and Related Information," establishes standards for the way that public business enterprises report information about operating segments in annual financial statements and requires selected information about operating segments in interim financial reports. It also establishes standards for related disclosures about products and services, geographic areas and major customers. Disclosures required by this new standard are included in the notes to the consolidated financial statements under the caption "Segment Reporting and Related Information."

***(xv) Recent Accounting Standards***

In late 2000 and early 2001, the Financial Accounting Standards Board Emerging Issues Task Force ("EITF") reached consensus on a number of revisions to EITF Issue No. 98-5 "Accounting for Convertible Securities with Beneficial Conversions Features or

Contingently Adjustable Conversion Ratios.” The Securities and Exchange Commission’s (“SEC”) Observer to the EITF indicated the SEC’s preference that the revision relative to the computation of a beneficial conversion features associated with convertible securities be applied to all securities issued after May 20, 1999. The Company therefore applied this adjusted calculation to the beneficial conversion feature associated with its August 2000 issuance of \$3,250,000 of 3% Senior Subordinated Convertible Debentures and accordingly, the Company has included the effects of the revisions, as indicated by the SEC staff member. Approximately \$190,000 of this revised computation is reflected as the cumulative effect of a change in accounting principle in the accompanying financial statements for the year ended December 31, 2000.

In September 2000, the FASB issued SFAS No. 140 “Accounting for Transfers and Servicing of Financial Assets and Extinguishments of Liabilities—a replacement of FASB Statement No. 125”. SFAS No. 140 revises the standards for accounting for securitizations and other transfers of financial assets and collateral and requires certain disclosures, but it carries over most of SFAS No. 125’s provisions without reconsideration. This Statement is effective for transfers and servicing of financial assets and extinguishments of liabilities occurring after March 31, 2001. This Statement is effective for recognition and reclassification of collateral and for disclosures relating to securitization transactions and collateral for fiscal years ending after December 15, 2000. The Company does not believe the adoption of SFAS No. 140 has had a material effect on its financial statements.

In March 2000, the FASB issued FASB Interpretation No. 44, “Accounting for Certain Transactions Involving Stock Compensation,” (an Interpretation of Accounting Principles Bulletin Opinion No. 25 (“APB 25”)) (“FIN 44”). FIN 44 provides guidance on the application of APB 25, particularly as it relates to options. The effective date of FIN 44 was July 1, 2000, and the Company has adopted FIN 44 as of that date. The application of FIN 44 has not had a material effect on the Company’s financial statements.

Statement of Financial Accounting Standards No. 141, “Business Combinations” (SFAS 141), is effective for all business combinations initiated after June 30, 2001. The new standard requires companies to record business combinations using the purchase method of accounting. The Company has not done a business combination since the issuance of SFAS 141.

Statement of Financial Accounting Standards No. 142, “Goodwill and Other Intangible Assets” (SFAS 142), is effective for the Company beginning January 1, 2002. SFAS 142 requires, among other things, the cessation of the amortization of goodwill. In addition, the standard includes provisions for the reclassification of certain existing recognized intangibles as goodwill, reassessment of the useful lives of existing recognized intangibles, reclassification of certain intangibles out of previously reported goodwill and the identification of reporting units for purposes of assessing potential future impairments of goodwill. SFAS 142 also requires companies to complete a transitional goodwill impairment test six months from the date of adoption. The Company is assessing the impact of this new statement on its consolidated financial position and results of operations but does not believe its adoption will have a material effect on the Company’s financial statements.

Statement of Financial Accounting Standards No. 143, “Accounting for Asset Retirement Obligations” (SFAS 143), is effective January 1, 2003. SFAS 143 addresses the financial accounting and reporting for obligations and retirement costs related to the retirement of tangible long-lived assets. We do not expect that the adoption of SFAS 143 will have a significant impact on our financial statements.

Statement of Financial Accounting Standards No. 144, “Accounting for the Impairment or Disposal of Long-Lived Assets” (SFAS 144), is effective January 1, 2002. SFAS 144 supersedes FASB Statement No. 121, “Accounting for the Impairment of Long-Lived Assets and for Long-Lived Assets to Be Disposed Of,” and the accounting and reporting provisions relating to the disposal of long-lived assets. We do not expect that the adoption of SFAS 144 will have a significant impact on our financial statements.

#### *(xvi) Reclassifications*

Certain amounts included in the prior year’s financial statements have been reclassified to conform to the current years presentation.

## **(2) Disposition of Assets**

In December 2000, the Company made a decision to exit the clinical laboratory testing services segment and in February 2001, BBI Clinical Laboratories, Inc., a wholly-owned subsidiary of the Company, sold the business and certain assets and liabilities to a third party for an adjusted purchase price of \$8,958,000. The escrow account was terminated in December 2001 by mutual agreement between the buyer and the Company, resulting of approximately \$358,000 being received by the Company from the escrow account. The Company has retained certain other assets and liabilities of BBICL, primarily property, plant and equipment, together with the facility lease subsequent to the closing date, which the Company is attempting to sublease. The Company has written down all of the retained assets not otherwise redistributed to other business units to their estimated net realizable value. In accordance with a transition services agreement, the Company operated the business until December 2001; substantially all costs associated with operating the business subsequent to the closing date were borne by the purchaser.

The Company has recorded its estimate of remaining short and long term accrued liabilities to exit the Clinical Laboratory testing business, totaling approximately \$1,687,000 as of December 31, 2001. The major components of this accrual are estimated income taxes (\$420,000), severance and other employee related costs (\$75,000), estimated lease exit and facility related costs (\$750,000) and potential health care claims and other related potential audit adjustments (\$318,000), with the remainder for other miscellaneous costs associated with exiting this business segment.

The Company has recorded an after-tax gain of \$4,334,000 in 2001, which may be subject to future adjustments as the Company completes the process of exiting this business and permanently closing the facility. The remaining closing costs include an estimate to dispose of any remaining assets and retire all existing liabilities including the facility lease. The Company will utilize in year 2001 certain prior period net operating loss carryforwards, previously reserved for by the Company, to partially offset the income tax effect of this gain. All financial data presented in the accompanying financial statements has been reclassified to reflect discontinued operations of this segment of the business for all periods presented. Revenues from discontinued operations, net of intercompany eliminations of \$0, \$197,287, and \$368,979, were \$973,000, \$8,366,995, and \$9,472,741 in the period January 1, 2001 to February 20, 2001, the year 2000 and

the year 1999 respectively.

### (3) Inventories

The Company purchases human plasma and serum from various private and commercial blood banks. Upon receipt, such purchases generally undergo comprehensive testing, and associated costs are included in the value of raw materials. Most plasma is manufactured into Basematrix and other diagnostic components to customer specifications. Plasma and serum with the desired antibodies or antigens are sold or manufactured into QC Panels, Accurun<sup>®</sup> Run Controls, and reagents ("Finished Goods"). Panels and reagents are unique to specific donors and/or collection periods, and require substantial time to characterize and manufacture due to stringent technical specifications. Panels play an important role in diagnostic test kit development, licensure and quality control. Panels are manufactured in quantities sufficient to meet expected user demand, which may exceed one year. Inventory also includes component parts used in the manufacture of laboratory instrumentation. Inventory balances at December 31, 2001 and 2000 consisted of the following:

	2001	2000
Raw materials.....	\$ 2,855,390	\$ 3,029,962
Work-in-process.....	2,151,359	1,753,867
Finished goods.....	1,756,395	1,681,719
	<u>\$ 6,763,144</u>	<u>\$ 6,465,548</u>

### (4) Property and Equipment

Property and equipment at December 31, 2001 and 2000 consisted of the following:

	2001	2000
Laboratory and manufacturing equipment.....	\$ 3,370,925	\$ 3,228,054
Management information systems.....	3,373,132	3,315,397
Office equipment.....	919,947	882,584
Automobiles.....	156,726	135,485
Leasehold improvements.....	2,816,108	2,696,561
Land, building and improvements.....	2,687,661	2,672,240
	<u>13,324,499</u>	<u>12,930,321</u>
Less accumulated depreciation.....	<u>6,790,828</u>	<u>5,471,038</u>
Net book value.....	<u>\$ 6,533,671</u>	<u>\$ 7,459,283</u>

Depreciation expense for the years ended December 31, 2001, 2000 and 1999 was approximately \$1,327,000, \$1,410,000, and \$1,126,000 respectively.

In accordance with Statement of Position ("SOP") 98-1, "Accounting for the Costs of Computer Software Developed or Obtained for Internal Use", the Company capitalized approximately \$448,000 of internal labor and related costs, in 1999, in connection with its ERP System Implementation. These costs are included in the Management Information Systems line item and are being depreciated over the same life as the system, 5 years. Depreciation expense related to these capitalized costs was approximately \$90,000, \$90,000 and \$7,000 for the years ended December 31, 2001, 2000 and 1999, respectively.

### (5) Intangible Assets

Intangible assets at December 31, 2001 and 2000 consisted of the following:

	2001	2000
Patents, Licenses and Other Intangibles.....	\$ 1,622,487	\$ 1,622,487
Less accumulated amortization.....	<u>(767,623)</u>	<u>(688,694)</u>
Net book value.....	<u>\$ 854,864</u>	<u>\$ 933,793</u>

Amortization expense for the years ended December 31, 2001, 2000, and 1999 was approximately \$79,000, \$173,000, and \$213,000, respectively.

As part of an ongoing strategic review process, the Company's Board of Directors met in late September 2000 to review the progress of its Laboratory Instrumentation segment, and that segment's prospects for the future. Based on new updated information presented at this meeting and subsequent analyses showing lower revenue expectations, management approved implementation of a cost reduction plan including a headcount reduction, salary freeze, and sublease of excess manufacturing space. Using the assumptions associated with this revised business plan, the Company estimated future net undiscounted cash inflows and cash outflows over the remaining original amortization period of that segment's goodwill, and concluded an impairment had occurred. These annual net future cash inflows and outflows were then discounted at a rate commensurate with the business risks inherent with the future operations of the Laboratory

Instrumentation segment, and thus, in accordance with the provisions of both "Accounting Principles Board Opinion No. 17 - Intangible Assets" and "Statement of Financial Accounting Standards No. 121 - Accounting for the Impairment of Long-Lived Assets and for Long-Lived Assets to Be Disposed Of," this segment's goodwill was written down by approximately \$1,464,000 in year 2000. The net balance of the remaining intangible assets associated with the Laboratory Instrument segment is approximately \$227,000 as of December 31, 2001.

#### (6) Segment Reporting and Related Information (all dollar amounts in thousands)

Operating segments are components of an enterprise for which separate financial information is available that is evaluated regularly by senior management in deciding how to allocate resources and in assessing the performance of each segment. The Company is organized along legal entity lines and senior management regularly reviews financial results for all entities, focusing primarily on revenue and operating income.

The Company had four operating segments as of December 31, 2001, as a result of its decision in late 2000 to exit the clinical laboratory segment of the business. The Diagnostics segment serves the worldwide in vitro diagnostics industry, including users and regulators of their test kits, with quality control products, and test kit components. The Biotech segment pursues third party contracts to help fund the development of products and services for the other segments, primarily with agencies of the United States Government. The Laboratory Instrumentation segment sells diagnostic instruments primarily to the worldwide in vitro diagnostic industry on an OEM basis, and also performs in-house instrument servicing. The PCT segment consists of research and development primarily in pressure cycling technology ("PCT"). The Company performs research in the development of PCT, with particular focus in the areas of nucleic acid purification and pathogen inactivation. While the PCT segment's research and development operation does not currently have any significant product or service revenue, the Company expects to commercialize certain PCT products in year 2002. Revenue to date consists of both private and public (NIH) funding of segment research. Most of the expenditures incurred by this segment are for research and development expenses, and general management expenses including patent costs.

The Company's underlying accounting records are maintained on a legal entity basis for government and public reporting requirements, as well as for segment performance and internal management reporting. Inter-segment sales are recorded on a "third party best price" basis and are significant in measuring segment operating results. Throughout 1999, the cost of most corporate functions are included in the Diagnostic Products segment as the senior management group has dual responsibility to this segment as well as the Company. Pursuant to the August 1999 reorganization, many of the senior managers and a few other employees were segregated from the Diagnostics segment to form a Corporate operating unit, effective January 2000. The following segment information has been prepared in accordance with the internal accounting policies of the Company, as described above. Prior year data has been restated, where feasible, to conform to the current year presentation format.

Operating segment revenue for the years ended December 31, 2001, 2000 and 1999 were as follows:

	2001	2000	1999
Diagnostics	\$ 11,489	\$ 10,863	\$ 11,837
Biotech	9,181	7,428	6,297
Laboratory Instrumentation	2,365	2,309	2,923
PCT	392	371	434
Panacos	-	161	-
Eliminations	(1,601)	(1,662)	(1,693)
Total revenue	\$ 21,826	\$ 19,470	\$ 19,798

Operating segment income (loss) for the years ended December 31, 2001, 2000 and 1999 were as follows:

	2001	2000	1999
Diagnostics	\$ 1,674	\$ 1,015	\$ 2,436
Biotech	(212)	(398)	(482)
Laboratory Instrumentation (1)	(460)	(2,819)	(1,163)
PCT	(1,493)	(1,298)	(2,006)
Panacos	-	(1,027)	-
Reclassifications/Other	-	(341)	(236)
Total loss from operations	\$ (491)	\$ (4,868)	\$ (1,451)

Operating segment depreciation and amortization expense for the years ended December 31, 2001, 2000 and 1999 were as follows:

	2001	2000	1999
Diagnostics	598	692	537
Biotech	593	582	419
Laboratory Instrumentation (1)	140	1,717	299
PCT	84	83	84
Total depreciation and amortization	\$ 1,415	\$ 3,074	\$ 1,339

(1) Included in the Laboratory Instrumentation segments loss for 2000 is a \$1,464 write down of a portion of the Laboratory Instrumentation segment's goodwill. (See also Note 5)

Identifiable operating segment assets are all located in the United States, and as of December 31, 2001 and 2000 were as follows:

	2001	2000
Corporate	\$ 3,186	\$ 3,635
Diagnostics	10,600	11,183
Biotech	5,286	4,693
Laboratory Instrumentation	1,628	2,141
PCT	714	897
Total assets	<u>\$ 21,414</u>	<u>\$ 22,549</u>

Operating segment capital expenditures for the years ended December 31, 2001, 2000 and 1999 were as follows:

	2001	2000	1999
Diagnostics	\$ 205	\$ 283	\$ 1,315
Biotech	207	818	944
Laboratory Instrumentation	4	19	164
PCT	21	1	34
Total capital expenditures	<u>\$ 437</u>	<u>\$ 1,121</u>	<u>\$ 2,457</u>

Revenue by geographic area for the years ended December 31, 2001, 2000 and 1999 are as follows:

	2001	2000	1999
United States	18,389	\$ 15,295	\$ 15,758
Europe	2,397	2,594	2,509
Pacific Rim	624	841	818
Total all others	416	740	713
Total	<u>\$ 21,826</u>	<u>\$ 19,470</u>	<u>\$ 19,798</u>

Revenue of Product and Service classes in excess of 10% of consolidated revenue from continuing operations (excludes inter-segment sales) for the years ended December 31, 2001, 2000 and 1999 were as follows:

	2001	2000	1999
Quality Control Products	\$ 8,343	\$ 8,210	\$ 9,445
Government Contracts	7,617	5,929	4,530
Diagnostic Components	2,629	1,788	1,905
Laboratory Instrument Products	1,895	1,953	2,578

The government contract revenues are from United States government agencies, primarily various branches of the National Institutes of Health (NIH) and represent the only customer with revenue in excess of 10% of consolidated revenue in each of the years ended December 31, 2001, 2000 and 1999. During the fiscal years 2001, 2000, and 1999, the combined revenues from all branches of the NIH accounted for approximately 31%, 30% and 23%, respectively, of total consolidated revenues from continuing operations of the Company.

## (7) Debt

Effective June 30, 1999, the Company entered into an amended revolving line of credit agreement (the "Amended Line") with its bank, increasing the facility to \$10 million from \$7.5 million. The Amended Line bears interest at the Company's option based on either the base rate plus ¼% or LIBOR plus 2.75%; carries a facility fee of ¼% per annum, payable quarterly; and is collateralized by substantially all of the assets of the Company, excluding real property. Borrowings under the Amended Line are limited to commercially standard percentages of accounts receivable, inventory and equipment. The Amended Line contains covenants regarding the Company's total liabilities to tangible net worth ratio, minimum debt service coverage ratio, and maximum net loss. The Amended Line further provides for restrictions on the payment of dividends, incurring additional debt, and the amount of capital expenditures.

The December 31, 2000 balance sheet reflects the classification of the Company's \$5,762,635 outstanding line-of-credit balance as short-term debt. The Company has reclassified this debt to short-term because in March 2000 and through the remainder of the year, the Company was in violation of a financial covenant limiting the amount of allowable losses. In December 2000, the line of credit was limited to a maximum borrowing level of \$5,762,635 and the interest rate was raised four percentage points above the normal rate associated with this line of credit. In February 2001, the Company utilized a portion of the proceeds from the sale of BBICL to pay off in full the outstanding balance (together with accrued interest) on this line of credit, at which time the bank released all liens associated with this line of credit and terminated the line of credit. There were no payment defaults at any time associated with this line of credit.

