BOSTON BIOMEDICA INC
Form 10-K/A
June 28, 2004

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UNITED STATES
SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

Form 10-K/A

(Mark One)

ý **Annual Report Pursuant to Section 13 or 15(d) of the Securities Exchange Act of 1934**

For the fiscal year ended December 31, 2003,

or

o **Transition Report Pursuant to Section 13 or 15(d) of the Securities Exchange Act of 1934**

For the transition period from to
Commission file number 000-21615

BOSTON BIOMEDICA, INC.

(Exact Name of Registrant as Specified in its Charter)

Massachusetts (State or Other Jurisdiction of Incorporation or Organization)	**04-2652826** (I.R.S. Employer Identification No.)
375 West Street, **West Bridgewater, Massachusetts** (Address of Principal Executive Offices)	**02379-1040** (zip code)

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

Securities registered pursuant to Section 12(b) of the Act:
None

Securities registered pursuant to Section 12(g) of the Act:
Common Stock, par value $.01 per share

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 ý No o

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

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

The aggregate market value of the voting common stock held by non-affiliates of the registrant at December 31, 2003 was $11,913,113, based on the closing price of the common stock as quoted on the Nasdaq National Market on that date. The aggregate market value of the voting common stock held by non-affiliates of the registrant at June 30, 2003 was $14,004,067 based on the closing price of the common stock as quoted on the Nasdaq National Market on that date.

As of February 27, 2004, there were 6,827,592 shares of the registrant's common stock outstanding.

INTRODUCTORY NOTE

This amendment to BBI's Form 10-K for the fiscal year ended December 31, 2003 is being filed to amend the following items as follows:

Part I, Item 1, Business, is amended to provide further disclosure regarding the Company's material contracts identified under the heading "Contract Research and Services" and to clarify that the seasonality of the Company's off-the-shelf Diagnostics Products as described under the heading "Seasonality" is due to customer purchasing patterns;

Part II, Item 5, is amended to clarify that the Company did not sell any unregistered securities during fiscal 2003;

Part II, Item 7, Management's Discussion and Analysis of Results of Operation and Financial Condition, is amended to (i) revise the disclosure under the heading "Years Ended December 31, 2003 and 2002" to provide further quantification regarding the Company's change in service revenue, (ii) revise the disclosure under the heading "Years Ended December 31, 2002 and 2001" to further explain why the Company believed product sales at the Biotech segment decreased from 2001 to 2002, (iii) revise the disclosure under the heading "Liquidity and Capital Resources" to discuss and analyze the material changes in the underlying drivers of cash flows from operations and to discuss the Company's liquidity on both a long-term and short-term basis, and (iv) revise the disclosure under the heading "Risk Factors" to delete certain risk factors which the Company believes present immaterial risks and to provide additional disclosure in the risk factor relating to claims of infringement by the Company on other parties intellectual property; and

Part III, Item 10, Executive Officers and Directors, is amended to provide the business experience for Mr. Thomas Vogel for the past five years.

In connection with these amendments, the Company's Chief Executive Officer and Chief Financial Officer have each provided the certifications required under Section 302 of the Sarbanes-Oxley Act of 2002 and under Section 906 of the Sarbanes-Oxley Act of 2002. These certifications are filed as exhibits 31.2, 31.2, 32.1 and 32.2.

Other than the changes outlined above, the Company has made no other changes (including, without limitation, to its financial statements) to the Form 10-K as filed with the SEC on March 29, 2004.

PART I

ITEM 1. BUSINESS.

General

Boston Biomedica, Inc. ("BBI") 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 as a "C" corporation in Massachusetts on August 15, 1978 and commenced significant operations in 1986. The Company has the following 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 13485 (as of December 12, 2002) certified manufacturer of quality control and other diagnostic products used to ensure the accuracy of in vitro diagnostic tests;

(2) BBI Biotech Research Laboratories ("BBI Biotech"), 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;

(3) BBI Source Scientific ("BBI Source"), an ISO 9001-2000 and ISO 13485 certified developer and manufacturer of laboratory and medical instruments, including proprietary and OEM; and

(4) Pressure Cycling Technology ("PCT"), the research, development and commercialization of products utilizing the Company's patented pressure cycling technology, to provide new solutions for a number of healthcare issues, including extraction of nucleic acids, inactivation of pathogens in human plasma, food safety, and genomics.

As used in this report, the terms "we," "us," "our, the "Company" and "BBI" mean Boston Biomedica, Inc. and its wholly-owned subsidiaries (unless the context indicates a different meaning).

Recent Business Developments

In 2003, the Company continued to pursue its strategy to leverage its scientific capabilities in virology, microbiology, immunology and molecular biology to (1) capitalize on the end-user market for quality control products especially the molecular testing market, (2) develop new products and services for the diagnostics and life sciences industries, (3) enhance technical leadership, and (4) capitalize on complementary business operations. William Blair & Company, L.L.C., an investment banking firm engaged by the Company in October of 2002, is continuing to advise the Company in the evaluation of strategic opportunities aimed at increasing shareholder value and increasing the capital needed for growth.

In 2003, the Company expended significant resources on research and development of its PCT products and on efforts to place Barocycler instruments and disposable PULSE tubes in academic and industrial research laboratories. The PCT segment, which includes both private and public (National Institutes of Health) funding of segment research, has experienced lower than expected product sales since commercial launch in September 2002 primarily associated with a longer than expected selling cycle as discussed n further detail hereunder.

In January 2003, the $1,000,000 held in an interest bearing deposit account pledged to a financial institution to secure the Company's limited guaranty of loans in the aggregate amount of $2,418,000 from the financial institution to an entity controlled by Mr. Richard T. Schumacher, the Company's former Chairman and Chief Executive Officer and a current Director of the Company, was used to satisfy the Company's limited guaranty obligation to the financial institution. The Company has no further obligations to the financial institution and has a loan receivable in the amount for $1,000,000 from Mr. Schumacher which is reflected on its balance sheet in stockholders' equity as of December 31, 2003. The Company maintains a junior security interest in the collateral pledged by Mr. Schumacher to the financial institution. As of December 31, 2003, the remaining collateral included certain of Mr. Schumacher's common stockholdings in the Company. For a further description of the Company's limited guaranty and the loans for which the guaranty secured, please see "Management's Discussion and Analysis Related Party Transaction."