On August 25, 2000, the Company entered into Securities Purchase Agreements providing for the issuance of \$3,250,000 (face value) 3% Senior Subordinated Convertible Debentures due August 25, 2003, (the "Debentures"). Proceeds to the Company, net of a 5% original issue discount and debt issuance costs, amounted to \$2,858,000, of which \$327,000 has been allocated to the relative fair value of the associated common stock purchase warrants. The fair value of the warrants was determined using the Black Scholes option-pricing model and the following assumptions: a risk free interest rate of 6.02%, a volatility factor of 91.17%, a contractual life of 5 years and no expected



dividend yield. The Company then allocated the proceeds of the Debentures, net of the original issue discount (\$3,087,500), on a pro-rata basis using the calculated fair value of the warrants (\$318,000) and the fair value of the Debentures (\$2,685,000). This resulted in proceeds of approximately \$327,000 and \$2,761,000 being allocated to the relative fair value of the warrants and the Debentures, respectively. The Debentures are convertible into the Company's common stock commencing November 24, 2000, at a conversion price equal to the lesser of (i) \$3.36 per share or (ii) 90% of the average of the five lowest volume weighted average sales prices of Common Stock as reported by Bloomberg L.P. during the twenty-five business days immediately preceding the date on which the Debenture holders notify the Company of their intention to convert all or part of the Debenture into Common Stock. In connection with this transaction, the Company issued warrants to purchase up to 135,556 shares of the Company's common stock at an exercise price of \$3.60 per share. Interest on the Debentures is payable quarterly in arrears commencing September 30, 2000. The Debentures are subordinate to both the Company's line of credit (which was terminated in February 2001) and mortgage on its West Bridgewater, MA facility. The Company may elect at any time to redeem all or any portion of the remaining unpaid principal amount of the Debentures for cash. In addition, upon receipt of a notice of conversion from a holder of the Debentures, the Company may elect to redeem that portion being converted for cash in lieu of common stock of the Company. In both cases, the redemption price equals the number of shares of common stock into which the Debenture being redeemed is convertible, times the average closing bid price of the Company's common stock for the five preceding trading days.

The Securities Purchase Agreements and related documents place certain restrictions on the Company's ability to incur additional indebtedness, to make certain payments, investments, loans, guarantees and/or transactions with affiliates, to sell or otherwise dispose of a substantial portion of assets, and/or to merge or consolidate with an unaffiliated entity.

Original issue discount and associated debt issuance costs of \$162,500 and \$230,000, respectively, are being amortized ratably over the three-year life of the underlying debt as additional interest expense. Also, in accordance with Emerging Issues Task Force Issues 98-5 and 00-27, proceeds of \$840,000 have been allocated to the beneficial conversion feature of the Debentures by decreasing the value of the debt and increasing additional paid in capital.

Of this, \$351,000 was originally calculated in the third quarter of 2000 when the Debentures were issued. The additional amount of \$489,000 was calculated in the fourth quarter of 2000 using the accounting conversion method preferred by the SEC pursuant to EITF 00-27 which clarified the method of calculating the beneficial conversion feature. The amount allocated to the beneficial conversion feature was valued using conversion method (ii) from above as of the date of the transaction as it was determined to be the most beneficial to the holders of the Debentures. This amount was expensed over the initial 90-day non-convertible period. For the year ended December 31, 2000, the Company recorded a charge of \$898,000 (including \$190,223 for the cumulative effect of a change in accounting principle noted above) due to amortization of the beneficial conversion feature, warrant costs and original issue discount/debt issuance costs associated with the Company's August 2000 issuance of \$3,250,000 3% Senior Subordinated Convertible Debentures.

In the first quarter of 2001, certain holders of the Company's outstanding 3% Senior Convertible Debentures (the "Debentures") exercised their rights to convert \$1,210,000 of such Debentures into shares of the Company's common stock, in accordance with the conversion formula. These conversions resulted in the issuance of 801,325 additional shares of common stock in 2001. In addition, the Company redeemed the remaining \$2,040,000 of Debentures at face plus a \$190,000 premium and accrued interest. Unamortized debt discount, debt issuance costs and warrant-related costs associated with the converted Debentures, approximating \$231,000 was debited to additional paid-in capital, with the remaining \$377,000 of such costs associated with the redeemed Debentures being included in the loss on extinguishment of the Debentures. In addition, the Company reversed approximately \$528,000 of expense previously recorded in 2000 associated with the Debentures beneficial conversion feature. Accordingly, the Company recorded a net loss of approximately \$39,000 relative to this early extinguishment of debt in the first quarter of 2001. As a result of both the conversions and redemptions, which occurred in the first quarter of 2001, none of the 3%, Senior Subordinated Convertible Debentures remain outstanding subsequent to February 27, 2001.

On April 5, 2000, the Company borrowed \$2,447,000, net of related costs, under a mortgage agreement on its West Bridgewater, MA facility, of which approximately \$2,421,000 remains outstanding as of December 31, 2001. The Company used the funds to reduce the outstanding balance of its existing line of credit. The principal amount of the note issued in connection with the mortgage is due on March 31, 2010. During the first five years the note carries an interest rate of 9.75%; after five years the rate charged will be .75% greater than the Corporate Base Rate then in effect. The mortgage precludes the payment of dividends on the Company's common stock and contains certain other restrictive covenants. Under this mortgage agreement the Company is subject to certain financial covenants. Monthly payments on this mortgage are based on a 20 year amortization schedule with a balloon payment representing the remaining balance due in full on March 10, 2010. The mortgage is collateralized by the Company's West Bridgewater, MA facility. Principal payments due on the Company's mortgage agreement are approximately \$54,000, \$60,000, \$66,000, \$72,000 and \$80,000 for each of the years ended December 31, 2002, 2003, 2004, 2005, and 2006, respectively.

## **(8) Other Liabilities**

Included in long-term liabilities at December 31, 2001 and 2000 are the present value of future minimum royalty payments of approximately \$19,700 and \$55,000 payable to the former owners of BioSeq, Inc.

## **(9) Income Taxes**

The components of the (benefit) provision for income taxes from continuing operations are as follows:

	2001	2000	1999
Current (benefit) provision: federal	\$ -	\$ -	\$ (226,368)
Current provision: state	15,678	-	2,168
Total current (benefit) provision	15,678	-	(224,200)
Deferred (benefit) provision: federal	-	879,557	(373,497)
Deferred (benefit) provision: state	-	272,383	(146,396)
Total deferred (benefit) provision	-	1,151,940	(519,893)
Total (benefit) provision for income taxes from continuing operations	\$ 15,678	\$ 1,151,940	\$ (744,093)

Significant items making up deferred tax liabilities and deferred tax assets were as follows:

	2001	2000
Current deferred taxes:		
Inventory	\$ 271,949	\$ 562,134
Accounts receivable allowance	58,159	355,611
Technology licensed	254,617	277,250
Other accruals	141,801	173,504
Less: valuation allowance	(726,526)	(1,368,499)
Total current deferred tax assets	-	-
Long term deferred taxes:		
Accelerated tax depreciation	(144,011)	(232,282)
Goodwill and intangibles	533,646	594,657
Tax credits	577,197	252,589
Operating loss carryforwards	1,503,528	3,094,247
Less: valuation allowance	(2,470,360)	(3,709,211)
Total long term deferred tax assets (liabilities), net	-	-
Total net deferred tax assets	\$ -	\$ -

A valuation allowance is established if it is more likely than not that all or a portion of the deferred tax asset will not be realized. Accordingly, a valuation allowance has been established for the full amount of the deferred tax asset due to the uncertainty of realization.

The Company had net operating loss carryforwards for federal income tax purposes of approximately \$2,700,000 and \$7,550,000 at December 31, 2001 and 2000, respectively. These net operating loss carryforwards expire at various dates from 2012 through 2020. Included in this number are loss carryforwards of approximately \$1,350,000 that were obtained through the acquisition of BioSeq, Inc. These carryforwards expire from 2012 through 2018.

The Company had net operating loss carryforwards for state income tax purposes of approximately \$9,400,000 and \$9,200,000 at December 31, 2001 and 2000, respectively. These net operating loss carryforwards expire at various dates from 2002 through 2021. Included in this number are loss carryforwards of approximately \$2,000,000 that were obtained through the acquisition of BioSeq, Inc. These carryforwards expire from 2011 through 2018.

As of December 31, 2001, the Company had approximately \$150,000 of alternative minimum tax credits, which do not expire, and \$372,000 of federal research credits, which expire from 2011 to 2020.

Included in the net operating loss and credit carryforwards discussed above is a deferred tax asset of approximately \$360,000 reflecting the benefit of deductions from the exercise of stock options. The benefit from this deferred tax asset will be recorded to additional paid-in capital when realized.

The Company's effective income tax rate from continuing operations differs from the statutory federal income tax rate as follows:

	2001	2000	1999
Federal tax (benefit) provision rate	(34%)	(34%)	(34%)
State tax (benefit) provision, net of federal benefit	(4%)	(6%)	(6%)
Non-cash deductions and other permanent items	(10%)	(14%)	
Effect of subsidiary leaving the group		4%	
Valuation allowance	50%	67%	2%
Effective income tax (benefit) provision rate from continuing operations	2%	17%	(38%)

The Company's federal income tax returns for fiscal years 1997 and 1998 are currently under examination by the Internal Revenue Service. Any assessments or potential assessments are not expected to have a material adverse effect on the accompanying financial statements.

## (10) Commitments and Contingencies

The Company leases certain office space, repository, research and manufacturing facilities under operating leases with various terms through October 2007. All of the real estate leases include renewal options at either market or increasing levels of rent. In May 2000, the Company acquired laboratory equipment pursuant to a three-year capital lease at 12% financing, resulting in total payments of approximately \$115,000 over the life of the lease agreement.

At December 31, 2001, future minimum lease payments under non-cancelable leases, excluding discontinued operations, is as follows:

<u>Year Ended</u>	<u>Operating Leases</u>	<u>Capital Leases</u>
2002	\$ 1,090,000	\$ 43,000
2003	1,151,000	21,000
2004	1,178,000	5,000
2005	904,000	5,000
2006	874,000	2,000
2007 and thereafter	270,000	
Total minimum lease payments	<u>\$ 5,467,000</u>	76,000
Less amount representing interest		<u>(12,000)</u>
Present value of minimum lease payments		<u>\$ 64,000</u>

The Company has entered into a non-cancelable sublease agreement with a third party, through January 2002, that will offset the future minimum lease payments by \$14,000. Rent expense, net of sublease income consisted of the following:

	<u>2001</u>	<u>2000</u>	<u>1999</u>
Basic expense	\$ 1,274,000	\$ 1,109,000	\$ 1,094,000
Sublease income	(169,000)	(42,000)	-
Rent expense, net	<u>\$ 1,105,000</u>	<u>\$ 1,067,000</u>	<u>\$ 1,094,000</u>

In addition, as discussed further in Note 2, the Company is subject to future minimum lease payments in connection with the discontinued operations of its Clinical Laboratory segment of \$161,000, \$161,000, \$161,000, and \$94,000 in 2002, 2003, 2004, and 2005, respectively. The Company has included an estimate of this remaining lease commitment in 2001 as part of the calculation of the gain on the sale of certain assets from the Clinical Laboratory segment.

The Company's California and Maryland facility's leases include scheduled base rent increases over the term of the lease. The amount of base rent payments is charged to expense using the straight-line method over the term of the lease. As of December 31, 2001 and 2000, the Company has recorded a long-term liability of \$306,000 and \$262,000, respectively (\$312,000 and \$337,000 including the current portion) to reflect the excess of rent expense over cash payments since inception of the lease. In addition to base rent, the Company pays a monthly allocation of the operating expenses and real estate taxes for the California and Maryland facilities.

#### **(11) Retirement Plan**

In January 1993, the Company adopted a retirement savings plan for its employees, which has been qualified under Section 401(k) of the Internal Revenue Code. Eligible employees are permitted to contribute to the plan through payroll deductions within statutory limitations and subject to any limitations included in the plan. Company contributions are made at the discretion of management. As of December 31, 2001, no such contributions have been made, however, subsequent to December 31, 2001, the Company formally adopted a limited matching contribution program. During 2001, 2000 and 1999 the Company recognized administrative expense of approximately \$23,000, \$30,000, and \$30,000, respectively in connection with the plan.

#### **(12) Stockholders' Equity**

##### ***Common Stock***

In July 1999, the Company's Board of Directors approved the 1999 Employee Stock Purchase Plan. The Company adopted this plan, which allows eligible employees to purchase shares of the Company's stock at 85% of market value as determined at the beginning and the end of the offering period. A total of 250,000 shares have been reserved for this plan. As of December 31, 2001, 23,750 shares had been issued under this plan.

In December 2001, an additional 600,000 shares of common stock were subscribed to and paid for by a group of investors for \$1,500,000. These shares were issued in the first quarter of 2002 and therefore were not included in the total shares outstanding as well as in the calculation of earnings (loss) per share for the year ended December 31, 2001.

##### ***Options and Warrants***

The Company has a nonqualified stock option plan and an incentive stock option plan (1996 Employee Stock Option Plan) both of which are administered by a committee of the Board of Directors. In July 1999 the Company's Board of Directors approved the designation of an additional 1,250,000 shares to become available for distribution under the 1996 Employee Stock Option Plan. The Board of Directors also approved the 1999 Non- Qualified Stock Option Plan, and designated 500,000 shares for distribution under this plan. The exercise

price of an option generally equals the fair market value of the stock at grant date. Generally, options become exercisable at the rate of 25% at the end of each of the four years following the anniversary of the grant. Options expire ten years from the date of grant, or 30 days from the date the grantee's affiliation with the Company terminates.

At December 31, 2001, 1,770,163 shares were reserved for incentive stock options, of which 1,072,738 are available for future grants. At December 31, 2001, 744,162 shares were reserved under the nonqualified stock option plans of which 314,800 are available for future grants.

In August 1999, the Company sold 500,000 warrants to purchase the Company's stock to Paradigm Group, a private investment company. The private placement consisted of 400,000 common stock purchase warrants with an exercise price of \$4.25 and 100,000 common stock purchase warrants with an exercise price of \$5.25. Paradigm Group paid the Company \$50,000 for the warrants. In addition, National Securities received 40,000 common stock purchase warrants with an exercise price of \$4.25, 10,000 common stock purchase warrants with an exercise price of \$5.25, and 25,000 common stock purchase warrants with an exercise price of \$8.00, as transaction fee. In February 2000, the Company received notice that Paradigm Group, LLC exercised all of their warrants to purchase the Company's common stock. The holders of the warrants were required to pay the exercise price when the registration of the underlying shares became effective which was in December 2000. In August 2000, the Company received a summons and complaint from Paradigm Group, LLC naming the Company as a defendant. The suit, filed in the Circuit Court of Cook County, Illinois, alleged breach of contract claims and fraud against the Company in connection with the sale by the Company to the Paradigm Group, LLC of the above warrants, the exercise of those warrants by Paradigm Group, LLC and a delay in the registration of those shares with the U. S. Securities and Exchange Commission. In December 2000, Paradigm Group, LLC withdrew this lawsuit. In the fourth quarter of 2000, the Company expensed approximately \$265,000 of costs related to these warrants and the registration of the underlying shares. On June 15, 2001 the Company and Paradigm Group, LLC entered into an agreement to permanently settle their disputes. Under the terms of the agreement, Paradigm Group, LLC rescinded their exercise of the common stock purchase warrants, which have since expired, and the Company retained the 500,000 shares associated with their exercise. These shares were included in the total shares outstanding as well as in the calculation of earnings (loss) per share from February 17, 2000 (the date of exercise) through June 15, 2001 (the date of the agreement). As of September 30, 2001, these shares were cancelled by the Company.

In November 1999, the Company sold 29,153 equity units to MDBio, Inc., a Maryland not-for-profit corporation. Each equity unit consists of one share of common stock and one common stock purchase warrant with an exercise price of \$10.00. MDBio paid the Company \$175,000 for the equity units and has until September 2003 to exercise the warrants.

The Company has elected to follow Accounting Principles Board Opinion No. 25, "Accounting for Stock Issued to Employees" (APB 25) and related interpretations in accounting for its employee stock options. Under APB 25, because the exercise price of employee stock options equals the market price of the underlying stock on the date of grant, no compensation expense is recorded. The Company has adopted the disclosure-only provisions of Statement of Financial Accounting Standards No. 123, "Accounting for Stock-Based Compensation" (SFAS 123). Pro forma information regarding net income and earnings per share is required by SFAS 123 and has been determined as if the Company had accounted for its employee stock options under the fair value method of that statement. The fair value of these options was estimated at the date of grant using a Black-Scholes option pricing model with the following weighted average assumptions for 2001, 2000, and 1999.