On February 14, 2003, the Company announced that its Board of Directors terminated Mr. Schumacher as Chairman and Chief Executive Officer, effective immediately. Mr. Schumacher remains a Director of the Company. Kevin W. Quinlan, President and Chief Operating Officer, continued to lead day-to-day operations. A special committee of the Board of Directors was appointed to oversee the management of the affairs of the Company until such time as a new Chief Executive Officer is employed.

On July 9, 2003, the Company announced that Mr. Schumacher agreed to accept an engagement with the Company as an Executive Project Consultant to advise the Company with respect to the strategic direction of the Company's PCT and BBI Source Scientific activities and the Company's ownership interest in Panacos Pharmaceuticals, Inc. BBI Source Scientific, Inc. is the Company's California-based instrument subsidiary, which developed and manufactures the PCT Barocycler

instrument. As part of this engagement, Mr. Schumacher has continued to reevaluate the ongoing business prospects for both the Company's Laboratory Instrumentation segment and PCT activities. On February 9, 2004, the Company announced it had extended until December 31, 2004 the Executive Consultant Agreement it has with Mr. Schumacher. Under the terms of the Consulting Agreement, Mr. Schumacher is serving in an advisory role directing the Company's PCT and BBI Source Scientific activities, the Company's interest in Panacos Pharmaceuticals, Inc. and such other duties as the President or the Board of Directors of the Company assigns to him. In connection with his Consulting Agreement, Mr. Schumacher is being paid an annualized salary of $250,000. In addition to his salary, Mr. Schumacher may receive, in the discretion of the Company's Board of Directors, a bonus in an amount to be determined by the Board of Directors in recognition of the successful completion of his duties and responsibilities under the agreement, and he is also eligible to participate in the Company's health and medical insurance, disability insurance, group life insurance and group travel insurance, and 401(k) retirement plans.

Beginning in February 2004, the Company has brought to market the BBI IgM and IgG *Borrelia burdorferi* Western Blot Test Kit for the detection of antibodies to the agent that causes Lyme Disease, its first test kit cleared by the U.S. Food and Drug Administration ("FDA") for in vitro diagnostic use.

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 indicators (or 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, quality control products used with them, and test kits themselves, will account for a larger portion of the Company's business. This expectation for quality control products is based on the rapid growth to date of sales of BBI's controls for molecular diagnostics methods. For test kits, the expectation that these will account for a larger portion of the Company's business is based on the fact that BBI has not previously offered commercial test kits and is seeing good interest in its first such offering, the BBI *Borrelia burgdorferi* IgM and IgG Western Blot Test Kit (to detect antibodies to the organism that causes Lyme Disease), launched in January 2004.

Quality Control for In Vitro Diagnostic Test Kits. Customers use quality control products in order to develop, evaluate and monitor the performance of test kits (both for infectious diseases and other disease states). 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. This method of 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

The Company's products and services are classified into the following four business segments: BBI Diagnostics, Laboratory Instrumentation, Biotech and PCT.

BBI Diagnostics. Through its business unit BBI Diagnostics, the Company offers a broad array of "Quality Control Products," for use in clinical laboratories, consisting of Quality Control Panels, Accurun® External Run Controls and ACCUCHART quality control software, and Diagnostic Components. BBI's Quality Control 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® External 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. The Company's ACCUCHART quality control software is a data management program for customers who use BBI's quality control products. In addition, the Company provides Diagnostic Components, which are custom processed human plasma and serum products, to test kit manufacturers, as well as the newly introduced Lyme Western Blot Test Kit.

Laboratory Instrumentation. 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 wine and food testing laboratories. Built with 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. The Company's PCT products are produced at the BBI Source production facility. BBI Source also serves as a contract manufacturer of analytical and diagnostic instruments and biomedical devices.

Biotech. BBI Biotech Research Laboratories, Inc., another wholly-owned subsidiary, is the research and development "arm" of the Company, assisting in the development of new products and services for the other business units, such as the development of the PCT Barocycler and PULSE tubes and related protocols used to prepare specimens, and the ACCURUN nucleic acid controls. BBI Biotech also developed the BBI IgM and IgG *Borrelia burgdorferi* Western Blot Test Kit, initially for use at BBI Clinical Laboratories. BBI Biotech seeks to obtain government grants and other research support wherever possible to help fund the cost of this research and development. In addition, BBI Biotech provides repository services for the United States government and industry, and specialty reagents and molecular and cellular biology services for laboratories and test kit manufacturers.

PCT. The PCT segment involves research, development and commercialization of products utilizing the Company's patented Pressure Cycling Technology. In September 2002, the Company

released for sale the Barocycler instrument and disposable PULSE tubes, the first products manufactured by the Company that utilize the PCT. PCT uses high pressure equipment to rapidly, reversibly, and repeatedly modulate solid and liquid phases of solutions and the binding interactions of biomolecules. PCT, as applied in the Barocycler and PULSE tubes, releases biologically active nucleic acids and proteins from plant and animal tissues, as well as from other organisms that are not easily disrupted by standard chemical methods.

During each of the last three years, BBI Diagnostics and BBI Biotech contributed at least 15% of the Company's consolidated revenues. The combined revenues from all branches of the National Institutes of Health ("NIH"), a United States Government agency and the largest customer of BBI Biotech, accounted for approximately 25%, 31% and 31%, respectively, of total consolidated revenues from continuing operations of the Company for the years ended December 31, 2003, 2002, and 2001, respectively. The Company's consolidated financial statements set forth in Item 8 of this report provide financial information relating to each of the Company's operating segments. See also the discussion on "Customers" below.

Quality Control Products

The Company manufactures its Quality Control 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) that provide most of the raw material for its products. Within the Quality Control Products class are Quality Control Panels, Accurun® External Run Controls and ACCUCHART quality control software.

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 FDA licensed test kits and 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 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 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.

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), West Nile Virus (WNV) and Epstein-Barr Virus (EBV). The following table describes the types, usage and customers of Quality Control Panel products currently offered by the Company:

Quality Control Panels

Product Line	Description	Use	Customers
Seroconversion Panels	Rare 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 and researchers.
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, clinical laboratories that evaluated test kits, 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 linearity and low-end analytical sensitivity of a test kit.	Test kit manufacturers, regulators and researchers.
Qualification Panels	Dilutions of human plasma or serum manifesting a full range of reactivity 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 expectations: also used to troubleshoot system problems and to document problem resolution.	Clinical reference laboratories, blood banks, hospital laboratories.