	2001	2000	1999
Risk-free interest rate	4.12%	5.77%	5.26%
Volatility factor	99.17%	98.54%	76.68%
Weighted average expected life	4.0 years	5.1 years	5.1 years
Expected dividend yield	-	-	-

The Black-Scholes option valuation model was developed for use in estimating the fair value of traded options, which have no vesting restrictions and are fully transferable. In addition, option valuation models require the input of highly subjective assumptions including the expected stock price volatility. Because the Company's employee stock options have characteristics significantly different from those of traded options, and because changes in the subjective input assumptions can materially affect the fair value estimate, in management's opinion, the existing models do not necessarily provide a reliable single measure of the fair value of its employee stock options.

For purposes of pro forma disclosures, the estimated fair value of the options is amortized to expense over the options' vesting period. The Company's pro forma net income and pro forma net loss per share is as follows:

	2001	2000	1999
Net income (loss) - as reported	\$ 3,447,737	\$ (8,000,959)	\$ (814,112)
Net income (loss) - pro forma	\$ 3,511,491	\$ (8,231,935)	\$ (1,394,564)
Net income (loss) per share - as reported, basic and diluted	\$ 0.56	\$ (1.46)	\$ (0.17)
Net income (loss) per share - pro forma, basic and diluted	\$ 0.57	\$ (1.51)	\$ (0.30)

The average fair value of options granted during 2001, 2000 and 1999 is estimated as \$1.75, \$2.67, and \$2.63, respectively.

The Company has reserved shares of its authorized but unissued common stock for the following:

	Stock Options		Warrants		Total	
	Shares	Weighted Average price per share	Shares	Weighted Average price per share	Shares	Exercisable
Balance outstanding, December 31, 1998	1,174,666	2.75 *	260,000	8.34	1,434,666	829,434
Granted	260,500	3.91	579,153	4.73	839,653	
Exercised	(47,249)	0.52	(5,000)	2.50	(52,249)	
Cancelled	(107,688)	3.56	-	-	(107,688)	
Balance outstanding, December 31, 1999	1,280,229	3.00	834,153	5.80	2,114,382	1,591,795
Granted	489,600	3.05	145,556	3.64	635,156	
Exercised	(352,879)	2.51	(521,979) **	4.38	(874,858)	
Cancelled	(171,772)	3.51	-	-	(171,772)	
Balance outstanding, December 31, 2000	1,245,178	3.06	457,730	6.81	1,702,908	1,068,403
Granted	341,900	2.57	-	-	341,900	
Exercised	(162,750)	2.43	(829)	2.75	(163,579)	
Cancelled	(337,041)	2.94	(210,000)	9.80	(547,041)	
Balance outstanding, December 31, 2001	1,087,287	3.02	246,901	4.13	1,334,188	857,574

\* Includes the effect of 411,417 options repriced in December 1998 from a weighted average price of \$6.72 to \$3.25 per share.

\*\* Includes a net exercise of 11,397 warrants for which 7,232 shares of the Company's common stock were issued.

The following table summarizes information concerning options outstanding and exercisable as of December 31, 2001:

Range of Exercise Prices	Weighted Average Remaining Life	Options Outstanding		Options Exercisable	
		Number of Options	Weighted Average Exercise Price	Number of Options	Weighted Average Exercise Price
0.00 - 2.50	6.0	430,400	2.50	199,450	2.50
2.51 - 3.00	7.9	198,298	2.66	60,373	2.67
3.01 - 3.50	5.6	290,689	3.25	258,875	3.25
3.51 - 4.00	6.9	36,900	4.00	12,225	4.00
4.01 - 4.50	7.4	103,500	4.33	52,250	4.31
4.51 - 5.00	2.6	25,000	4.68	25,000	4.68
5.01 - 5.50	-	-	-	-	-
5.51 - 7.00	4.2	2,500	7.00	2,500	7.00
0.00 - 7.00	6.3	1,087,287	3.02	610,673	3.13

### Preferred Stock

In 1996, the Company authorized the issuance of 1,000,000 shares of preferred stock having a par value of \$0.01. None of these shares have been issued to date.

### (13) Related Party Transaction

As of December 31, 2001, the Company had entered into a one year loan of \$525,000 to its Chief Executive Officer ("CEO"), renewable at the Company's option, and collateralized by 90,000 of his shares of Boston Biomedica common stock. Interest on the loan was payable monthly at the annual rate of 7%. The loan is shown on the balance sheet as a decrease to stockholders equity. In January 2002, the loan was repaid in full. The loan was replaced by the Company's pledge of a \$1,000,000 interest bearing deposit at a financial institution to provide additional security for loans in the aggregate amount of \$2,418,000 from the financial institution to an entity controlled by the CEO. The loans are personally guaranteed by the CEO. The Company's pledge is secured by a junior interest in the collateral provided by the CEO to the financial institution. Such collateral includes all of his real property and common stock holdings in Boston Biomedica, Inc. The original loan and subsequent pledge of \$1,000,000 were made to assist the CEO in refinancing indebtedness related to, among other things, his divorce settlement and to enable him to avoid the need to sell his common stock holdings in Boston Biomedica, Inc. on the open market to satisfy his debts. The Company's Board of Directors and, with respect to the decision to pledge the \$1,000,000 cash collateral, a special committee of the independent directors, evaluated a number of alternatives and concluded that the original loan to the CEO and the subsequent pledge were the best alternative and in the best interests of the Company's stockholders because it would, among other things, avoid selling pressure on the Company's common stock and relieve the financial pressures on the CEO that could otherwise divert his attention from the Company.

### (14) Selected Quarterly Financial Data (Unaudited - Amounts in thousands, except for per share data)

	1st Qtr	2nd Qtr	3rd Qtr	4th Qtr
<b>2001</b>				
Total revenue	\$ 4,982	\$ 5,500	\$ 5,409	\$ 5,935
Gross profit	2,122	2,238	2,259	2,086
(Loss) income from continuing operations	(486)	38	(211)	(227)
Income from discontinued operations	3,964	-	-	370
Net income (loss)	<u>\$ 3,478</u>	<u>\$ 38</u>	<u>\$ (211)</u>	<u>\$ 143</u>
(Loss) income per share from continuing operations, basic & diluted	(0.08)	0.01	(0.03)	(0.04)
Income per share from discontinued operations, basic & diluted	0.64	-	-	0.06
Net income (loss) per share, basic & diluted	<u>\$ 0.56</u>	<u>\$ 0.01</u>	<u>\$ (0.03)</u>	<u>\$ 0.02</u>
<b>2000</b>				
Total revenue	\$ 4,539	\$ 5,535	\$ 4,534	\$ 4,862
Gross profit	1,631	2,160	1,537	1,291
Net loss from continuing operations before cumulative effect of change in accounting principle	(608)	(276)	(4,695)	(2,035)
Loss from continuing operations	(608)	(276)	(4,695)	(2,225)
Loss from discontinued operations	(63)	(16)	(71)	(47)
Net (loss)	<u>\$ (671)</u>	<u>\$ (292)</u>	<u>\$ (4,766)</u>	<u>\$ (2,272)</u>
(Loss) per share from continuing operations before cumulative effect of change in accounting principle, basic & diluted	\$ -	\$ -	\$ -	\$ (0.36)
(Loss) per share from continuing operations, basic & diluted	(0.12)	(0.05)	(0.84)	(0.39)
(Loss) per share from discontinued operations, basic & diluted	(0.01)	-	(0.01)	(0.01)
Net (loss) per share, basic & diluted	<u>\$ (0.13)</u>	<u>\$ (0.05)</u>	<u>\$ (0.85)</u>	<u>\$ (0.40)</u>

### Report of Independent Accountants

To the Board of Directors and Stockholders of  
Boston Biomedica, Inc.:

In our opinion, the consolidated financial statements listed in the index appearing under Item 14(a) of this Form 10-K, present fairly, in all material respects, the financial position of Boston Biomedica, Inc. and its subsidiaries at December 31, 2001 and 2000, and the results of their operations and their cash flows for each of the three years in the period ended December 31, 2001 in conformity with accounting principles generally accepted in the United States of America. In addition, in our opinion, the financial statement schedule listed in the index appearing under Item 14(a) presents fairly, in all material respects, the information set forth therein when read in conjunction with the related consolidated financial statements. These financial statements and the financial statement schedule are the responsibility of the Company's management; our responsibility is to express an opinion on these financial statements and financial statement schedule based on our audits. We conducted our audits of these statements in accordance with auditing standards generally accepted in the United States of America, which require that we plan and perform the audit to obtain reasonable assurance about whether the financial statements are free of material misstatement. An audit includes examining, on a test basis, evidence supporting the amounts and disclosures in the financial statements, assessing the accounting principles used and significant estimates made by management, and evaluating the overall financial statement presentation. We believe that our audits provide a reasonable basis for our opinion.

/s/ PricewaterhouseCoopers LLP

Boston, Massachusetts  
February 25, 2002

### ITEM 9. CHANGES IN AND DISAGREEMENTS WITH ACCOUNTANTS ON ACCOUNTING AND FINANCIAL DISCLOSURE

None.

### PART III

### ITEM 10. DIRECTORS AND EXECUTIVE OFFICERS OF THE REGISTRANT

The information called for by Item 10 is hereby incorporated by reference to the information under Part I, Item 1 - Business under the heading "Executive Officers of the Registrant" at page 15 of this report, and to the information in the registrant's definitive proxy statement, which is expected to be filed by the registrant within 120 days after the close of its fiscal year.

#### ITEM 11. EXECUTIVE COMPENSATION

The information called for by Item 11 is hereby incorporated by reference to the information in the registrant's definitive proxy statement under the heading "Executive Compensation", which is expected to be filed by the registrant within 120 days after the close of its fiscal year.

#### ITEM 12. SECURITY OWNERSHIP OF CERTAIN BENEFICIAL OWNERS AND MANAGEMENT

The information called for by Item 12 is hereby incorporated by reference to the information in the registrant's definitive proxy statement under the heading "Security Ownership of Directors, Officers and Certain Beneficial Owners," which is expected to be filed by the registrant within 120 days after the close of its fiscal year.

#### ITEM 13. CERTAIN RELATIONSHIPS AND RELATED TRANSACTIONS.

The information called for by Item 13 is hereby incorporated by reference to the information in the registrant's definitive proxy statement under the heading "Certain Relationships and Related Transactions", which is expected to be filed by the registrant within 120 days after the close of its fiscal year.

### PART IV

#### ITEM 14. EXHIBITS, FINANCIAL STATEMENT SCHEDULES AND REPORTS ON FORM 8-K.

##### (a) 1. Index to Financial Statements:

Consolidated Balance Sheets as of December 31, 2001 and 2000.....	32
Consolidated Statements of Income for the three years ended December 31, 2001.....	33
Consolidated Statements of Changes in Stockholders' Equity for the three years ended December 31, 2001.....	34
Consolidated Statements of Cash Flows for the three years ended December 31, 2001.....	35
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##### (a) 2. Financial Statement Schedule:

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All supplemental schedules other than as set forth above are omitted as inapplicable or because the required information is included in the Consolidated Financial Statements or the Notes to Consolidated Financial Statements.

##### (a) 3. Exhibits:

<u>Exhibit No.</u>		<u>Reference</u>
3.1	Amended and Restated Articles of Organization of the Company	A**
3.2	Amended and Restated Bylaws of the Company	A**
4.1	Specimen Certificate for Shares of the Company's Common Stock	A**
4.2	Description of Capital Stock (contained in the Restated Articles of Organization of the Company filed as Exhibit 3.1)	A**
4.3	Form of warrants issued in connection with Paradigm Group	H**
4.4	3% Senior Subordinated Convertible Debenture issued to GCA Strategic Investment Fund Limited	K**
4.5	Warrant issued to GCA Strategic Investment Fund Limited	K**
4.6	Warrant issued to Wharton Capital Partners, Ltd.	K**
4.7	Warrant issued to DP Securities, Inc.	K**
4.8	Registration Rights Agreement, dated as of August 25, 2000, by and among Boston Biomedica, Inc., Wharton Capital Partners, Ltd., DP Securities, Inc. and GCA Strategic Investment Fund Limited	K**
4.9	3% Senior Subordinated Convertible Debenture issued to Richard P. Kiphart	K**
4.10	3% Senior Subordinated Convertible Debenture issued to Shoreline Micro-Cap Fund, L.P.	K**
4.11	Warrant issued to Richard P. Kiphart	K**
4.12	Warrant issued to Shoreline Micro-Cap Fund, L.P.	K**
4.13	Registration Rights Agreement dated as of August 25, 2000, by and among Boston Biomedica, Inc., Richard P. Kiphart and Shoreline Micro-Cap Fund, L.P.	K**
10.1	Agreement, dated January 17, 1994, between Roche Molecular Systems, Inc. and the Company	A**
10.2	Exclusive License Agreement, dated April 28, 1999, between the University of North Carolina at Chapel Hill and the Company	A**

10.3	Agreement, dated October 1, 1995, between Ajinomoto Co., Inc. and the Company	A**
10.4	Lease Agreement, dated July 28, 1995, for New Britain, Connecticut Facility between MB Associates and the Company	A**
10.4	1987 Non-Qualified Stock Option Plan*	A**
10.6	Employee Stock Option Plan*	A**
10.7	1999 Non-Qualified Stock Option Plan*	I**
10.8	1999 Employee Stock Purchase Plan*	I**
10.9	Underwriters Warrants, each dated November 4, 1996, between the Company and each of Oscar Gruss & Son Incorporated and Kaufman Bros., L.P.	B**
10.11	Contract, dated March 1, 1997, between National Cancer Institute and the Company	D**
10.12	Lease Agreement, dated May 16, 1997, for Gaithersburg, Maryland facility between B.F. Saul Real Estate Investment Trust and the Company	E**
10.13	Lease Agreement dated January 30, 1995 for Garden Grove, California facility between TR Brell, Cal Corp. and Source Scientific, Inc., and Assignment of Lease, dated July 2, 1997, for Garden Grove, California facility between Source Scientific, Inc. and BBI Source Scientific	F**
10.14	Contract, dated July 1, 1998, between the National Institutes of Health and the Company (NO1-A1-85341)	G**
10.15	Contract, dated July 1, 1998, between the National Heart Lung and Blood Institute and the Company (NO1-HB-87144)	G**
10.16	Line of Credit Agreement with BankBoston dated June 30, 1999	H**
10.17	Agreement with Paradigm Group for the purchase of warrants dated August 18, 1999	H**
10.18	Agreement with MDBio for the purchase of common stock and common stock warrants, dated September 30, 1999	J**
10.19	Lease Agreement dated September 30, 1999, for Frederick, Maryland facility, between MIE Properties, Inc., and the Company.	J**
10.20	Sponsored Research Agreement with the University of North Carolina, Chapel Hill and the Company, dated, April 28, 1999 and the Company.	J**
10.21	Repository Contract with National Institute of Allergy and Infectious Disease, Division of AIDS (NO1-A1-95381), dated August 16, 1999.	J**
10.22	Securities Purchase Agreement dated as of August 25, 2000, by and among Boston Biomedica, Inc., and GCA Strategic Investment Fund Limited.	K**
10.23	Securities Purchase Agreement dated as of August 25, 2000, by and among Boston Biomedica, Inc., Richard P. Kiphart and Shoreline Micro-Cap Fund, L.P.	K**
10.24	Mortgage and Security Agreement dated March 31, 2000	L**
10.25	Asset Purchase Agreement dated February 20, 2001, by and between BBI Clinical Laboratories, Inc., Boston Biomedica, Inc., and Specialty Laboratories, Inc.	M**
10.26	Promissory Note dated July 10, 2001, as amended on October 4, 2001, by and among Boston Biomedica, Inc. and Richard T. Schumacher.	N**
10.27	Subscription Agreement dated as of December 6, 2001 by and between Boston Biomedica, Inc., Richard P. Kiphart, Andrew Gluck, David Valentine, Rebecca Kiphart and Arthur Hill.	Filed herewith
10.28	Junior Participation Agreement dated as of January 15, 2002, by and between Commerce Bank and Trust Company, Resorts Accommodations International, LLC, Richard T. Schumacher and Boston Biomedica, Inc.	Filed herewith
10.29	Pledge and Security Agreement dated as of January 15, 2002, by and between Richard T. Schumacher, Boston Biomedica, Inc., and Commerce Bank and Trust Company.	Filed herewith
10.30	Pledge Agreement effective as of January 15, 2002, by and between Boston Biomedica, Inc. and Commerce Bank and Trust Company.	Filed herewith
10.31	Limited Guaranty dated as of January 15, 2002, by and between Boston Biomedica, Inc. and Commerce Bank and Trust Company.	Filed herewith
21.1	Subsidiaries of the registrant	Filed herewith
23.1	Consent of PricewaterhouseCoopers LLP, independent accountants	Filed herewith

- A Incorporated by reference to the registrant's Registration Statement on Form S-1 (Registration No. 333-10759) (the "Registration Statement"). The number set forth herein is the number of the Exhibit in said Registration Statement.
- B Incorporated by reference to Exhibit No. 10.17 of the Registration Statement.
- C Incorporated by reference to the registrant's Annual Report on Form 10-K for the fiscal year ended December 31, 1996.
- D Incorporated by reference to the registrant's Quarterly Report on Form 10-Q for the fiscal quarter ended March 31, 1997.
- E Incorporated by reference to the registrant's Quarterly Report on Form 10-Q for the fiscal quarter ended June 30, 1997.
- F Incorporated by reference to the registrant's Annual Report on Form 10-K for the fiscal year ended December 31, 1997.
- G Incorporated by reference to the registrant's Quarterly Report on Form 10-Q for the fiscal quarter ended June 30, 1998.
- H Incorporated by reference to the registrant's Quarterly Report on Form 10-Q for the fiscal quarter ended September 30, 1999.
- I Incorporated by reference to the registrant's proxy statement, filed with the Securities and Exchange Commission on June 14, 1999.
- J Incorporated by reference to the registrant's Annual Report on Form 10-K/A for the fiscal year ended December 31, 1999.
- K Incorporated by reference to the registrant's Report on Form 8-K filed September 8, 2000.
- L Incorporated by reference to the registrant's Quarterly Report on Form 10-Q for the fiscal quarter ended September 30,



- 1999.
- M Incorporated by reference to the registrant's Report on Form 8-K filed March 8, 2001.
- N Incorporated by reference to the registrant's Quarterly Report on Form 10-Q for the fiscal quarter ended September 30, 2001.
- \* Management contract or compensatory plan or arrangement.
- \*\* In accordance with Rule 12b-32 under the Securities Exchange Act of 1934, as amended, reference is made to the documents previously filed with the Securities and Exchange Commission, which documents are hereby incorporated by reference.