As mentioned above, the Company's Seroconversion and Performance Panels are comprised of rare plasma specimens that are 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 inventory is sold with another panel comprised of different specimens from a different individual, equally 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 these relationships will continue, that the market for these panels will remain strong, or that it will be able to continue to obtain such specimens.

Accurun® External Run Controls and ACCUCHART Software

End-users of test kits use run controls to monitor test performance, in order to minimize false negative and false positive 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 data management 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® 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® 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® 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® Run Control products in 1993 and has since developed and released for sale an additional 81 Accurun® products. Twelve products have been discontinued, for a total of 73 run controls available as of December 31, 2003. Forty-four of these products are available for clinical diagnostic purposes; the others currently are limited to research use. Current Accurun® External Run Control products generally range in price from $5 to $60 per milliliter.

Diagnostic Components and Test Kits

Diagnostic Components

Diagnostic Components are custom processed human plasma and serum materials or virus cultures 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 four product lines: Normal Human Plasma and Serum, Basematrix, Characterized Disease State Serum and Plasma, and cultured virus. 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. Cultured virus, including a non-infectious strain of HIV, and isolates from all of the major HIV subtypes, are manufactured under current Good Manufacturing Practices (cGMP) and

according to BBI or customer specifications. 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 $3,000 per milliliter.

Test Kits

The Company's first FDA-cleared test kit, the Boston Biomedica, Inc. *Borrelia burgdorferi* IgM and IgG Western Blot Test Kit, was launched in January 2004. The test was originally designed at BBI Biotech and BBI Clinical Laboratories for manufacture at the former and use at the latter. In 2003, after a market research study, a decision was made to commercialize the test, and it was submitted to the FDA and cleared.

Laboratory Instrumentation

BBI Source, the Laboratory (and Diagnostics) 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 wine 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 custom 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 PCT Barocycler and PULSE tubes.

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 prior to the acquisition of this segment in 1997. The Barocycler represents the Company's first major instrument-based product launch for the PCT segment. 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® and MicroChemII® Photometers. A compact, low-cost, single tube photometer designed for immunoassay and general chemistry applications, including infectious disease immunoassays, food and water safety testing.

ChemStat® 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® 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® 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 washing system is fully compatible with a variety of other Company products, such as the ChemStat Automated Photometer 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 EXECWASH Washing 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.

PCT Products

The BBI Source facility manufactures the Company's products for the PCT segment. The Company's pressure cycling technology uses high pressure equipment to rapidly, reversibly, and repeatedly modulate solid and liquid phases of solutions and the binding interactions of biomolecules. In September 2002, the Company released for sale the Barocycler instrument and disposable PULSE tubes, the Company's first products manufactured by the Company which utilize the Company's patented PCT. The PCT protocols utilized in the Barocycler and PULSE tubes releases nucleic acids and biologically active proteins from plant and animal tissues, as well as from other organisms, that are not easily disrupted by standard chemical methods. The PCT segment, which includes both private and public (National Institutes of Health) funding of segment research, continues to experience lower than expected product sales since September 2002 primarily associated with a longer than expected selling cycle. The Company believes that sales of PCT products have been adversely affected primarily as a result of the longer than anticipated sales cycle associated with these products. Factors associated with this sales cycle include the initial selling price of the PCT Barocycler and the limited amount of research data presently available demonstrating its capabilities and potential. Additional refinements in PCT instrumentation include the development of a less expensive and smaller, bench top version of the Barocycler which was just introduced in 2004.

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, virology 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.

In 1998, the Company was awarded a 7-year, $9.4 million contract for work on the AIDS Vaccine development program by the National Institute of Allergy and Infectious Diseases (NIAID) branch of the National Institutes of Health (NIH), of which approximately $6.8 million of revenue has been recorded as of December 31, 2003.

In 2003, efforts were focused on development of an ELISpot assay for use in monitoring the efficacy of candidate HIV Vaccines and providing proficiency panels and reagents. In 2003, BBI Biotech was also re-awarded a $780,000 5-year contract from the Food and Drug Administration (FDA) for the production of lot release panels which the agency uses for evaluation of test kits for HIV, HBV, West Nile Virus and other viruses. The Company has recorded $98,000 of revenues in year 2003 relative to this five year agreement with the FDA.

In 2004, the Company completed its Phase I studies under a $123,000 Small Business Technology Transfer Research (SBTTR) Grant from the NIH for the development of an immuno-polymerase chain reaction (I-PCR) test for the detection of prion proteins in the blood of humans and animals. This collaborative effort with the University of Maryland demonstrated performance of a prototype prion detection system that was 10,000-fold more sensitive than the standard antigen capture test. A proposal to continue these studies under a Phase II Grant was submitted. Another Phase I Small Business Innovation Research Grant (SBIR) in the amount of $101,000 was awarded in year 2003 for the development of a system which would significantly extend the viability and maintain the quality of frozen cells, of which $62,000 of revenue was recorded in year 2003.

Repository and Clinical Trial Services

Since 1983, BBI Biotech has provided blood processing and biological specimen repository services for the National Cancer Institute ("NCI"), and other agencies of the National Institutes of Health ("NIH"). The repository stores over 11,000,000 specimens and processes or ships up to several thousand specimens per week in support of various NIH cancer and virus research programs.

In 1998, BBI Biotech received a six-year $4.7 million repository contract- involving storage, specimen processing and testing services (including five one-year extension options) with the National Heart, Lung and Blood Institute of the NIH, of which $4.4 million had been recorded as revenues through year 2003. In 1999, BBI Biotech received a similar seven-year, $9.6 million repository contract with the National Institute of Allergy and Infectious Disease, of which approximately $5.4 million had been recorded as revenues through year 2003.

In 2000, BBI Biotech was awarded a subcontract, currently valued at $2.2 million, 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. The Company has recorded approximately $2.15 million of revenues under this subcontract through year 2003. From time to time, the Company is requested to provide additional services relating to this project pursuant to informal arrangements, and accordingly, the Company receives additional revenue for providing these services.

In 2001, BBI Biotech was awarded another $10.3 million NCI five year repository contract, of which $5.3 million had been recorded as revenue through year 2003.