(b) REPORTS ON FORM 8-K.

The Registrant did not file any Current Reports on Form 8-K during the quarter ended December 31, 2001.

**SIGNATURES**

Pursuant to the requirements of Section 13 or 15(d) of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned, thereunto duly authorized.

Date: March 25, 2002

Boston Biomedica, Inc.

By: /s/ Richard T. Schumacher

Richard T. Schumacher

Chief Executive Officer

Pursuant to the requirements of the Securities Exchange Act of 1934, this report has been signed below by the following persons on behalf of the registrant and in the capacities and on the dates indicated.

<u>SIGNATURES</u>	<u>TITLES</u>	<u>DATE</u>
<u>/s/ Richard T. Schumacher</u> Richard T. Schumacher	Director and Principal Executive Officer	March 25, 2002
<u>/s/ Kevin W. Quinlan</u> Kevin W. Quinlan	Director and Principal Accounting and Financial Officer	March 25, 2002
<u>/s/ Francis E. Capitanio</u> Francis E. Capitanio	Director	March 25, 2002
<u>/s/ William A. Wilson</u> William A. Wilson	Director	March 25, 2002
<u>/s/ Calvin A. Saravis, Ph.D.</u> Calvin A. Saravis, Ph.D.	Director	March 25, 2002

**SCHEDULE II**

**BOSTON BIOMEDICA, INC. AND SUBSIDIARIES**

**VALUATION AND QUALIFYING ACCOUNTS**

<b>Allowance for Doubtful Accounts</b>	<b>Balance at Beginning of Period</b>	<b>Additions</b>	<b>Recoveries</b>	<b>Deductions</b>	<b>Balance at End of Period</b>
2001.....	\$ 88,981	\$ 55,808	\$ 11,310	\$ (30,482)	\$ 125,617
2000.....	86,796	2,064	2,185	(2,064)	88,981
1999.....	151,564	1,751	-	(66,519)	86,796
<b>Inventory Reserve</b>					
2001.....	\$ 765,700	\$ 64,891	-	\$ (34,527)	\$ 796,064
2000.....	601,167	176,397	-	(11,864)	765,700
1999.....	533,252	145,497	-	(77,582)	601,167

**CONSENT OF INDEPENDENT ACCOUNTANTS**

We hereby consent to the incorporation by reference in the Registration Statements on Form S-8 (File Nos. 333-30320 and 333-24749) and Form S-3 (File Nos. 333-94379 and 333-46426) of Boston Biomedica, Inc. of our report dated February 25, 2002 relating to the financial statements and financial statement schedule, which appears in this Form 10-K.

/s/ PricewaterhouseCoopers LLP

Boston, Massachusetts  
March 29, 2002

**Subsidiaries of the Company as of March 2002**

<b><u>Name</u></b>	<b><u>Jurisdiction of Organization</u></b>	<b><u>Location</u></b>
BEI Clinical Laboratories, Inc.	Massachusetts	New Britain, CT
BEI Biotech Research Laboratories, Inc.	Massachusetts	Gaithersburg, MD
BEI Source Scientific, Inc.	Massachusetts	Garden Grove, CA
BEI BioSeq, Inc.	Massachusetts	Gaithersburg, MD

Names of Subscribers:  
Richard P. Kiphart  
Andrew Gluck  
David Valentine  
Rebecca Kiphart  
Arthur Hill

## SUBSCRIPTION AGREEMENT

Boston Biomedica, Inc.  
375 West Street  
West Bridgewater, Massachusetts 02379  
December 6, 2001

Gentlemen:

The undersigned persons (collectively, the "Investors"), by executing this Subscription Agreement, hereby subscribe for the number of shares of Common Stock, \$0.01 par value per share (the "Common Stock"), of Boston Biomedica, Inc., a Massachusetts corporation (the "Company") set forth in paragraph 2 and agree to be bound by the terms and conditions hereof.

1. Acknowledgement of Receipt. Each of the Investors acknowledges receipt of a copy of the Company's Annual Report on Form 10-K, as amended by Form 10-K/A, for the year ended December 31, 2000 (the "Annual Report"), 2000 Annual Report to Stockholders, Proxy Statement for the Annual Meeting of Stockholders held on June 21, 2001, Quarterly Reports on Form 10-Q for each of the quarters ended March 31, 2001, June 30, 2001 and September 30, 2001, and the Registration Statements filed in the year 2000 on Form S-3 (each as amended by Form S-3/A), filed by the Company with the Securities and Exchange Commission subsequent to the filing of the Annual Report (together, the "SEC Reports").

2. Subscription and Payment. The Investors hereby collectively subscribe for 600,000 shares of the Common Stock of the Company (the "Shares") with each Investor to receive a number of shares as listed in the attached Exhibit A hereto. The subscription price is \$2.50 for each Share being acquired, or a total of \$1,500,000, payable in cash with this Subscription Agreement.

3. Agreement to be Bound by Securities Laws.

(a) Each Investor understands and acknowledges that the Shares have not been registered under the Securities Act of 1933, as amended (the "Securities Act"), or state securities laws, and the transferability of the Shares is therefore subject to restrictions imposed by those laws, and the certificates representing the Shares shall bear a restrictive legend restricting the resale of the Shares;

(b) Each Investor agrees that it will not sell or otherwise transfer the Shares unless they are registered under the Securities Act and state securities laws of the applicable jurisdiction or unless an exemption from registration is available.

4. Representations. Each Investor represents and warrants that:

(a) Each Investor is acquiring the Shares for its own account for investment and not for the account of another nor with a view to, or for resale in connection with, any distribution or public offering thereof within the meaning of the Securities Act, the state securities laws of the applicable jurisdiction, or the rules and regulations promulgated thereunder;

(b) Each Investor is able financially to bear the risk of losing its entire investment, has adequate means of providing for its current needs and possible personal contingencies, and has no need for liquidity of this investment;

(c) Each Investor has or is relying on a qualified purchaser representative who has sufficient knowledge and expertise in business, tax and financial matters to be able to evaluate the risks and merits inherent in investments of this type;

(d) Each Investor and/or its professional adviser or purchaser representative has carefully read and understood the SEC Reports and this Subscription Agreement, has received information with respect to all matters it considers material to its investment decision, has had the opportunity to ask questions of the officers of the Company on any matter material to its investment decision, and all such questions have been answered to its satisfaction;

(e) Each Investor acknowledges that no representations have been made to it orally or in writing regarding the Company except by means of the SEC Reports or by means of responses by the officers of the Company to questions asked pursuant to paragraph 4(d) above, and by executing this Subscription Agreement, each Investor acknowledges that it is not relying upon any representations or information other than representations or information contained in the SEC Reports or furnished in response to questions under paragraph 4(d), and the results of its own investigation or that of its financial adviser or purchaser representative; and

(f) Each Investor understands that any projections or forward-looking statements in the SEC Reports are estimates only, that there can be no assurance of their accuracy, and that such projections and forward-looking statements depict what would happen only upon the occurrence of certain events, based on certain assumptions which may not prove to be correct.

Each Investor understands that the Company will rely upon these representations and warranties and those contained in paragraph 5 in determining its exemption from registration of the offering and sale of the Shares to the Investors under the Securities Act and applicable

state securities laws.

5. Additional Representations. Each Investor represents and warrants, for the purpose of compliance with federal and state securities laws, as follows:

(a) Each Investor's residence is as listed in the attached Exhibit B hereunder; all offers of the Shares were made to each Investor at that address listed in the attached Exhibit B or elsewhere within that state; no offer or solicitation was made to any Investor in any state other than the state as listed in the attached Exhibit B; and each Investor accepted the offer to purchase Shares in the Company by executing this Subscription Agreement within that state; and prior to such acceptance, each Investor did not accept the offer in any other state, orally, in writing, or otherwise;

(b) If the Investor has an individual net worth (i.e., total assets in excess of total liabilities), or joint net worth with his or her spouse, as of the date hereof in excess of \$1,000,000 exclusive of home, furnishings, and automobiles, or his or her individual annual gross income for each of the most recent two calendar years was in excess of \$200,000 (or joint annual gross income in excess of \$300,000), and each Investor anticipates that it will be in excess of that amount for the current calendar year; and

(c) Each Investor has an overall commitment to investments which are not readily marketable which is not disproportionate to each Investor's net worth and which, with the investment in the Shares, will not cause such overall commitment to become excessive.

6. Indemnity. Each Investor agrees to indemnify and hold harmless the Company, its directors and officers and its affiliates from and against all damages, losses, costs and expenses (including reasonable attorneys' fees) which they may incur by reason of the failure of any Investor to fulfill any of the terms, conditions or agreements of this Subscription Agreement, or by reason of any breach of the representations and warranties by the Investors herein or in any document provided by any Investor to the Company.

7. Miscellaneous.

(a) It is understood that all documents, records and books pertaining to this investment have been made available for inspection by each Investor's attorney and/or each Investor's accountant and/or each Investor's purchaser representative and each Investor, and that the books and records of the Company will be available for inspection by the Investors upon reasonable notice during reasonable business hours at its principal place of business and the Investors will have the opportunity to ask questions and get answers regarding the business of the Company.

(b) This Agreement may not be modified or amended except in writing signed by all the Investors and the Company.

(c) This Agreement shall be governed by and interpreted under the laws of the Commonwealth of Massachusetts.

EXHIBIT A

SHARE OWNERSHIP INFORMATION

Investor	Total Shares Purchased	Purchase Price
Richard P. Kiphart	430,000	\$1,075,000
David Valentine	40,000	100,000
Andrew Gluck	40,000	100,000
Rebecca Kiphart	40,000	100,000
Arthur Hill	50,000	125,000

EXHIBIT B

REGISTRATION INFORMATION

The following information is required for each Investor.

Richard P. Kiphart

C/o William Blair & Company  
222 W. Adams St

608 Elm Street



-----  
Social Security No. or Tax ID No.

Arthur Hill

687 Lincoln Ave	C/o Arthur Hill & Co 900 Clark St
-----	-----
Home Address	Address for Sending Notices (if different)
Winnetka, IL 60093	Evanston, IL 60201
-----	-----
City, State and Zip Code	City, State and Zip Code
847-446-3411	847-570-4800
-----	-----
Telephone No. (including area code)	Telephone No. (including area code)

###-##-####

-----  
Social Security No. or Tax ID No.

-----	-----
Mailing Address	Address for Sending Notices (if different)
-----	-----
City, State and Zip Code	City, State and Zip Code
-----	-----
Telephone No. (including area code)	Telephone No. (including area code)
-----	-----
Social Security No. or Tax ID No. of Trustee Contact Person of Trustee	

IN WITNESS WHEREOF, the undersigned Investors have hereunto executed this Agreement on the day and year first above written.

-----  
Print Name

-----  
Signature

-----  
Print Name

-----  
Signature of Investor

-----  
Print Name

-----  
Signature

-----  
Print Name

-----  
Trustee

The foregoing Subscription Agreement is accepted and agreed to by the Company as of the date set forth below.

BOSTON BIOMEDICA, INC.

By: \_\_\_\_\_  
Richard T. Schumacher, Chief Executive Officer

Date of Acceptance: \_\_\_\_\_



## JUNIOR PARTICIPATION AGREEMENT

This JUNIOR PARTICIPATION AGREEMENT (this "Agreement"), dated as of January 15, 2002, is by and between (i) Commerce Bank and Trust Company ("Lender"), the lender under that certain Sixth Restated Loan Agreement dated the date hereof (the "Sixth Agreement"), by and between the Lender and Resort Accommodations International, LLC ("RAI"), a Massachusetts limited liability company (as amended, modified, restated, replaced, refinanced, substituted or otherwise supplemented from time to time, the "Loan Agreement"), (ii) Richard T. Schumacher ("Schumacher"), (iii) RAI, and (iv) Boston Biomedica, Inc., a Massachusetts corporation (the "Company").

### Recitals

WHEREAS, Lender and RAI are parties to the Loan Agreement, pursuant to which the Lender has made and may in the future make loans and/or extend other credit or accommodations to RAI (the "Loans");

WHEREAS, the Loans are evidenced by that certain Promissory Note dated February 27, 1998, as amended on each of July 18, 1998, August 20, 1999, May 20, 2000, December 12, 2000, and May 31, 2001 and further by that certain Sixth Note Modification Agreement dated January 15, 2002 (as amended, modified, restated, replaced, refinanced, substituted or otherwise supplemented from time to time, the "Note");

WHEREAS, it is a condition precedent to the execution and delivery by Lender of the Sixth Agreement that the Company guaranty the performance of certain obligations of Schumacher under Schumacher's Unlimited Guaranty dated February 27, 1998, as ratified on each of July 18, 1998, August 20, 1999, May 20, 2000, December 12, 2000, and May 31, 2001 and further by that certain Sixth Ratification of Unlimited Guaranty dated January 15, 2002 (as modified or otherwise supplemented from time to time, "Schumacher's Guaranty"), up to the amounts set forth in the Company's Guaranty (as defined below);

WHEREAS, the obligations of Schumacher under Schumacher's Guaranty are secured, in part, by that certain Pledge Agreement dated February 27, 1998, as amended on July 18, 1998, August 20, 1999, May 20, 2000, December 12, 2000 and May 31, 2001 and further by that certain Sixth Amendment to Pledge Agreement dated January 15, 2002 (as modified or otherwise supplemented from time to time, the "Lender's Pledge Agreement");

WHEREAS, in order to provide additional security for the performance of certain obligations of Schumacher under Schumacher's Guaranty, the Company executed and delivered that certain Limited Guaranty, dated the date hereof, in favor of Lender (as modified or otherwise supplemented from time to time, the "Company's Guaranty");

WHEREAS, to secure the payment of the obligations of the Company under the Company's Guaranty, the Company and the Lender have entered into a Pledge Agreement, dated the date hereof, pursuant to which the Company has pledged \$1.0 million in cash (such cash, in its present or any other form and all proceeds of and interest on the same, the "Company Collateral") to be held by the Lender in an interest bearing account (as modified or otherwise supplemented from time to time, the "Company's Pledge Agreement"); and

WHEREAS, in connection with the Loan Agreement, Lender is willing to sell and convey, and Company is willing to purchase and acquire, the Junior Participation (as defined below) in the Loans made by Lender under the Loan Agreement as described herein.

NOW, THEREFORE, in consideration of the premises and of the mutual covenants herein contained, and intending to be legally bound hereby, the parties hereto agree as follows:

#### Section 1. Sale and Purchase of Junior Participation.

(a) Lender hereby agrees that, if Lender at any time or from time to time pays or otherwise satisfies (directly or indirectly) any part of the Loans from the Company Collateral (or by any other payment made by the Company on account of the Loans) (each a "Payment" and collectively, "Payments"), the Lender shall be deemed to have sold, assigned, transferred and conveyed to the Company, and the Company shall be deemed to have purchased, acquired, accepted and assumed from Lender, without recourse to Lender, for the account and risk of the Company, an undivided junior interest (equal to the amount of the Payment(s)) in all of the Lender's rights and benefits in or to or under or with respect to the Loans, and insofar as the following relate to or secure the Loans, the Loan Agreement, the Note, any collateral (and any substitutions therefor and additions thereto) (the "Collateral") and any guaranties (the "Guaranties") now held by or hereafter granted to Lender with respect thereto, and all documents relating to any thereof (the "Credit Documents"), such interest of the Company in such Loans being referred to herein as the Company's "Junior Participation" in such Loans. The Company shall not be liable for any expenses, costs or fees of the Lender, or any liabilities, obligations, losses, damages, penalties, actions, judgments, suits, costs, expenses or disbursements of any kind or nature whatsoever which may be imposed upon, incurred by or asserted against the Lender, except as a result of any claims brought with respect to the Company's Pledge Agreement.