In 2002 BBI Biotech was awarded another subcontract, valued at approximately $2.2 million, by the University of Pittsburgh to provide repository, specimen processing and testing services on a NIDDK funded grant to study the viral resistance to antiviral therapy of chronic Hepatitis-C

(ViraHepC). The Company has recorded approximately $1.6 million of revenues under this contract through year 2003.

In 2002 BBI Biotech also signed a $275,000 contract with the American Red Cross to provide repository services for their National Testing Laboratory.

In 2003 BBI Biotech signed a contract with the Fred Hutchinson Cancer Research Center (FHCRC) to act as a central processing laboratory for the HIV Vaccine Trial Network. Revenue from this project is expected to exceed $1,000,000 annually. Also in 2003, BBI Biotech signed a new three year contract with the New England Research Institute to act as a repository and HCV testing center for the Thalassemia Clinical Research Network (TCRN) with a budget of $207,590. In 2003, BBI Biotech was awarded a $250,000 contract by the University of California San Francisco to act as a central processing laboratory and repository for the Solid Organ Transplantation in HIV: Multi-Site Study.

The aforementioned government contracts contain standard terms and conditions relative to audits, and/or termination, which permit the government to audit or terminate the agreement in whole or in part, without prior notice and at the Government's convenience. The Company has never had any government contracts terminated pursuant to these provisions. To date all renewal options under all the above referenced contracts are continuing into 2004. BBI Biotech is currently focusing on expanding the Company's repository customer base to include more industry clients.

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 PCT for nucleic acid extraction and pathogen inactivation, which the Company made available for sale in 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 reagents for

protein and nucleic acid-based tests, and of test kits themselves; and (iv) the design and development of new laboratory instruments and mechanical and optical detection techniques, as demonstrated in its Verif-EYE® reflectance reader.

The Company has approximately 16 full or part-time employees involved in its research and development effort associated with continuing operations as of December 31, 2003. Since the Company's acquisition of BioSeq Inc. in 1998, the Company has invested 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, as it seeks to develop new applications for PCT. See "Management's Discussion and Analysis of Financial Condition and Results of Operations Results of Operations." The Company's research scientists also work closely with sales, marketing, manufacturing, regulatory and finance personnel to identify and prioritize the development of new products and services in areas of its core businesses. Whenever it can, the Company seeks to supplement its research and development funding from grants provided by various agencies and departments of the United States government. See also "Contract Research and Services."

In 2003, the Company developed and launched a series of West Nile Virus RNA panels to help IVD manufacturers launch the West Nile Virus RNA screening of by US blood supply under IND, and is currently supplying WNV RNA controls used by blood banks. Additional research efforts have been devoted to the development of Human Papilloma Virus (HPV) DNA controls which will be launched in 2004 for use with nucleic acid tests used with PAP screening for cervical cancer risk. Work was also resumed on the validation of BBI Biotech's Western blot kit for Borrelia burgdorferi, the infectious agent of Lyme Disease, culminating in the award of 510(k) clearance of this test by the Food and Drug Administration. This clearance will permit the Company to market this test kit to clinical labs for supplementary testing of EIA and IF positive patients in diagnosis of Lyme Disease. Work in the PCT area was focused on optimizing and extending the extraction of nucleic acids from a wide range of microbial, plant, animal and human tissues. Excellent results were reported with obtaining RNA from frozen tumor tissues, and from difficult to lyse bacillus spores. Work under a Phase I SBIR grant demonstrated the use of PCT for preferential killing of normal oral bacteria while maintaining viability of mycobacteria tuberculosis, for faster and more sensitive testing of this organism in bronchial fluids. Additional refinements in PCT instrumentation include the development of a less expensive and smaller, bench top version of the Barocycler which was just introduced in 2004.

The Company's research and development expenses were approximately $1.8M, $2.6M, and $2.3M in each of the three years ended December 31, 2003, 2002 and 2001, respectively.

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 2003, the Company introduced 7 new Seroconversion, Performance, and Sensitivity Panel products, and 7 new Accurun® external run controls. The Company is developing new Quality Control Products for use with tests for Human Papilloma Virus (HPV) and for HIV incidence tests. Additional controls are being developed for both immunological and molecular diagnostic tests for subtypes and variants of HIV, HCV, HBV and West Nile Virus, controls for HIV drug resistance assays, and a variety of controls targeted to 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 by the end of 2003.

Laboratory Instrumentation. The Company's product development activities in year 2003 related to laboratory instruments were centered on development of prototype, demonstration and preproduction Barocycler and PULSE tubes, additional configurations of a "reflectance" reader to produce objective results from rapid *in vitro* diagnostic tests, and an updated version of the MicroChem® (the MicroChem® II). In addition, the Company continues to work on applications for existing products to

broaden their utilization and updates and enhancements made to current OEM customers and to broaden target markets.

Pressure Cycling Technology ("PCT"). The Company owns patented technology based on PCT. PCT research was 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 funded by Phase II Small Business Innovative Research Grants, that provide $750,000 each, over a two year period ending February 2004. The Company has developed a pressure cycling system utilizing a computer controlled instrument, the Barocycler NEP2017, and specialized PULSE Tubes that are capable of releasing biologically active nucleic acids and proteins from plant and animal tissues, and other organisms, such as mycobacteria, that are not easily disrupted by standard chemical methods. This pressure cycling system was made available for sale in September 2002. As of December 31, 2003, three instruments have been sold or placed as reagent rentals, with revenue generated by PULSE Tube sales. The PCT segment, which includes both private and public (National Institutes of Health) funding of segment research, continues to experience lower than expected product sales since commercial launch in September 2002 associated with a longer than expected selling cycle. Factors associated with this sales cycle include the initial selling price of the PCT Barocycler and the limited amount of research data presently available demonstrating its capabilities and potential. Additional refinements in PCT instrumentation include the development of a less expensive and smaller, bench top version of the Barocycler which was just introduced in 2004.

Sales and Marketing

The Company's sales and marketing efforts are organized by business unit consistent with the unit's business objectives, and coordinated through frequent planning with senior management. Overall, the Company employs approximately 25 people in sales, marketing, and customer service functions associated with continuing operations as of December 31, 2003. The Company's overall marketing strategy is to focus on the needs of its customers in four areas: (*i*) quality control 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 manufacturers and researchers, and (*iii*) the Company's first FDA-cleared test kit for the clinical laboratory market, and *(iv*) a sample preparation system introduced in 2002 based on PCT.