(b) In the event of a Payment, the Company shall be considered for all purposes to be the legal and equitable owner of the rights, benefits and obligations sold and conveyed and purchased and acquired pursuant to Section 1(a) hereof, to the extent of its Junior Participation interest. Notwithstanding anything herein to the contrary, the Company's Junior Participation interest shall not exceed the amount equal to the aggregate dollar amount of any Payments actually paid to or received by Lender.

(c) Upon the request of the Company, the Lender will deliver to the Company a Junior Participation Certificate, substantially in the form of Exhibit 1 hereto, with the blanks therein appropriately filled, further evidencing the Company's Junior Participation.

(d) Upon Payment in Full (as that term is defined below) to Lender of the Credit Obligations (as that term is defined below), Lender shall assign, without recourse, all of its rights, title and interest in and to the Loan Agreement and the Credit Documents to the Company. As used herein "Credit Obligations" shall mean the difference between (i) the Obligations (as that term is defined in the Note) and (ii) the Junior Participation. As used herein "Paid in Full," "Payment in Full" or any similar terms when used in this Agreement with respect to Credit Obligations shall mean the payment in full to Lender of such Credit Obligations in cash or immediately available funds

(other than the payment or repayment thereof with the proceeds of loans provided by one or more of lenders in connection with any refinancing transaction or transactions) and termination of all lending commitments. All rights of the Company received pursuant to this Agreement on account of its Junior Participation, including the right to principal and interest at the rates charged by the Lender to RAI, shall be accrued by, but not paid to, it until Payment in Full of the Credit Obligations is received by Lender and thereafter any amounts owed to the Company shall be paid by RAI or Schumacher.

## Section 2. Distributions.

(a) The Company shall not be entitled to payment of any portion of any amounts received by, from, or for the account of RAI representing repayment of principal, payment of interest, fees, or charges on the Loans until such time as the Credit Obligations payable to Lender shall have been Paid in Full. The Company hereby acknowledges and agrees that unless otherwise agreed to in writing by Lender, all payments made to Lender on account of the Loan Agreement and the Credit Documents, whether made on account of or applied as principal, interest, fees or charges shall be applied first in reduction of the Credit Obligations (the Company having no interest in any such payments), and to the extent available, and only after the Credit Obligations have been Paid in Full, the balance shall be distributed to the Company on account of the Junior Participation.

(b) If any payment received by Lender, or any application made by Lender on account of any amount payable to Lender in respect of the Loans shall be required to be rescinded, returned or paid over by Lender to RAI for any reason at any time, whether before or after the termination of this Agreement, the Company, promptly upon notice from Lender, shall pay over to Lender any such amounts that are required to be returned by Lender to RAI that were actually and unconditionally received by the Company.

Section 3. Reservation of Rights. Lender reserves the right, in its sole discretion and without notice to or the consent of the Company: to increase or add additional interest, fees or other charges to the present balance of the Credit Obligations, as Lender may deem desirable; to exercise or refrain from exercising any powers or rights or remedies which Lender has or may have under the Loan Agreement or the Credit Documents or at law or in equity including, without limitation, to foreclose upon or release any Collateral; to take or refrain from taking any action or actions to which it may be entitled against any person or entity under the Loan Agreement or the Credit Documents; in the event of any acquisition by Lender of any or all of the Collateral, to hold title to such Collateral for the benefit of Lender, and either directly or by employing others, to operate, manage, preserve and dispose of such Collateral. The Company acknowledges and agrees that until, subject to Section 2(b) hereof, the Credit Obligations are Paid in Full, the Company (a) has no right to vote its Junior Participation or be counted in any way in any decision or determination of the Lender and (b) it has no other rights whatsoever and may not exercise any remedies on account of its Junior Participation with respect to the Loans, the Collateral, the Loan Agreement, and the Credit Documents.

Section 4. Assignments. The Company hereby expressly acknowledges that Lender may sell, assign or otherwise transfer or convey other interests in the Loans without notice to or the consent of the Company; provided, however, that such assignment, transfer or conveyance shall be subject to the Company's undivided Junior Participation interest.

## Section 5. Lender's Duties.

(a) The Company acknowledges and agrees that the Junior Participation is a participation in Lender's rights and that the Company's Junior Participation interest in the Loans is claimed through the Lender.

(b) Lender generally shall service the Loans in accordance with its usual practices in the ordinary course of business. The Company agrees that the Lender does not assume and the Company hereby releases, discharges and exonerates Lender from any and all responsibility or liability to the Company, express or implied, for any loss or depreciation of or failure to realize upon the Collateral or the Loan Agreement or the Credit Documents or the Guaranties or the failure or delay to collect or receive payment of any sums owing from Company or others or for any mistake, omission or error of judgment in approving or accepting the Collateral, the Loan Agreement, the Credit Documents or the Guaranties or the making of any examination thereof, or for granting extensions or indulgences to RAI or any other party.

(c) The duties of Lender hereunder shall be mechanical and administrative in nature. Lender shall not by reason of this Agreement have a fiduciary relationship in respect of the Company.

(d) Upon Payment in Full of the Credit Obligations, the Lender will not take any action to dispose of any remaining Collateral or terminate any financing statements or take any other action to terminate Lender's perfected security interest in the remaining Collateral unless the Company has notified the Lender in writing to do so (such notification to be made within 20 days after Payment in Full of the Credit Obligations). Following Payment in Full of the Credit Obligations, the Company shall become subrogated as to the Loans and the Company's junior security interest in the Collateral shall become a first priority security interest in the remaining Collateral, including any pledged or mortgaged Collateral, until the Company is repaid from RAI or Schumacher the entire amount of the Company's Junior Participation.

## Section 6. Duties of RAI and Schumacher.

At any reasonable time, during normal business hours, RAI and Schumacher will, from time to time, at the Company's reasonable request, furnish such information as may be provided to Lender by RAI or Schumacher with respect to the Collateral and such other information pertaining to the financial condition or operating results of RAI or Schumacher that may be given to Lender by RAI or Schumacher in connection with servicing the Loans or that otherwise may reasonably be requested by the Company.

## Section 7. Rights of Lender.

Nothing contained herein shall limit or in any way affect the Company's obligations to the Lender under the Company's Guaranty and the Company's Pledge Agreement, including, but not limited to, the payment of any costs and expenses described therein.

Section 8. Reliance.

(a) Lender may consult with legal counsel, independent public accountants and other experts selected by it in connection with this Agreement, the Loans, the Loan Agreement, the Guaranties and the Credit Documents, and shall be entitled to rely upon the advice of such counsel, independent accountants and experts.

(b) Lender makes no representation or warranty to the Company regarding (1) the collectibility of the Loans; (2) the existing or future financial condition of RAI, or any other party liable for repayment of the Loans under the Loan Agreement or the Credit Documents; (3) the value or any other condition of the Collateral; or (4) the accuracy of any information supplied or to be supplied by Company. The Company has entered into this Agreement upon its own independent investigation of RAI, the Collateral, the Loan Agreement, the Credit Documents and all parties who are or may be liable under the Loan Agreement or the Credit Documents. The Company acknowledges that it has had an opportunity to inquire of Lender and RAI to the extent the Company feels necessary or appropriate in connection with this Agreement.

Section 9. Notices. Except as otherwise provided herein, all notices, requests, demands and other communications hereunder shall be in writing and shall be sent by first class, registered or certified mail (which shall be effective when deposited in the mail, postage prepaid), or by telegraph or cable (which shall be effective when delivered to the telegraph or cable company, charges prepaid). All notices shall be sent to the applicable party at the address stated on the signature page hereof or in accordance with the last unrevoked written direction from such party.

Section 10. Modification. This Agreement shall not be modified or amended except by an instrument in writing signed by or on behalf all of the parties hereto.

Section 11. Prior Understandings. This Agreement supersedes all prior understandings, whether written or oral, among the parties hereto relating to the transactions provided for herein.

Section 12. Governing Law. This Agreement shall be governed by and construed and enforced in accordance with the laws of the Commonwealth of Massachusetts, without regard to conflict of laws principles.

Section 13. Counterparts. This Agreement may be executed in original or by facsimile in as many counterparts as may be deemed necessary and convenient, and by the different parties hereto on separate counterparts, each of which, when so executed, shall be deemed to be an original, but all such counterparts and facsimiles together shall constitute but one and the same instrument.

Section 14. Successors and Assigns. Except as otherwise provided herein, this Agreement shall be binding upon and inure to the benefit of the parties and their respective successors and assigns.

Section 15. Headings. The Section headings in this Agreement are for convenience of reference only and shall not be deemed to alter or affect the meaning or interpretation of any of the provisions hereof.

Section 16. Severability. If any provision of this Agreement shall for any reason be held to be invalid or unenforceable, such invalidity or unenforceability shall not affect any other provision hereof, but this Agreement shall be construed as if such invalid or unenforceable provision had never been contained herein.

Section 17. Effective Date. This Agreement shall be effective upon the receipt by Agent of a counterpart hereof executed by or on behalf of the Company, Lender, RAI and Schumacher.

Section 18. Miscellaneous. The parties hereto intend that the transactions effected pursuant to this Agreement shall constitute the sale and purchase of the ownership interests referred to in Sections 1(a) hereof, and not extensions of credit. The parties hereto intend that this Agreement and the transactions contemplated by this Agreement represent commercial transactions, and not investments, and not transactions in securities for purposes of any securities law.

thereunto duly authorized as an instrument under seal as of January 15, 2002.

COMMERCE BANK & TRUST COMPANY

By:  
Name: Roger Allard  
Title: Senior Loan Officer, duly authorized

Address for Notices:  
Commerce Bank & Trust Company  
P.O. Box 15020

Worcester, MA 01615  
Attn: Senior Loan Officer and Roger Allard, Senior Vice President  
Telephone: (800) 698-2265

Or if by hand delivery:

Commerce Bank & Trust Company  
386 Main Street  
Worcester, MA 01608

Attn: Senior Loan Officer and Roger Allard, Senior Vice President

BOSTON BIOMEDICA, INC.

By:  
Name: Kevin Quinlan  
Title: President

Address for Notices:  
Boston Biomedica, Inc.  
375 West Street  
West Bridgewater, MA 02379  
Attn: Kevin Quinlan  
Telephone: (508) 580-1900  
Facsimile: (508) -580-2050

With a copy to:

Steven R. London, Esquire  
One Financial Center  
Boston, MA 02111  
Telephone: (617) 856-8200  
Facsimile: (617) 856-8201

Richard T. Schumacher

Address for Notices:  
Richard T. Schumacher  
349 Foundry Street  
North Easton, MA 02356  
Telephone: (508) 238-4470  
Facsimile: (\_\_\_\_) \_\_\_\_\_

With a copy to:

Howard Levin, Esquire  
Perkins, Smith & Cohen, LLP  
One Beacon Street  
30th Floor  
Boston, MA 02108  
Telephone: (617) 854-4000  
Facsimile: (617) 854-4040

EXHIBIT 1  
TO PARTICIPATION AGREEMENT

Supplement No. \_\_ to JUNIOR PARTICIPATION AGREEMENT dated as of January 15, 2002, is by and between (i) Commerce Bank and Trust Company ("Lender"), the lender under that certain Sixth Restated Loan Agreement dated the date hereof (the "Sixth Agreement"), by and between the Lender and Resort Accommodations International, LLC ("RAI"), a Massachusetts limited liability company (as amended, modified, restated, replaced, refinanced, substituted or otherwise supplemented from time to time, the "Loan Agreement"), (ii) Richard T. Schumacher ("Schumacher"), (iii) RAI, and (iv) Boston Biomedica, Inc., a Massachusetts corporation (the "Company").

1. Company: ("Company")
2. Lender: ("Assigning Lender")
3. Credit Agreement: ("Credit Agreement")
4. Loans: ("Loans")
5. Company's Junior Participation: ("Junior Participation")
6. Other Provisions:

Pursuant to Section 1 of the Participation Agreement, Assigning Lender hereby sells, assigns, transfers and conveys to the Company, and the Company hereby purchases, acquires, accepts and assumes from Lender, without recourse to Lender, for the account and risk of the Company, a Junior Participation in the above Loans to RAI made or to be made by Assigning Lender pursuant to the Credit Agreement. This Supplement is hereby incorporated by reference in and made a part of the Participation Agreement.

WITNESS the due execution hereof as of \_\_\_\_\_, \_\_\_\_\_.

COMMERCE BANK & TRUST COMPANY

BOSTON BIOMEDICA, INC.

as Lender

By:

By:

Name:

Name:

Title:

Title:

## PLEDGE AND SECURITY AGREEMENT

THIS PLEDGE AND SECURITY AGREEMENT (the "Pledge Agreement") dated as of January 15, 2002 is entered into by and between Richard T. Schumacher an individual with a residence at 349 Foundry Street, North Easton, MA 02356 (the "Pledgor"), Boston Biomedica, Inc., a Massachusetts corporation with its principal executive offices located at 375 West Street, West Bridgewater, MA 02379 (the "Company") and solely for purposes of Section 2 of this Pledge Agreement, Commerce Bank and Trust Company (the "Bank").

### WITNESSETH

WHEREAS, on the date hereof, the Bank and Resort Accommodations International, LLC ("RAI") have executed and delivered that certain Sixth Restated Loan Agreement (the "Loan Agreement") (as amended, modified, restated, replaced, refinanced, substituted or otherwise supplemented from time to time, the "Loan Agreement"), pursuant to which the Bank has made and may in the future make loans and/or extend other credit or accommodations to RAI (the "Loans");

WHEREAS, the Loans are evidenced by that certain Promissory Note dated February 27, 1998, as amended on each of July 18, 1998, August 20, 1999, May 20, 2000, December 12, 2000, and May 31, 2001 and as further amended by that certain Sixth Note Modification Agreement dated the date hereof (as amended, modified, restated, replaced, refinanced, substituted or otherwise supplemented from time to time, the "Note");

WHEREAS, Pledgor has guaranteed the repayment of the Loans to the Bank pursuant to Pledgor's Unlimited Guaranty dated February 27, 1998, as ratified on each of July 18, 1998, August 20, 1999, May 20, 2000, December 12, 2000, and May 31, 2001 and further by that certain Sixth Ratification of Unlimited Guaranty dated the date hereof (as modified or otherwise supplemented from time to time, "Schumacher's Guaranty"), up to the amounts set forth in the Company's Guaranty (as defined below);

WHEREAS, Schumacher's Guaranty is secured, in part, pursuant to a Pledge Agreement dated February 27, 1998, as amended on each of July 18, 1998, August 20, 1999, May 20, 2000, December 12, 2000 and May 31, 2001 and as further amended by that certain Sixth Amendment to Pledge Agreement dated the date hereof (as modified or otherwise supplemented from time to time, the "Bank Pledge Agreement");

WHEREAS, in connection with the Loan Agreement, the Company executed and delivered that certain Limited Guaranty dated the date hereof, in favor of the Bank (as modified or otherwise supplemented from time to time, the "Company's Guaranty"), to guaranty certain obligations of Pledgor under Schumacher's Guaranty;

WHEREAS, to secure the payment of the Company's obligations under the Company's Guaranty, the Company and the Bank executed and delivered a Pledge Agreement dated the date hereof, pursuant to which the Company has pledged \$1.0 million in cash (such cash, in its present or any other form and all proceeds of and interest on the same, the "Company Collateral") to be held by the Bank in an interest bearing account (as modified or otherwise supplemented from time to time, the "Company's Pledge Agreement");

WHEREAS, in connection with the Company's Guaranty, the Company, the Bank, RAI and Schumacher entered into a Junior Participation Agreement dated January 15, 2002 ("Junior Participation Agreement"), pursuant to which the Company acquired a Junior Participation (as defined in the Junior Participation Agreement) interest in the Loans and upon Payment in Full (as defined in the Junior Participation Agreement) will be subrogated as to the Loans and the Company's junior security interest in the Collateral (as defined in the Junior Participation Agreement) shall become a first priority security interest in the Collateral; and

WHEREAS, to secure repayment from Schumacher of the Company's Payments (as defined in the Junior Participation Agreement), the Company is requiring that Schumacher pledge the Pledged Securities (as defined herein) and to deliver or cause to be delivered the Pledged Securities to the Company immediately following the Payment in Full of the Credit Obligations (as that term is defined in the Junior Participation Agreement) to the Bank.

NOW, THEREFORE, in consideration of the premises and for other good and valuable consideration, the receipt and sufficiency of which are hereby acknowledged, the Pledgor agrees for the benefit of the Company as follows:

#### SECTION 1. PAYMENT OBLIGATION; PLEDGE AND SECURITY INTEREST.

(a) Pledgor hereby agrees and promises to pay to the order of the Company, any and all amounts of the Loans paid or otherwise satisfied by the Company from the Company Collateral (or by any other payment made by the Company on account of the Loans), together with interest accruing on the unpaid amounts at the Wall Street Journal Prime Rate the Note (the "Obligations"), such Obligations to be paid by Pledgor to the Company upon demand of the Company; provided, however, that the Company shall not make a demand for payment of the Obligations until the Bank's Loans have been Paid in Full (as defined in the Junior Participation Agreement).

(b) To secure the timely payment and performance of the Obligations, Pledgor hereby pledges, hypothecates, assigns and transfers (subject to subsection (c) below) to the Company all of the Pledged Collateral (as defined herein) and hereby grants to the Company, a second in priority lien on (subject only to the first priority lien of the Bank), and a security interest in the Pledged Collateral together with all cash dividends, stock dividends, interest, profits, premiums, redemptions, warrants, subscription rights, options, substitutions, exchanges and other distributions now or hereafter made on the Pledged Securities and all cash and non-cash proceeds thereof. For purposes of this Pledge Agreement, "Pledged Collateral" shall include any and all property, including but not limited to any real and personal property, that now or hereafter secures the Loans from the Bank, including the Pledged Securities, (whether described herein or not) and all income therefrom and proceeds thereof. In addition, for purposes of this Agreement, "Pledged Securities" shall mean all of the shares of stock, instruments, securities and other interests listed on Exhibit A hereto and any investment property, securities accounts, securities entitlements, securities or options and all rights therein or thereunder of the Pledgor now existing or hereafter arising or existing.

(c) Pledgor agrees that from time to time, Pledgor shall promptly execute and deliver all instruments and documents, and take all action, that may be reasonably necessary in order to perfect the security interest granted or intended to be granted hereby or to enable the

Company to exercise and enforce its rights and remedies hereunder with respect to the Pledged Collateral. Without limiting the generality of the foregoing, Pledgor shall (i) execute and file such financing or continuation statements, or amendments thereto, and such other instruments, endorsements or notices, as may be reasonably necessary or desirable or as the Company may request, in order to perfect and preserve the security interests granted or purported to be granted hereby; and (ii) shall cause the Bank, and the Bank hereby agrees, to deliver to the Company, any certificates evidencing the Pledged Securities identified on Exhibit A hereto, together with appropriate undated powers and/or endorsements duly executed in blank, all as collateral security for the payment and performance of the Obligations; provided, however, that the delivery of any certificates evidencing the Pledged Securities or any other evidence of title to the other Pledged Collateral shall be subject to the prior Payment in Full (as defined in Junior Participation Agreement) of the Credit Obligations (as defined in the Junior Participation Agreement).

(d) Notwithstanding anything contained herein to the contrary, all of the rights and obligations contained herein are subject to the Bank's first priority security interest in the Pledged Collateral and shall take effect immediately upon Payment in Full to the Bank of the Credit Obligations.

## SECTION 2. DIVIDENDS AND DISTRIBUTIONS.

If, while this Pledge Agreement is in effect, the Pledgor becomes entitled to receive or receives any stock certificate (including, without limitation, any certificate representing a stock dividend or a distribution in connection with any reclassification, increase or reduction of capital or issued in connection with any reorganization), option or rights, whether as an addition to, in substitution of, or in exchange for, any Pledged Securities or otherwise, the Pledgor agrees to accept the same as agent for the Company, to hold the same in trust on behalf of and for the benefit of the Company and after the Payment in Full of the Bank's Credit Obligations, to deliver the same forthwith to the Company in the exact form received, with the endorsement of the Pledgor when necessary and/or appropriate undated stock or other powers duly executed in blank, to be held by the Company, subject to the terms hereof, as additional collateral security for the Obligations. Any sums paid on or in respect of the Pledged Securities on the liquidation or dissolution of the issuer thereof shall be held subject to the terms and conditions hereof, as additional collateral security for the Obligations.

## SECTION 3. VOTING RIGHTS.

The Pledgor shall be entitled to vote the Pledged Securities and to give consents, waivers and ratifications in respect of the Pledged Securities until such time as an Event of Default (as defined below) exists or has occurred and is continuing and the Company elects to terminate Pledgor's rights hereunder by written notice to Pledgor. For purposes of this Pledge Agreement, an "Event of Default" shall mean any one of the following specified events: (a) Pledgor's failure to pay the Obligations when demanded by the Company; (b) after Payment in Full of the Bank's Credit Obligations any representation, warranty, statement or certificate made to the Company by Pledgor in connection with this Pledge Agreement proves to have been or becomes untrue; (c) after Payment in Full of the Bank's Credit Obligations, the commencement, whether voluntary or involuntary, of a case under the United States Bankruptcy Code or any other proceeding or action seeking reorganization, liquidation, dissolution or other relief under federal bankruptcy or insolvency statutes or similar laws, or seeking the appointment of a receiver, trustee or custodian for the Pledgor or all or a part of Pledgor's assets; or (d) after Payment in Full of the Bank's Credit Obligations, Pledgor makes an assignment for the benefit of creditors, or is unable to pay debts as they mature.

## SECTION 4. RIGHTS OF THE COMPANY.

4.1. Certain Rights of the Company. The Company shall not be liable for failure to collect or realize upon the Obligations or any collateral security or guaranty thereof, or any part thereof, or for any delay in so doing, nor shall the Company be under any obligation to take any action whatsoever with regard thereto. Any or all shares of the Pledged Securities held by the Company hereunder may, if an Event of Default has occurred and is continuing, and upon written notice by the Company, be registered in the name of the Company or its nominee, for the benefit of the Company, and the Company or its nominee may at any time thereafter, without notice, exercise all voting and corporate rights of any issuer of any and all rights of conversion, exchange, subscription or any other rights, privileges or options pertaining to any shares of the Pledged Securities as if the Company were the absolute owner thereof, including (without limitation) the right to exchange, at its discretion, any and all of the Pledged Securities upon the merger, consolidation, reorganization, recapitalization or other readjustment of any issuer of any such shares or upon the exercise by any such issuer or the Company of any right, privilege or option pertaining to any shares of the Pledged Securities and, in connection therewith, to deposit and deliver any and all of the Pledged Securities with any committee, depository, transfer agent, registrar or other designated agency on such terms and conditions as the Company may determine, all without liability except to account for property actually received by it, but the Company shall have no duty to exercise any of the aforesaid rights, privileges or options and shall not be responsible for any failure to do so or delay in so doing.

4.2. Company as Attorney-in-Fact. After Payment in Full of the Bank's Credit Obligations, the Company is hereby appointed the attorney-in-fact of the Pledgor for the purpose of carrying out the provisions of this Pledge Agreement and taking any action and executing any instruments, in the name of the Pledgor or otherwise, that the Company may deem necessary or advisable to accomplish the purposes hereof, which appointment as attorney-in-fact is irrevocable and coupled with an interest. Without limiting the generality of the foregoing, the Company shall, to the extent permitted hereunder, have the right and power, upon the Company's good faith determination in its sole discretion that such action is necessary or desirable to preserve and protect its interest in the Pledged Collateral, to receive, endorse and collect all checks and other orders for the payment of money made payable to the Pledgor representing any dividend, interest payment or other distribution payable or distributable with respect to the Pledged Collateral or any part thereof and to give full discharge for the same.

4.3. Protection of Pledged Collateral. The Company shall not have any obligations to protect, secure, perfect or insure any Pledged Collateral at any time held as security for the Obligations.

## SECTION 5. UNCONDITIONAL LIABILITIES.

The Obligations and liabilities of the Pledgor hereunder shall not be conditioned or contingent upon the pursuit by the Company or any other person at any time of any right or remedy against any other person that may be or become liable in respect of all or any part of the Obligations or against any collateral security or guaranty therefor or right of offset with respect thereto. This Pledge Agreement shall remain in full force and effect and be binding in accordance with and to the extent of its terms upon the Pledgor until all of the Obligations

have been fully satisfied.

## SECTION 6. PERFORMANCE BY COMPANY OF PLEDGOR'S OBLIGATIONS.

If the Pledgor fails to perform or comply with any of its agreements contained herein and the Company, as provided for by the terms of this Pledge Agreement, itself performs or complies, or otherwise causes performance or compliance, with such agreement, the expenses of the Company incurred in connection with such performance or compliance shall be borne and paid by the Pledgor on demand and until so paid shall be added to the principal amount of the Obligations and shall bear interest (calculated on the basis of a 360-day year for the actual days elapsed) from the date incurred until paid at the highest rate applicable to any of the Obligations.

## SECTION 7. REMEDIES.

If an Event of Default has occurred and is continuing, then, and in any such event, the Company may exercise, in addition to all other rights and remedies granted to it in this Pledge Agreement and in any other instrument or agreement securing, evidencing or relating to the Obligations, all rights and remedies of a secured party under the Uniform Commercial Code (the "Code") or other applicable law. Without limiting the generality of the foregoing, the Pledgor expressly agrees that in any such event, the Company, without demand of performance or other demand, advertisement or notice of any kind (except the notice specified below of time and place of public or private sale) to or on the Pledgor or any other person (all and each of which demands, advertisements and/or notices are hereby expressly waived), may forthwith collect, receive, appropriate and realize on the Pledged Collateral, or any part thereof, and forthwith sell, assign, give option or options to purchase, contract to sell or otherwise dispose of and deliver the Pledged Collateral, or any part thereof, in one or more units, parcels, or lots at one or more public or private sales, at any exchange or broker's board or at any of the Company's offices or elsewhere, on such terms and conditions as it may deem advisable and at such prices as it may deem appropriate, for cash or on credit or for future delivery without assumption of any credit risk, with the right to the Company upon any such sale or sales, public or private, to purchase the whole or any part of said Pledged Collateral so sold. Any purchaser at any such sale or sales shall acquire the property sold absolutely free from any claim or right on the part of Pledgor, and Pledgor hereby waives (to the extent permitted by applicable law) all rights, redemptions, stays and appraisal rights which Pledgor now has, or may at any time in the future have, under any rule of law or statute now existing or hereafter enacted. The net proceeds of any such collection, recovery, receipt, appropriation, realization or sale, after allowing two (2) Business Days for collection and after deducting all reasonable costs and expenses of every kind incurred therein or incidental to the care, safekeeping or otherwise of any and all of the Pledged Collateral or in any way relating to the rights of the Company hereunder, including reasonable attorneys' fees and legal expenses, shall be applied to the payment of the Obligations in such order as the Company may determine, and, after all of the Obligations have been paid in full and after payment of any other amount required by any provision of law, including (without limitation) Section 9-610 of the Code, the balance (if any) of such proceeds shall be remitted to the Pledgor or as otherwise required by a court of competent jurisdiction. To the extent permitted by applicable law, the Pledgor waives all claims, damages and demands against the Company arising out of the retention or sale of the Pledged Collateral unless resulting from such Company's willful misconduct or gross negligence. The Pledgor agrees that the Company need not give more than ten (10) days' notice (which notice shall be deemed given on the earlier of mailing or receipt) of the time and place of any public sale or of the time after which a private sale or other intended disposition is to take place and that such notice is reasonable notification of such matters. No notification need be given to the Pledgor if it has signed after default a statement renouncing or modifying any right to notification of sale or other intended disposition. The Company may, without notice or publication, adjourn any public or private sale, or cause such sale to be adjourned from time to time by announcement at the time and place fixed for sale, and such sale may, without further notice, be made at the time and place to which such sale is so adjourned. Pledgor shall remain liable for any deficiency if the net proceeds of any sale or disposition of the Pledged Collateral are insufficient to pay all Obligations.

## SECTION 8. REPRESENTATIONS AND WARRANTIES.

The Pledgor represents and warrants to the Company that:

### 8.1. Intentionally Omitted.

8.2. No Prohibition. The Pledgor is empowered to enter into, execute, deliver and perform this Pledge Agreement. The execution, delivery and performance of this Pledge Agreement do not and will not violate, or cause Pledgor to be in default in any material respect under, any provision of any law, rule, regulation, order, writ, judgment, injunction, decree, determination or award in effect having applicability to Pledgor; result in a breach of or constitute a default in any material respect under any indenture or loan or credit agreement or any other agreement lease or instrument to which Pledgor is a party or by which Pledgor's properties may be bound or affected; or result in, or require, the creation or imposition of any lien upon or with respect to any of the properties now owned or hereafter acquired by Pledgor.

8.3. Legally Enforceable Agreement. This Pledge Agreement has been duly executed and delivered by the Pledgor and is a legal, valid and binding obligation, enforceable against the Pledgor in accordance with its terms, except as enforceability may be limited by bankruptcy, insolvency, or other laws relating to or affecting generally the enforcement of creditor's rights by general principles of equity (regardless of whether such principles are considered in a proceeding at law or in equity).

8.4. Title. The Pledgor is the record and beneficial owner of, and has good and valid title to the Pledged Collateral, including the Pledged Securities described on Exhibit A hereto, and it will be owner of, and have such title to, all other Pledged Securities described in Section 3 hereof owned by it, subject to no lien whatsoever except the liens created hereby and the senior priority lien in favor of the Bank pursuant to the Bank's Pledge Agreement and the Loan Agreement.

### 8.5. Intentionally Omitted.

8.6. Creation of Valid Lien. The pledge and assignment and together with the filing of appropriate financing statements with respect to the Pledged Collateral including the Pledged Securities described on Exhibit A hereto will create, a valid lien on, and perfected security interest in, such Pledged Collateral and the proceeds thereof, subject to no prior lien or option or any agreement purporting to grant to any third party a prior lien on the Pledgor's property or assets that would include such Pledged Securities, except for the senior priority



lien in favor of the Bank under the Bank's Pledge Agreement and the Loan Agreement. Upon Payment in Full of the Bank's Credit Obligations, the Pledged Collateral, including the Pledged Securities will be delivered to the Company and upon such delivery (and the delivery of any Pledged Securities described in Section 3 hereof), will create, a valid lien on, and first priority perfected security interest in, such Pledged Collateral and the proceeds thereof, subject to no prior lien or any agreement purporting to grant to any third party a prior lien on the Pledgor's property or assets that would include such Pledged Collateral.

8.7. Pledged Securities not Margin Stock. None of the Pledged Securities is "margin stock", as such term is defined in Section 221.2 of Regulation U of the Board of Governors of the Federal Reserve System.

#### SECTION 9. COVENANTS.

The Pledgor covenants and agrees with the Company that so long as any Obligations are outstanding:

9.1. Defense of Claims. It will, upon the Company's written request, defend the Company's right, title and security interest in and to the Pledged Collateral and the proceeds thereof against the claims and demands of all persons whomsoever, subject only to the Bank's first priority security interest in and to such Pledged Collateral and proceeds thereof.

9.2. Obtain Good Title. It will have or obtain promptly good title to (subject to no lien whatsoever, except the liens created by this Pledge Agreement and the Bank's Pledge Agreement and Loan Agreement) and the right to pledge any other property at any time hereafter pledged to the Company as collateral security hereunder and will likewise defend the Company's right and title thereto and liens thereon.

9.3. Limitation on Transfers and Liens. It will not sell, assign, transfer, exchange or otherwise dispose of, or grant any option with respect to any of the Pledged Collateral, nor will it create, incur or permit to exist any lien with respect to any of the Pledged Collateral, any interest therein or any proceeds thereof (except for the liens created by this Pledge Agreement and the Bank's Pledge Agreement and Loan Agreement).

#### SECTION 10. LIMITATIONS ON RESALE.

10.1. Private Sale of Pledged Securities. The Pledgor recognizes that the Company may be unable to effect a public sale of any or all of the Pledged Securities by reason of certain prohibitions contained in the Securities Act and applicable state securities laws and may be compelled to resort to one or more private sales thereof to a restricted group of purchasers who will be obliged to agree, among other things, to acquire such securities for their own accounts for investment and not with a view to the distribution or resale thereof. The Pledgor acknowledges and agrees that any such private sale may result in prices and other terms less favorable to the seller than if such sale were a public sale and, notwithstanding such circumstances, agrees that the private (rather than public) nature of such sale shall be deemed to be commercially reasonable. The Company shall be under no obligation to delay a sale of any of the Pledged Securities for the period of time necessary to permit the issuer thereof to register such securities for public sale under the Securities Act or under applicable state securities laws, even if such issuer would agree to do so.

10.2. Assistance of Pledgor: Specific Performance. The Pledgor further agrees to do or cause to be done all such other acts and things required to be done by it to make such sale or sales of any portion or all of the Pledged Securities valid and binding and in compliance with any and all applicable laws, regulations, orders, writs, injunctions, decrees or awards of any and all courts, arbitrators or governmental instrumentalities, domestic or foreign, having jurisdiction over any such sale or sales, all at the Pledgor's expense. The Pledgor further agrees that a breach of any of the covenants contained in this Section 10.2 will cause irreparable injury to the Company, that the Company has no adequate remedy at law in respect of such breach and, as a consequence, agrees that each and every covenant contained in this Section 10.2 shall be specifically enforceable against the Pledgor, and the Pledgor hereby waives (to the extent permitted by applicable law) and agrees not to assert any defenses against an action for specific performance of such covenants except for a defense that no Event of Default has occurred.