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® External Run Controls, TQS Panels, 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® line of run control products. In addition, the Company continues to expand the Accurun® 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 Quality Control Products sales program is led by a Director of Sales and Marketing and currently sold through a combination of telephone, mail, third party distributors

and direct sales efforts. Domestically, Quality Control Products are sold through two direct sales forces led by a Group Sales Manager. The TQS domestic sales force consists of a Field Sales Manager and 7 direct sales representatives. The IVD Sales force consists of 4 direct sales persons. 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 and regional sales manager oversee the Company's Ex-USA distributors.

The Company's Laboratory Instruments are sold through BBI Source. BBI Source's marketing strategy is to focus on new contract manufacturing, increase share of business of current contracted customers, and increase sales of Source brand instruments and service through a direct domestic and international sales force consisting of one director and one sales manager.

The Company incurred significant marketing and promotion related costs in 2003 and 2002 primarily associated with its introduction of the PCT Barocycler at the Pittsburgh Conference industry trade show in year 2002 and subsequent related ongoing sales, marketing and promotion efforts associated with the September 2002 commercial launch of the PCT Barocycler . As of February 2004, the Company had one sales associate dedicated to the PCT segment of the business.

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) 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 primarily driven by customer purchasing patterns involving end-of-year expenditures, 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 Coulter Inc., Vicam, Edwards Life Science, Nihon Kohden and Vysis (Abbott).

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.

During the fiscal years 2003, 2002 and 2001, the Company's international sales were $4,671,000, $3,305,000 and $3,437,000, respectively. During those years, most of the Company's international sales were made in European countries. The Company's Consolidated Financial Statements, including the Notes thereto, set forth in Item 8 of this report provide additional information relating to the Company's foreign and domestic sales. The Company expects international sales to represent a significant portion of revenue in the foreseeable future. The Company cannot guarantee that revenues by geographic region in the foreseeable future will be comparable to those achieved in recent years. The Company's international operations expose it to a number of difficulties in coordinating its activities abroad and in dealing with multiple regulatory environments.

During the fiscal years 2003, 2002, and 2001, sales (from continuing operations) to the Company's three largest customers (when each branch agency of the National Institute of Health is counted as an individual customer) accounted for an aggregate of approximately 21%, 28% and 30%, respectively, of the Company's net sales, although the customers were not identical in each period. 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, 2003, 2002 and 2001. During the fiscal years 2003, 2002, and 2001, the combined revenues from all branches of the National Institutes of Health, a United States Government agency, accounted for approximately 25%, 31% and 31%, 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 government contracts terminated. 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 facilities in West Bridgewater, Massachusetts and in Gaithersburg Maryland. 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 and diagnostic instruments and PCT products 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 the West Bridgewater and the Garden Grove facilities are ISO 9001-2000 certified and both BBI Diagnostics (as of December 12, 2002) and BBI Source are ISO 13485 certified manufacturers of quality control, instrumentation and other diagnostic products. BBI Source is also EN46001 certified. The Gaithersburg facility is in the final stages of preparation for ISO certification.

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.

Diagnostics. In the area of Quality Control Products, the Company competes in the United States with Acrometrix, and BioClinical Partners in run controls and quality control panel products, with Ambion, Bio-Rad Laboratories, Inc., Blackhawk Biosystems Inc. and MAS in run controls, and with some 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 area of commercial test kits, BBI's first offering, the BBI *Borrelia burgdorferi* IgM and IgG Western Blot Test Kit, faces one major competing test kit in the marketplace, the Marblot Western blot kit from Trinity Biotech. The Company believes, on the basis of comparison studies, that its product is superior to the Marblot test in specificity, convenience and objectivity of results interpretation.

In the Diagnostic Components area, the Company competes with integrated plasma collection and processing companies such as Serologicals, Inc. and SeraCare, 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.

Laboratory Instrumentation. 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, Kollsman Manufacturing Company, Inc., Bio-Tek Instruments Inc., Peak Industries, Inc., APW, and Plexus (SeaMed), as well as numerous smaller companies, such as Awareness Technology Inc.

PCT. The Company believes that there are substantial benefits of its PCT system over current methods of sample preparation for "hard to lyse" cells. The Company believes the PCT system offers faster, safer and more reproducible results. The current products incorporating PCT for sample preparation are substantially more expensive than competing offerings from Coors, Qiagen, Fisher, Scientific Industries, Misonix, Biospec, Andwin, Glenn Mills, Branson, Ultrasonic Power Corp., Microfluidizer, American Instrument, French Press, IKA Sonicators, and ISC Inc. and to date sales of

PCT products have been limited. The Company believes that sales of PCT products have been adversely affected primarily as a result of the longer than anticipated sales cycle associated with these products. Factors associated with this sales cycle include the initial selling price of the PCT Barocycler and the limited amount of research data presently available demonstrating its capabilities and potential. Additional refinements in PCT instrumentation include the development of a less expensive and smaller, bench top version of the Barocycler which was just introduced in 2004.

Biotech. BBI Biotech competes primarily on the basis of price and reputation with BioReliance Corporation and several universities for research and development contracts and with ATCC, Cyronix, 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 eleven patents issued and several pending patent applications for its Pressure Cycling Technology. Several of these have been followed up with foreign applications, for which two patents were issued in Europe in 2002. The Company expects to file additional foreign applications in the future relating to PCT. The patents which have been issued expire between 2015 and 2021.

The Company does not 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®, Accurun®, and Verif-EYE® are registered trademarks of the Company.

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® External 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. The Company 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 the 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 December 31, 2003, there were a total of 44 Accurun ® external run control products currently on the market that 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® external 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.

As of December 31, 2003, a total of 30 Accurun ® | external run control products designed for the European market have met the regulatory requirements to carry the CE Mark under the European Union's In Vitro Diagnostics (IVD) Directive. The IVD Directive describes criteria that must be met and steps that must be taken for IVD products to be qualified for sale in European Union countries beginning at the end of 2003. In the IVD Directive, the European Union classifies products according to the risks associated with their failure or misuse, and establishes a process leading to a CE Mark (approval to sell a product in EU countries) for each category.