#### SECTION 11. FURTHER ASSURANCES.

The Pledgor agrees that at any time and from time to time, on the written request of the Company, the Pledgor will execute and deliver such further documents and do such further acts and things as the Company may reasonably request in order to effectuate the purposes of this Pledge Agreement.

#### SECTION 12. LIMITATION ON COMPANY'S DUTY IN RESPECT OF PLEDGED COLLATERAL.

Beyond the safe custody thereof, the Company shall not have any duty as to any Pledged Collateral in its possession or control or in the possession or control of a nominee of it or any income thereon or as to the preservation of rights against prior parties or any other rights pertaining thereto.

#### SECTION 13. NOTICES.

Except as otherwise provided herein, all notices, requests and demands to or upon a party hereto, to be effective, shall be in writing and shall be sent by certified or registered mail, return receipt requested, by personal delivery against receipt, by overnight courier or by facsimile and, unless otherwise expressly provided herein, shall be deemed to have been validly served, given or delivered immediately when delivered against receipt, one Business Day after deposit in the mail, postage prepaid, or with an overnight courier or, in the case of facsimile notice, when sent, addressed as follows:

If to the Company:

Boston Biomedica, Inc.  
375 West Street  
West Bridgewater, MA 02379

Attention: Kevin Quinlan, President  
Telephone No.: (508) 580-1900  
Facsimile No.: (508) 580-0250

with a copy to:

Brown, Rudnick, Freed & Gesmer  
One Financial Center  
Boston, MA 02111  
Attention: Steven R. London, Esq.  
Telephone No.: (617) 856-8200  
Facsimile No.: (617) 857-8201

If to Pledgor:

Richard T. Schumacher  
349 Foundry Street  
North Easton, MA 02356  
Telephone No.: (508) 238-4470  
Facsimile No.:

with copy to:

Howard Levin, Esq.  
Perkins, Smith & Cohen, LLP  
One Beacon Street  
30th Floor  
Boston, MA 02108  
Telephone No.: (617) 854-4000  
Facsimile No.: (617) 854-4040

If to Bank:

Commerce Bank and Trust Company  
586-590 Main Street  
Worcester, MA 01615  
Attn: Roger Allard  
Telephone No.: (800) 692-2265  
Facsimile No.: (508) 791-9668

or to such other address as each party may designate for itself by notice given in accordance with this Section.

#### SECTION 14. SEVERABILITY.

Wherever possible, each provision of this Pledge Agreement shall be interpreted in such manner as to be effective and valid under applicable law, but if any provision of this Pledge Agreement shall be prohibited by or invalid under applicable law, such provision shall be ineffective only to the extent of such prohibition or invalidity, without invalidating the remainder of such provision or the remaining provisions of this Pledge Agreement.

#### SECTION 15. NO WAIVER, CUMULATIVE REMEDIES.

The Company shall not by any act, delay, omission or otherwise be deemed to have waived any of its rights or remedies hereunder, and no waiver shall be valid unless in writing, signed by the Company, and then only to the extent therein set forth. A waiver of any right or remedy hereunder on any occasion shall not be construed as a bar to any right or remedy that the Company would otherwise have on any future occasion. No failure to exercise nor any delay in exercising, on the part of the Company, any right, power or privilege hereunder shall operate as a waiver thereof; nor shall any single or partial exercise of any right, power or privilege hereunder preclude any other or further exercise of any right, power or privilege. The rights and remedies herein provided are cumulative, may be exercised singly or concurrently and are not exclusive of any rights or remedies provided by law.

#### SECTION 16. NO ORAL MODIFICATION, SUCCESSORS, GOVERNING LAW.

None of the terms or provisions of this Pledge Agreement may be waived, altered, modified or amended except by an instrument in writing, duly executed by the Company. This Pledge Agreement and all Obligations of the Pledgor hereunder shall be binding on its successors and assigns and shall, together with the rights and remedies of the Company hereunder, inure to the benefit of the Company and its respective successors and assigns. This Pledge Agreement shall be governed by, and construed and interpreted in accordance with, the laws of the Commonwealth of Massachusetts.

#### SECTION 17. SUBMISSION TO JURISDICTION; WAIVER OF TRIAL BY JURY.

17.1. GOVERNING LAW; CONSENT TO FORUM. THIS PLEDGE AGREEMENT HAS BEEN NEGOTIATED, EXECUTED AND DELIVERED AT AND SHALL BE DEEMED TO HAVE BEEN MADE IN BOSTON, MASSACHUSETTS. THIS PLEDGE AGREEMENT SHALL BE GOVERNED BY AND CONSTRUED IN ACCORDANCE WITH THE LAWS OF THE COMMONWEALTH OF MASSACHUSETTS: PROVIDED, HOWEVER, THAT IF ANY OF THE PLEDGED COLLATERAL SHALL BE LOCATED IN ANY JURISDICTION OTHER THAN MASSACHUSETTS, THE LAWS OF SUCH JURISDICTION SHALL GOVERN THE METHOD, MANNER AND PROCEDURE FOR FORECLOSURE OF THE COMPANY'S LIEN UPON SUCH

PLEGGED COLLATERAL AND THE ENFORCEMENT OF THE COMPANY'S OTHER REMEDIES IN RESPECT OF SUCH PLEGGED COLLATERAL TO THE EXTENT THAT THE LAWS OF SUCH JURISDICTION ARE DIFFERENT FROM OR INCONSISTENT WITH THE LAWS OF MASSACHUSETTS. PLEDGOR HEREBY CONSENTS AND AGREES THAT THE SUPERIOR COURT OF SUFFOLK COUNTY, MASSACHUSETTS, OR, AT THE COMPANY'S OPTION, THE UNITED STATES DISTRICT COURT FOR THE DISTRICT OF MASSACHUSETTS, SHALL HAVE EXCLUSIVE JURISDICTION TO HEAR AND DETERMINE ANY CLAIMS OR DISPUTES BETWEEN PLEDGOR AND THE COMPANY PERTAINING TO THIS PLEDGE AGREEMENT OR TO ANY MATTER ARISING OUT OF OR RELATED TO THIS PLEDGE AGREEMENT. PLEDGOR EXPRESSLY SUBMITS AND CONSENTS IN ADVANCE TO SUCH JURISDICTION IN ANY ACTION OR SUIT COMMENCED IN ANY SUCH COURT, AND PLEDGOR HEREBY WAIVES ANY OBJECTION WHICH PLEDGOR MAY HAVE BASED UPON LACK OF PERSONAL JURISDICTION, IMPROPER VENUE OR FORUM NON CONVENIENS AND HEREBY CONSENTS TO THE GRANTING OF SUCH LEGAL OR EQUITABLE RELIEF AS IS DEEMED APPROPRIATE BY SUCH COURT. PLEDGOR HEREBY WAIVES PERSONAL SERVICE OF THE SUMMONS, COMPLAINT AND OTHER PROCESS ISSUED IN ANY SUCH ACTION OR SUIT AND AGREES THAT SERVICE OF SUCH SUMMONS, COMPLAINT AND OTHER PROCESS MAY BE MADE BY REGISTERED OR CERTIFIED MAIL ADDRESSED TO PLEDGOR AT THE ADDRESS SET FORTH IN THIS PLEDGE AGREEMENT AND THAT SERVICE SO MADE SHALL BE DEEMED COMPLETED UPON THE EARLIER OF PLEDGOR'S ACTUAL RECEIPT THEREOF OR 3 DAYS AFTER DEPOSIT IN THE U.S. MAILED, PROPER POSTAGE PREPAID. NOTHING IN THIS PLEDGE AGREEMENT SHALL BE DEEMED OR OPERATE TO AFFECT THE RIGHT OF THE COMPANY TO SERVE LEGAL PROCESS IN ANY OTHER MANNER PERMITTED BY LAW, OR TO PRECLUDE THE ENFORCEMENT BY THE COMPANY OF ANY JUDGMENT OR ORDER OBTAINED IN SUCH FORUM OR THE TAKING OF ANY ACTION UNDER THIS PLEDGE AGREEMENT TO ENFORCE SAME IN ANY OTHER APPROPRIATE FORUM OR JURISDICTION.

17.2. WAIVERS BY PLEDGOR. PLEDGOR WAIVES THE RIGHT TO TRIAL BY JURY (WHICH THE COMPANY HEREBY ALSO WAIVES) IN ANY ACTION, SUIT, PROCEEDING OR COUNTERCLAIM OF ANY KIND ARISING OUT OF OR RELATED TO ANY OF THE PLEDGE AGREEMENT OR THE PLEGGED COLLATERAL AND NOTICE OF ACCEPTANCE HEREOF. PLEDGOR ACKNOWLEDGES THAT THE FOREGOING WAIVER IS A MATERIAL INDUCEMENT TO THE COMPANY'S ENTERING INTO THIS PLEDGE AGREEMENT AND THAT THE COMPANY IS RELYING UPON THE FOREGOING WAIVERS IN ITS FUTURE DEALINGS WITH PLEDGOR. PLEDGOR WARRANTS AND REPRESENTS THAT IT HAS REVIEWED THE FOREGOING WAIVERS WITH ITS LEGAL COUNSEL AND HAS KNOWINGLY AND VOLUNTARILY WAIVED ITS JURY TRIAL RIGHTS FOLLOWING CONSULTATION WITH LEGAL COUNSEL. IN THE EVENT OF LITIGATION, THIS PLEDGE AGREEMENT MAY BE FILED AS A WRITTEN CONSENT TO A TRIAL BY THE COURT.

#### SECTION 18. FEES AND EXPENSES

If, at any time or times regardless of whether or not an Event of Default then exists, the Company incurs legal or accounting expenses or any other costs or out-of-pocket expenses in connection with (i) any litigation, contest, dispute, suit, proceeding or action (whether instituted by Company, Pledgor or any other person) in any way relating to the Pledged Collateral or this Pledge Agreement; (ii) any attempt to enforce any rights of Company against Pledgor or any other Person which may be obligated to Company by virtue of this Pledge Agreement; or (iii) any attempt to inspect, verify, protect, preserve, restore, collect, sell, liquidate or otherwise dispose of or realize upon the Pledged Collateral; then all such legal and accounting expenses, other costs and out of pocket expenses of Company shall be charged to Pledgor. All amounts chargeable to Pledgor under this Section shall be Obligations secured by all of the Pledged Collateral, shall be payable on demand to Company and shall bear interest from the date such demand is made until paid in full at the rate applicable to Obligations from time to time.

#### SECTION 19. TERMINATION.

This Pledge Agreement shall terminate when all of the Obligations have been fully satisfied, at which time Company shall reassign and deliver to Pledgor, against receipt, the Pledged Collateral, or such part thereof as shall not have been sold or otherwise applied by the Company pursuant to the terms hereof, and shall still be held by it hereunder, together with appropriate instruments of reassignment. Any such reassignment shall be without recourse to or warranty by Company and at the expense of Pledgor.

#### SECTION 20. COUNTERPARTS.

This Pledge Agreement may be executed in any number of separate counterparts, and all of said counterparts taken together shall be deemed to constitute one and the same instrument.

#### SECTION 21. DESCRIPTIVE HEADINGS.

The captions in this Pledge Agreement are for convenience of reference only and shall not define or limit the provisions hereof.

IN WITNESS WHEREOF, the parties hereto have caused this Pledge Agreement to be duly executed and delivered by their respective officers thereunto duly authorized as an instrument under as of the date first written above.

\_\_\_\_\_  
Richard T. Schumacher, individually

BOSTON BIOMEDICA, INC.

By: \_\_\_\_\_  
Name: Kevin Quinlan  
Title: President

For purposes of Article 2 of this Agreement only:

COMMERCE BANK AND TRUST COMPANY

By: \_\_\_\_\_

Name: Roger Allard

Title: \_\_\_\_\_

EXHIBIT A to Pledge and Security Agreement  
(Stock and Other Securities) between  
Richard T. Schumacher  
and  
Boston Biomedica, Inc.  
dated January 15, 2002

PLEDGED SECURITIES

Issuer: Boston Biomedica, Inc., a Massachusetts corporation

Class: Common Stock

Number:

## PLEDGE AGREEMENT

This AMENDED PLEDGE AND SECURITY AGREEMENT effective as of the 15th day of January 2002, is by and between Boston Biomedica, Inc. (hereafter the "Pledgor") and Commerce Bank & Trust Company, a Massachusetts Trust Company organized pursuant to Chapter 172 of the laws of the Commonwealth of Massachusetts, with a principal place of business at 386 Main Street, Worcester, Massachusetts (hereafter the "Lender").

### PRELIMINARY STATEMENTS:

WHEREAS, Resort Accommodations International, LLC (the "Borrower") is a Massachusetts limited liability company owned by Richard T. Schumacher ("Guarantor").

WHEREAS, Guarantor is the Chairman and Chief Executive Officer of the Pledgor.

WHEREAS, on the date hereof, Borrower, Guarantor and Lender are executing and delivering loan documentation to amend certain terms of the loan arrangement currently existing between Borrower, Lender and Guarantor, pursuant to which (i) Lender will, among other things, increase its loan to Borrower by \$980,000 from \$1,438,000 to \$2,418,000 (the "Loan") pursuant to a Sixth Restated Loan Agreement between Borrower and Lender dated the date hereof (the "Loan Agreement") and a Sixth Note Modification Agreement between Borrower and Lender dated the date hereof (the "Note"); and (ii) Guarantor will ratify his Unlimited Guaranty dated February 27, 1998 (the "Unlimited Guaranty") of Borrower's obligations under the Loan Agreement and the Note, and will secure the obligations of Borrower under the Loan Agreement and the Note and the obligations of Guarantor under the Unlimited Guaranty by further amending that certain Pledge Agreement between Guarantor and Lender dated February 27, 1998, as amended (the "Guarantor's Pledge Agreement").

WHEREAS, the additional proceeds to be received by Borrower in connection with the Loan will be used to satisfy various obligations of the Borrower and the Guarantor.

WHEREAS, Lender has determined that Borrower and Guarantor do not have sufficient collateral to secure the Loan and have thus conditioned the Loan on the receipt from Pledgor of (i) a guaranty of Guarantor's obligations under the Limited Guaranty, such guaranty to be in the form attached hereto (the "Pledgor's Guaranty"), and (ii) a pledge of a \$1.0 million to be held in an interest bearing account to be held by Lender for the purpose of securing Pledgor's obligations under the Pledgor's Guaranty.

WHEREAS, a special committee of the Board of Directors of Pledgor has reviewed the transactions contemplated between Borrower, Lender and Guarantor and, after deliberation and consideration of alternatives to such transactions, has determined that it is in the best interest of the Pledgor to enter into the Pledgor's Guaranty and this Pledge Agreement because, among other things, the proceeds from the Loan will (i) enable Guarantor to repay his personal financial debts and obligations which will relieve him of financial pressures that have been and would continue to be a substantial distraction to him and the Pledgor's business and (ii) avoid the need for the Guarantor to sell a significant portion of his stock of the Pledgor to repay the Loan, thereby eliminating the potential adverse effect on the Pledgor's stock price and the negative impression that such sales of stock would create to the public stockholders of Pledgor.

WHEREAS, in connection with this Pledge Agreement, the Pledgor is pledging up to \$1,000,000 held in an interest bearing account described in SECTION 1 below (the "Collateral").

NOW THEREFORE, in consideration of the mutual premises contained herein and in order to induce the Lender to make the Loan to the Pledgor, the Pledgor agrees as follows:

SECTION 1. Pledge. The Pledgor pledges to the Lender and grants to the Lender a security interest in, the following (the "Collateral"):

Up to \$1,000,000 held in Account Number 99001550 at Commerce Bank & Trust Company located at 386 Main Street, Worcester, MA or such other interest bearing account agreed to by the Lender and the Company.

SECTION 2. Security for Obligations. This Agreement secures the payment of up to \$1,000,000 of the obligations of the Borrower now or hereafter existing under the Note whether for principal, interest, fees, expenses or otherwise and all other obligations of the Pledgor now or hereafter existing under this Pledge and Security Agreement (all such obligations of the Pledgor being the "Obligations").

SECTION 3. Representation and Warranties. The Pledgor represents and warrants as follows:

(a) The execution, delivery and performance by the Pledgor of this Agreement (A) does not and will not violate (i) any provision of law applicable to the Pledgor, any governmental rule or regulation or (ii) any order of any court or other agency of government binding on the Pledgor or any material indenture, agreement or other instrument to which Pledgor is a party, or by which the Pledgor or any of the Pledgor's material property is bound, and (B) will not be in conflict with, result in a material breach of or constitute (with due notice and/or lapse of time) a material default under, any such indenture, agreement or other instrument, or result in the creation or imposition of any lien, charge or encumbrance of any nature whatsoever on any property or assets of the Pledgor other than as contemplated by this Agreement.

(b) The Pledgor is the legal owner of the Collateral free and clear of any lien, security interest, option or other charge or encumbrance except for the security interest created by this Agreement.

(c) The pledge of the Collateral pursuant to this Agreement secures the payment of the Obligations and creates a valid and perfected first priority security interest in the Collateral.

(d) No authorization, approval or other action by, and no notice to or filing with, any governmental authority or regulatory body is required either for the pledge by the Pledgor of the Collateral pursuant to this Agreement or for the execution, delivery or performance of this Agreement by the Pledgor.

(e) This Agreement constitutes the legal, valid and binding obligation of the Pledgor enforceable against the Pledgor in accordance with its terms, except as the enforceability thereof may be subject to bankruptcy, insolvency, moratorium and other laws affecting the rights and remedies of creditors and secured parties and to the exercise of judicial discretion in accordance with general equitable principles.

(f) The Pledgor is not engaged in the business of extending credit for the purpose of purchasing or carrying margin stock (within the meaning of Regulation U of the Board of Governors of the Federal Reserve System).

SECTION 4. Further Assurances. The Pledgor agrees that, at any time and from time to time at the expense of the Pledgor, the Pledgor will promptly execute and deliver all further instruments and documents, and take all further action, that may be necessary, or that the Lender may reasonably request, in order to perfect and protect any security interest granted or purported to be granted hereby or to enable the Lender to exercise and enforce its rights and remedies hereunder with respect to any Collateral.

SECTION 5. Lender May Perform. If the Pledgor fails to perform any agreement contained herein, the Lender may itself perform, or cause performance of, such agreement and the expenses of the Lender incurred in connection therewith shall be payable by the Pledgor.

SECTION 6. Events of Default. Each of the following events shall constitute an event of default hereunder ("Event of Default").

(a) The occurrence of any Event of Default under the Note, the Guaranty or the Pledgor's Guaranty; or

(b) Any written representation or warranty made by the Pledgor in this Agreement or in any certificate, agreement, instrument or statement contemplated hereby or made or delivered pursuant hereto or in connection herewith or the Note, the Guaranty or the Pledgor's Guaranty shall prove to be incorrect in any material respect; or

(c) The Pledgor shall fail to perform or observe any other term, covenant or agreement contained in this Agreement on its part to be performed or observed, and such failure remains unremedied for five (5) days after written notice thereof shall have been given to the Pledgor by the Lender; or

(d) This Agreement shall at any time for any reason cease to be in full force and effect or shall be declared to be null and void, or the validity or enforceability thereof shall be contested by the Pledgor, or Pledgor shall deny it has any or further liability or obligation hereunder.

SECTION 7. Remedies Upon Default. If any Event of Default shall have occurred and be continuing:

(a) The Lender may exercise in respect of the Collateral, in addition to other rights and remedies provided for herein or otherwise available to it, all the rights and remedies of a secured party on default under the Uniform Commercial Code (the "Code") in effect in the Commonwealth of Massachusetts at the time, sell the Collateral or any part thereof in one or more parts at public or private sale, at any exchange, broker's board or at any of the Lender's offices or elsewhere, for cash, on credit or for future delivery, and upon such other terms as the Lender may deem commercially reasonable. The Lender shall give the Pledgor at least the greater of the minimum notice required by law or seven days prior written notice of the date, time and place of any public sale thereof or of the time after which any private sale or any other intended disposition is to be made. The Lender shall not be obligated to make any sale of Collateral regardless of notice of sale having been given. The Lender may adjourn any public or private sale from time to time by announcement at the time and place fixed therefor, and such sale may, without further notice, be made at the time and place to which it was so adjourned.

(b) All cash proceeds received by the Lender in respect of any sale of, collection from, or other realization upon all or any part of the Collateral may, in the discretion of the Lender, be held by the Lender as collateral for, and/or then or at any time thereafter applied (after payment of any amounts payable to the Lender pursuant to Section 8) in whole or in part by the Lender against, all or any part of the Obligations in such order as the Lender shall elect. Any surplus of such cash or cash proceeds held by the Lender and remaining after payment in full of all the Obligations shall be paid over to the Pledgor or to whomever may be lawfully entitled to receive such surplus.

SECTION 8. Expenses. The Pledgor will, upon demand, pay to the Lender the amount of any and all reasonable expenses, including the reasonable fees and expenses of its counsel and of any experts and agents, which the Lender may incur in connection with (i) the preparation, execution, performance and administration of this Agreement, (ii) the custody or preservation of, or the sale of, collection from, or other realization upon, any of the Collateral, (iii) the exercise or enforcement of any of the rights of the Lender hereunder or (iv) the failure by the Pledgor to perform or observe any of the provisions hereof.

SECTION 9. Security Interest Absolute. All rights of the Lender and security interests hereunder, and all obligations of the Pledgor hereunder shall be absolute and unconditional irrespective of:

(i) any lack of validity or enforceability of the Pledgor's Guaranty or any other agreement or instrument relating thereto;

(ii) any change in time, manner or place of payment of, or in any other term of, all or any of the Obligations, or any other amendment or waiver of or any consent to any departure from the Pledgor's Guaranty;

(iii) any exchange, release or non-perfection of any other collateral, or any release or amendment or waiver of or consent to departure from any other guaranty, for all or any of the Obligations; or

(iv) any other circumstance which might otherwise constitute a defense available to, or a discharge of, the Pledgor in respect of the Obligations.

SECTION 10. Amendments, Etc. No amendment or waiver of any provision of this Agreement shall terminate or release any obligations of the Pledgor hereunder unless said amendment is in writing and executed by the Lender and the Pledgor.

SECTION 11. Addresses for Notices. All notices and other communications provided for hereunder shall be in writing and, if to the Pledgor, mailed by certified mail, return receipt requested or sent by a nationally recognized overnight delivery service requesting a receipt, addressed to it at Boston Biomedica, Inc., 375 West Street, West Bridgewater, Massachusetts 02379, or, if to the Lender mailed by certified mail, return receipt requested or sent by a nationally recognized overnight delivery service requesting a receipt addressed to it at, Commerce Bank & Trust Company, 386 Main Street, P.O. Box 15020, Worcester, Massachusetts, 01615-0020, with a copy to or as to either party in a written notice to each other party complying as to delivery with the terms of this Section. All such notices and other communications shall, when mailed be effective when deposited in the mails addressed aforesaid.

SECTION 12. Continuing Security Interest; Transfer of Note. This Agreement shall create a continuing security interest in the Collateral and shall (i) remain in full force and effect until payment in full of the Obligations, (ii) be binding upon the Pledgor, its administrators, executors, successors and assigns, and (iii) inure to the benefit of the Lender and its successors, transferees and assigns. Without limiting the generality of the foregoing clause (iii), the Lender may assign or otherwise transfer the Pledgor's Guaranty to any other person or entity, and such other person or entity shall thereupon become vested with the benefits in respect thereof granted to the Lender herein. Upon the payment in full of the Obligations, the Pledgor shall be entitled to the return, upon request and at its expense, of such of the Collateral as shall not have been sold or otherwise applied pursuant to the terms hereof.

SECTION 13. No Waiver; Cumulative Remedies. No failure on the part of the Lender to exercise, or to delay in exercising, any right, power or remedy hereunder shall operate as a waiver thereof, nor shall any single or partial exercise of any such right, power or remedy by the Lender preclude any other further exercise thereof or the exercise of any other right, power or remedy. All remedies hereunder are cumulative and are not exclusive of any other remedies provided by law.

SECTION 14. Termination. This Agreement shall terminate when the Note has been fully satisfied and all indebtedness secured hereby and all Obligations of the Pledgor hereunder have been fully paid and performed, at which time the Lender shall execute and deliver to the Pledgor an appropriate release and shall redeliver (or cause to be reassigned and redelivered) to the Pledgor, or to such person or persons as the Pledgor shall designate, against receipt, such of the Collateral (if any) as shall have been received by the Lender and not sold or otherwise applied pursuant to the terms hereof and shall still be held by the Lender hereunder, together with appropriate instruments of reassignment. Any such reassignment shall be without recourse upon warranty by the Lender and at the expense of the Pledgor.

SECTION 14. Governing Law; Terms. This Agreement shall be governed by and construed in accordance with the laws of the Commonwealth of Massachusetts (except as required by mandatory provisions of law and except to the extent that validity or perfection of the security interest hereunder, or remedies hereunder, in respect of any particular Collateral are governed by the laws of a jurisdiction other than the Commonwealth of Massachusetts). Unless otherwise defined herein, terms defined in Article 9 of the Uniform Commercial Code in the Commonwealth of Massachusetts are used herein as therein defined.

IN WITNESS WHEREOF, the parties hereto have duly executed this Agreement, under seal, as of the date first above written.

WITNESS:

BOSTON BIOMEDICA, INC.

\_\_\_\_\_ By: \_\_\_\_\_

Commerce Bank & Trust Company

\_\_\_\_\_ By: \_\_\_\_\_

## LIMITED GUARANTY

Date: January 15, 2002

FOR VALUABLE CONSIDERATION PAID, **BOSTON BIOMEDICA, INC.**, a Massachusetts corporation having a place of business at 375 West Street, West Bridgewater, MA 02379 (the "Guarantor"), who acknowledges that the Guarantor will benefit from the grant or extension of financial accommodations to **RESORT ACCOMMODATIONS INTERNATIONAL, LLC** (the "Borrower"), which financial accommodations of the Borrower are guaranteed by a Guaranty of **RICHARD T. SCHUMACHER**, of 340 Foundry Street, North Easton, Massachusetts ("Schumacher") dated February 28, 1998, as ratified on each of July 18, 1998, August 20, 1999, May 20, 2000, December 12, 2000, May 31, 2001 and of even date (the "Schumacher Guaranty") and that **COMMERCE BANK & TRUST COMPANY**, having a place of business at 386 Main Street, Worcester, MA 01608 (the "Lender"), is relying on the Guarantor's covenants herein in order to induce the Lender to grant or extend financial accommodations to the Borrower, and for other good and sufficient valuable consideration, covenants and agrees as follows:

1. Guaranty of Payment and Performance of Obligations. In consideration of the Lender's extending credit or otherwise in its discretion giving time, or extending credit or accommodations to the Borrower and subject to the limitations set forth in Section 2 hereof, the Guarantor hereby unconditionally guarantees to the Lender that Schumacher, pursuant to the Schumacher Guaranty, will duly and punctually pay or perform, at the place specified therefor, or if no place is specified, at the address set forth above, all indebtedness, obligations and liabilities, direct or indirect, matured or unmatured, primary or secondary, certain or contingent, of Schumacher pursuant to the Schumacher Guaranty to the Lender now or hereafter owing or incurred (including without limitation costs and expenses incurred by the Lender in attempting to collect or enforce any of the foregoing) which are chargeable to Schumacher either by law or under the terms of the Lender's arrangements with Schumacher, accrued in each case to the date of payment hereunder (collectively the "Obligations" and individually an "Obligation"). Subject to the limitations set forth in Section 2 hereof, this Guaranty is an absolute, unconditional and continuing guaranty of the full and punctual payment and performance by Schumacher pursuant to the Schumacher Guaranty of the Obligations and not of their collectability only. Upon any default by Schumacher pursuant to the Schumacher Guaranty in the full and punctual payment and performance of the Obligations, the liabilities and obligations of the Guarantor hereunder shall, at the option of the Lender, become forthwith due and payable to the Lender without demand or notice of any nature, all of which are expressly waived by the Guarantor. Subject to the limitations set forth in Section 2 hereof, payments by the Guarantor hereunder may be required by the Lender on any number of occasions.

2. Limited Liability of Guarantor. The liability of the Guarantor hereunder shall be limited to One Million Dollars (\$1,000,000.00) together with all reasonable costs and expenses (including court costs and legal expenses) incurred or expended by the Lender in connection with this Guaranty and the enforcement hereof which Guarantor agrees to pay.

3. Lender's Freedom to Deal with Borrower and Other Parties. The Lender shall be at liberty, without giving notice to or obtaining the assent of the Guarantor and without relieving the Guarantor of any liability hereunder, to deal with Schumacher and with each other party who now is or after the date hereof becomes liable in any manner for any of the Obligations, in such manner as the Lender in its sole discretion deems fit, and to this end the Guarantor gives to the Lender full authority in its sole discretion to do any or all of the following things: (a) extend credit, make loans and afford other financial accommodations to the Borrower at such times, in such amounts and on such terms as the Lender may approve, (b) vary the terms and grant extensions or renewals of any present or further indebtedness or obligation to the Lender of the Borrower or of any such other party, (c) grant time, waivers and other indulgences in respect thereto, (d) vary, exchange, release or discharge, wholly or partially, or delay in or abstain from perfecting and enforcing any security or guaranty or other means of obtaining payment of any of the Obligations which the Lender now has or acquires after the date hereof, (e) accept partial payments from Schumacher or any such other party, (f) release or discharge, wholly or partially, any endorser or guarantor, and (g) compromise or make any settlement or other arrangement with the Borrower, Schumacher, or any such other party; provided, however, that notwithstanding anything herein to the contrary, this Guaranty shall not be a guaranty of any additional loan or further indebtedness incurred by Borrower and guaranteed by the Schumacher Guaranty beyond the amount of indebtedness of the Borrower which is guaranteed by the Schumacher Guaranty on the date hereof.

4. Unenforceability of Obligations Against Borrower and Schumacher; Invalidity of Security or Other Guaranties. If for any reason the Borrower has no legal existence or is under no legal obligation to discharge any of the Obligations undertaken or purported to be undertaken by Schumacher pursuant to the Schumacher Guaranty for or on Borrower's behalf, or if any of the moneys included in the Obligations have become irrecoverable from the Borrower or Schumacher by operation of law or for any other reason, this Guaranty shall nevertheless be binding on the Guarantor to the same extent as if the Guarantor at all times had been the principal debtor on all such Obligations. This Guaranty shall be in addition to any other guaranty or other security for the Obligations, and it shall not be prejudiced or rendered unenforceable by the invalidity of any such other guaranty or security.

5. Waivers by Guarantor. The Guarantor waives notice of acceptance hereof, notice of any action taken or omitted by the Lender in reliance hereon, and any requirement that the Lender be diligent or prompt in making demands hereunder, giving notice of any default by the Borrower or Schumacher, or asserting any other right of the Lender hereunder.

6. No Contest with Lender. So long as any Obligation remains unpaid or undischarged, the Guarantor will not, by paying any sum recoverable hereunder (whether or not demanded by the Lender) or by any means or on any other ground, claim any set-off or counterclaim against Schumacher in respect of any liability of the Guarantor to Schumacher or, in proceedings under the Bankruptcy Act or insolvency proceedings of any nature, prove in competition with the Lender in respect of any payment hereunder or be entitled to have the benefit of any counterclaim or proof of claim or dividend or payment by or on behalf of Schumacher or the benefit of any other security of any Obligation which, now or hereafter, the Lender may hold or in which it may have any share.

7. Demands and Notices. Any demand on or notice to the Guarantor shall be in writing and shall be effective when delivered in hand to the Guarantor or five (5) days after being mailed by certified mail, postage prepaid, return receipt requested, to Guarantor at the address set forth below, or at such other address of which Guarantor shall have notified the Lender in writing.



8. Amendments, Waivers, Etc. No provision of this Guaranty can be changed, waived, discharged or terminated except by an instrument in writing signed by the Lender and the Guarantor expressly referring to the provision of this Guaranty to which such instrument relates, and no such waiver shall extend to, affect or impair any right with respect to any Obligation which is not expressly dealt with therein. No course of dealing or delay or omission on the part of the Lender in exercising any right shall operate as a waiver thereof or otherwise be prejudicial thereto.

9. Guarantor's Right As Against Borrower. In the event the Lender proceeds against the Guarantor pursuant to this Guaranty, the parties agree that in lieu of any right to indemnification that the Guarantor might have against Schumacher, which right is hereby waived, the Guarantor shall be subrogated to the right of the Lender to the extent that the Guarantor satisfies and discharges Schumacher's Obligations.

10. Security. This Guaranty is secured by a Pledge Agreement of even date between the Guarantor and Bank in the amount of \$1,000,000.00 to be held by the Lender.

11. Miscellaneous Provisions. This Guaranty is intended to take effect as a sealed instrument to be governed by and construed in accordance with the laws of the Commonwealth of Massachusetts and shall inure to the Lender and its successors in title and assigns, and shall be binding on the Guarantor and the Guarantor's successors in title, assigns and legal representatives.

IN WITNESS WHEREOF, the Guarantor has executed this Guaranty by its duly authorized officer on the day and year first above written.

BOSTON BIOMEDICA, INC.

\_\_\_\_\_ By \_\_\_\_\_  
Witness

Address of Guarantor: 375 West Street  
West Bridgewater, MA 02379