Test kits are required to be FDA cleared or approved by the 510(k) or PMA processes in order to be sold with labeling "For *In Vitro* Diagnostics Use" in the U.S. BBI's first commercialized test kit, the Boston Biomedica Inc. *Borrelia burgdorferi* IgM and IgG Western Blot Test Kit, received 510(k) clearance in November, 2003.

BBI Source generally obtains 510(k) and European 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, and Gaithersburg, Maryland for Diagnostic Products and in 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.

As of December 2002, the Company's Diagnostic Products business unit in West Bridgewater, Massachusetts is ISO 13485 certified, with registration by G-MED. The Company's Laboratory Instruments business unit is ISO9001 certified, with registration by the British Standard Institute. The Laboratory Instrument group is also certified to EN46001, a set of supplementary requirements applicable to their products. BBI Biotech's Gaithersburg facility is in the final stages of preparation for ISO certification.

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 products and services. These "Directives" cover both quality system requirements (ISO Series 9000 Standards, ISO 13485 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, and is 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, 2003 the Company employed 203 persons, all of whom were located in the United States. Of these, 96 persons were employed at the West Bridgewater, Massachusetts facility, 87 at its two Maryland facilities, and 20 at the Garden Grove, California facility. None of the Company's employees is covered by a collective bargaining agreement. The Company believes it has a satisfactory relationship with its employees.

Backlog

BBI Source had an instrument manufacturing backlog of approximately $981,000 as of December 31, 2003, as compared to approximately $1,124,000 as of December 31, 2002. Shipments expected within the next twelve-month period, included in this backlog, amounted to approximately $870,000 as of December 31, 2003 as compared to $755,000 as of December 31, 2002. Backlog at the other BBI subsidiaries is not material.

Available Information

Our internet website address is http://www.bbii.com. Through our website, we make available, free of charge, our annual report on Form 10-K, quarterly reports on Form 10-Q, current reports on Form 8-K and any amendments to those reports, as soon as reasonably practicable after we electronically file such material with, or furnish it to, the SEC. These SEC reports can be accessed

through the investor relations section of our website. The information found on our website is not part of this or any other report we file with or furnish to the SEC.

Executive Officers of the Registrant

The following table sets forth the names, ages and positions of the executive officers of the Company as of February 2004:

Name	Age	Position
Kevin W. Quinlan	54	President and Chief Operating Officer, Treasurer and Director
Patricia E. Garrett, Ph.D.	60	Senior Vice President, Science and Technology
Mark M. Manak, Ph.D.	54	Senior Vice President and General Manager of BBI Biotech
David F. Petersen	57	Senior Vice President and General Manager of BBI Source
Kathleen W. Benjamin	47	Vice President, Human Resources and Clerk
Richard D'Allessandro	57	Vice President, Information Technology

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 (now PricewaterhouseCoopers LLP) from 1975 to 1981. Mr. Quinlan, a Certified Public Accountant, received a M.S. in accounting from Northeastern University and a B.S. in resource economics from the University of New Hampshire.

Dr. Garrett has served as Senior Vice President, Science and Technology of the Company since 2001, 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 and Strategic Programs. From 1980 to 1988, 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 of BBI Biotech. 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 was also an Assistant Professor at California State University Dominguez

Hills, where for seventeen years he instructed 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 of the Company since January 1999 and has been Clerk of the Company since 2003. Prior to her promotion to Vice President, Ms. Benjamin served as Director of Human Resources and Investor Relations from 1997 to 1999 and was Assistant Clerk of the Company from 1997 to 2003. Prior to joining the Company in 1997 she was employed from 1987 - 1996 by Shields Health Care Group, a provider of Magnetic Resonance Imaging and radiation oncology, serving as their Director of Operations from 1992 to 1996. Prior to 1987, 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 of the Company 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 President and elected by the Board of Directors.

For additional information relative to the Company's liquidity and debt covenants, and critical accounting policies and estimates, see item 7 "Management's Discussion and Analysis of Financial Condition and Results of Operations" hereunder.

PART II

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

The Company's common stock, par value $0.01 per share (the "Common Stock"), is listed on the Nasdaq National Market under the symbol "BBII".

The following table sets forth, for the periods indicated, the high and low sales price per share of Common Stock, as reported by the Nasdaq National Market:

	Common Stock Price	
Fiscal Year Ended December 31, 2002	**High**	**Low**
First Quarter	$ 4.260	$ 2.790
Second Quarter	$ 5.020	$ 3.500
Third Quarter	$ 4.650	$ 2.130
Fourth Quarter	$ 3.010	$ 2.000
Fiscal Year Ended December 31, 2003	**High**	**Low**
First Quarter	$ 3.000	$ 1.69
Second Quarter	$ 2.800	$ 2.020
Third Quarter	$ 3.160	$ 2.510
Fourth Quarter	$ 3.040	$ 2.300

As of January 31, 2004, there were 20,000,000 shares of Common Stock authorized of which 6,827,592 shares were issued and outstanding, held of record by approximately 2,900 stockholders. See also Note 11 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 and the Company's revolving line of credit, 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

During fiscal 2003, the Company did not sell any securities that were not registered under the Securities Act of 1933, as amended.

Repurchases by the Company

During the fourth quarter of 2003, the Company did not repurchase any shares of its Common Stock on its own behalf or any affiliated purchaser.

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

Overview

Revenues. The Company generates revenue from products and services provided primarily to the *in vitro* diagnostic infectious disease industry. The Company currently has four operating segments: "Diagnostics," "Biotech," "Laboratory Instrumentation" and "Pressure Cycling Technology ("PCT")". Two of these segments, "Diagnostics" and "Laboratory Instrumentation" primarily manufacture products. Commencing in 2002, PCT products are being manufactured at the Laboratory Instrumentation segment. Within the Diagnostics segment, there are three major product lines: Quality Control Panels, Accurun® External Run Controls, and Diagnostic Components. The remaining two operating segments, Biotech and PCT, generate primarily service revenue. Within Biotech there are four major product lines: Contract Research, Repository Services, Specialty Reagents and Research Services. Revenue in the "PCT" segment consists primarily 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.

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 Company wrote down all of the retained assets to their estimated net realizable value. The Company recorded an after-tax gain of $4,334,000 in 2001 and an additional after tax gain of $225,000 in 2002. See also Notes 2 and 13 of Notes to Consolidated Financial Statements hereunder, included in Part II, Item 8 of this Form 10K.

The economics and cost structures of the Company's business segments have certain differences.

The Diagnostics segment has historically been the Company's 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 operates in a highly competitive, low margin business: contract manufacturing of instruments and medical devices. Since the Company's acquisition of Source Scientific in 1997, management has continued in its efforts to turn around this business. At the current low annual revenue level of less than $2.0 million, it operates significantly under capacity with high fixed overhead costs, and should therefore significantly benefit from relatively small revenue increases.

The BBI Biotech segment 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 of the Company 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, while contributing to the development of future products and services for the Company.

The PCT segment's research and development operation launched its first products for commercial sale in 2002. Revenue to date consists primarily of 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. Since its commercial introduction in 2002, sales of PCT products have

been limited primarily due to longer sales cycles than originally anticipated as discussed further hereunder. Factors associated with this sales cycle include the initial selling price of the PCT Barocycler and the limited amount of research data presently available demonstrating its capabilities and potential. Additional refinements in PCT instrumentation include the development of a less expensive and smaller, bench top version of the Barocycler which was just introduced in 2004.

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

Since the acquisition of BioSeq, Inc. in 1998, the Company has expended significant amounts for ongoing research and development of new technologies, including in connection with the development of PCT. In the past five years, the Company's BioSeq research subsidiary has incurred approximately $5.5M of research and development expenses substantially related to development of a unique instrument and disposable specimen processing tube in conjunction with PCT. As a result of its efforts, in September 2002, the Company was able to release for sale its first products based on its patented PCT. The Company is presently manufacturing the Barocycler instrument and disposable PULSE tubes utilizing PCT at its BBI Source Scientific facility, however, the sales cycle appears to be of longer duration than expected. The Company has received eleven domestic and four foreign patents for this technology as of the end of 2003. The Company has invested 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 as it seeks to continue to develop new applications for PCT.

EXPORT SALES

The Company has 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, 2003, 2002, and 2001 were $4.7 million, $3.3 million and $3.4 million, respectively. The Company expects that export sales will continue to be a significant source of revenue and gross profit.

CHALLENGES AND OPPORTUNITIES

The Company also continues to evaluate the performance of both the Laboratory Instrumentation segment and the PCT segment, both of which continue to experience significant operating losses. The PCT segment, which includes both private and public (National Institutes of Health) funding of segment research, continues to experience lower than expected product sales since its commercial

introduction in September 2002 primarily associated with a longer than expected selling cycle for its PCT Products. Factors associated with this sales cycle include the initial selling price of the PCT Barocycler and the limited amount of research data presently available demonstrating its capabilities and potential. Additional refinements in PCT instrumentation include the development of a less expensive and smaller, bench top version of the Barocycler which was just introduced in 2004. While the Company believes strongly in the benefits of PCT's novel technology, the market potential of the existing PCT Barocycler is uncertain. The manufacture of PCT products at the laboratory instrument segment of the business was part of the Company's plan to return BBI Source Scientific, Inc. to profitability in year 2003. The Company intends to evaluate other applications and products utilizing PCT, including expansion of the PCT product line, and to reexamine the core contract manufacturing business of BBI Source Scientific, Inc. If these segments do not become profitable, the Company may need to write off some or all of the current net book value of these assets in either or both of these segments.

To advise the Company with respect to the strategic direction of the Company's PCT and BBI Source Scientific activities, and the Company's remaining ownership interest in Panacos Pharmaceuticals, Inc., in July 2003, the Company engaged Mr. Richard T. Schumacher, the Company's former Chairman and Chief Executive Officer as an Executive Project Consultant. As part of this engagement, Mr. Schumacher is expected to reevaluate the ongoing business prospects for both the Laboratory Instrumentation segment and PCT activities. On February 9, 2004, the Company announced it has extended until December 31, 2004 the Executive Consultant Agreement it has with Mr. Schumacher. Under the terms of the Consulting Agreement, Mr. Schumacher is serving in an advisory role directing the Company's PCT and BBI Source Scientific activities, the Company's interest in Panacos Pharmaceuticals, Inc. and such other duties as the President or the Board of Directors of the Company assigns to him. In addition to these responsibilities, Mr. Schumacher will also take the lead role in working with William Blair & Co., the Chicago Illinois based investment banking firm retained by the Company in October 2002. In connection with his Consulting Agreement, Mr. Schumacher is being paid an annualized salary of $250,000. In addition to his salary, Mr. Schumacher may receive, in the discretion of the Company's Board of Directors, a bonus in an amount to be determined by the Board of Directors in recognition of the successful completion of his duties and responsibilities under the agreement, and he is also eligible to participate in the Company's health and medical insurance, disability insurance, group life insurance and group travel insurance, and 401(k) retirement plans.

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:

	Year Ended December 31,		
	2003	**2002**	**2001**
Revenue:			
Products	58.4%	55.8%	60.0%
Services	41.6	44.2	40.0
Total revenue	100.0	100.0	100.0
Gross profit	36.2	37.3	39.9
Operation expenses:			
Research and development	7.8	11.5	10.6
Selling and marketing	14.1	14.4	13.4
General and administrative	18.6	18.1	18.2
Total operating expenses	40.5	44.0	42.2
Operating loss from continuing operations	(4.3)	(6.7)	(2.3)
Interest expense, net	(1.2)	(0.9)	(1.7)
Loss before income taxes and cumulative effect of change in accounting principle	(5.5)	(7.6)	(4.0)
Provision for income taxes			(0.1)
Income from discontinued operations		1.0	19.9
Net income (loss)	(5.5)	(6.6)	15.8
Product gross profit	46.6%	48.5%	51.6%
Services gross profit	21.5%	23.2%	22.3%

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 addition, significant estimates were made in determining the gain on disposition of the company's discontinued operations including post-closing adjustments, in estimating future cash flows to quantify impairment of assets, in determining the ultimate cost of abandoning a lease (associated with discontinued operations) at a facility no longer being utilized, in estimates regarding the collectability of accounts receivable, realizability of a receivable from a Director/former Chairman and Chief Executive Officer including sufficiency of collateral (see Note 12), deferred tax assets, the net realizable value of its inventory, third party audits, as well as an estimate for other remaining liabilities associated with discontinued operations. On an on-going basis, the Company evaluates its estimates. The Company bases its 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.

Revenue Recognition

The Company recognizes revenue in accordance with the Securities and Exchange Commission's Staff Accounting Bulletin No. 103, *Update of Codification of Staff Accounting Bulletins* ("SAB 103").

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Revenue is recognized when realized or earned when all the following criteria have been met: persuasive evidence of an arrangement exists; delivery has occurred and risk of loss has passed; the seller's price to the buyer is fixed or determinable and collectibility is reasonably assured.

Product revenue is generally recognized upon shipment of the products. The Company will occasionally recognize revenue on a bill and hold basis after completion of manufacture for specific orders at the request of the customer. Bill and hold sales transactions are entered into after consideration of customer needs and capabilities relating to freezer capability to store biological substances at required temperatures. All bill and hold transactions meet specified revenue recognition criteria that include:

The risk of ownership has passed to the customer;

The customer has a fixed commitment to purchase the goods;

The customer, not the Company, has requested the transaction to be on a bill and hold basis;

There is a fixed schedule for delivery of the goods;

The Company does not retain any specific performance obligations such that the earnings process is not complete;

The ordered goods are segregated from the Company's inventory and not subject to being used to fill other orders; and

The goods are complete and ready for shipment.

The Company also considers the following prior to recognizing revenue:

The transaction is subject to normal billing and credit terms for the specific customer;

The Company's past experience with the pattern of bill and hold transactions;

Whether the customer has the expected risk of loss in the event of a decline in the market value of the goods;

Whether the Company's custodial risks are insurable and insured;

Whether APB 21, pertaining to the need for discounting the related receivables, is applicable; and

Whether extended procedures are necessary in order to assure that there are no exceptions to the customer's commitment to accept and pay for the goods.

Total revenue related to bill and hold transactions was approximately $622,000, $380,000 and $610,000, for the years ended December 31, 2003, 2002, and 2001, respectively.

Revenue from service contracts is earned as the related services are performed. Revenue arrangements where multiple products or services are sold together under one contract are evaluated to determine if each element represents a separate earnings process. In the event that an element of such multiple element arrangement does not represent a separate earnings process, revenue from this element is recognized over the term of the related contract. 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. Total revenue related to long-term contracts was approximately $5,855,000, $5,802,000, and $5,062,000, for the years ended December 31, 2003, 2002, and 2001, respectively. Total contract costs associated with these agreements were approximately $5,458,000 $5,610,000 and $4,911,000, for the years ended December 31, 2003, 2002 and 2001, 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 $30,000 at December 31, 2003 and less than $62,000 for all other years presented.

During the fiscal years 2003, 2002 and 2001, the combined revenues from all branches of the National Institutes of Health, a United States Government agency, accounted for approximately 25%, 31% and 31%, 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.

Accounts Receivable

Management periodically reviews outstanding balances in accounts receivable to estimate future collections. Based on the Company's historical experience, current business conditions and expected future collections, management established an allowance for uncollectible accounts. In the event circumstances change to affect the assumptions underlying this allowance, the Company might be required to take additional write-offs of its accounts receivable balances.

Inventory

Inventory is valued at the lower of cost or market. Certain factors may impact the realizable value of the Company's inventory including, but not limited to, technological changes, market demand, changes in product mix strategy, new product introductions and significant changes to the Company's cost structure. In addition, estimates of reserves are made for obsolescence based on the current product mix on hand and its expected net realizability. If actual market conditions are less favorable or other factors arise that are significantly different than those anticipated by management, additional inventory write-downs or increases in obsolescence reserves may be required. The Company treats lower of cost or market adjustments and inventory reserves as adjustments to the cost basis of the underlying inventory. Accordingly, favorable changes in market conditions are not recorded to inventory in subsequent periods.

Long-lived Assets and Goodwill

Intangible assets primarily relate to the remaining value of acquired patents associated with PCT. 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. The Company's policy regarding long-lived assets is to evaluate the recoverability or usefulness of these assets when the facts and circumstances suggest that these assets may be impaired. This analysis relies on a number of factors, including changes in strategic direction, business plans, regulatory developments, economic and budget projections, technological improvements, and operating results. The test of recoverability or usefulness is a comparison of the asset value to the undiscounted cash flow of its expected cumulative net operating cash flow over the asset's remaining useful life. Any write-downs would be treated as permanent reductions in the carrying amount of the asset and an operating loss would be recognized. To date, the Company has had recurring operating losses in the PCT segment and the recoverability of the Company's long-lived assets is contingent upon it executing its business plan that includes expected revenues and cash flows to be generated from sales of PCT products and services. The Company's goodwill relates to its acquisition of the Laboratory Instrumentation operating segment. This segment is expected to continue to manufacture PCT related products and the realizability of this goodwill is dependant, among other factors, on the success of the Company's PCT product line. If the Company is unable to execute its business plans related to PCT, it may be required to write down the remaining value of its long-lived assets and goodwill in future periods.

Deferred Tax Valuation Allowance

A valuation allowance is established if it is more likely than not that all or a portion of a deferred tax asset will not be realized. 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. The Company has not recognized an income tax benefit associated with the loss from continuing operations in 2003, 2002, and 2001, as these tax assets have been fully reserved for. Accordingly, a valuation allowance has been established for the full amount of the deferred tax asset due to the uncertainty of realization.

Discontinued Operations

The Company periodically reviews the adequacy of its reserve for discontinued operations associated with the Company's decision to exit the clinical laboratory testing segment of the business in 2000. The Company has established reserves to cover expected future costs including those associated with an existing facility lease expiring July 2005. See also Note 13 of Notes to Consolidated Financial Statements hereunder, included in Part II, Item 8 of this Form 10K.

Loan Receivable from Director and Former Chairman and Chief Executive Officer

As of December 31, 2003, the Company evaluated the recoverability of a $1,000,000 loan receivable from its former Chairman and Chief Executive Officer, which is reflected on its balance sheet in stockholders' equity as a loan receivable as of December 31, 2003. The Company's review includes an evaluation of the collateral associated with the loan. The Company maintains a junior interest in this collateral. As of December 31, 2003, the remaining collateral consists of common stock of the Company. When considering the adequacy of the collateral for the Company's $1,000,000 receivable, the Company considers the balance of a loan outstanding ($500,000 as of December 31, 2003) between an entity controlled by its former Chairman and Chief Executive Officer with a financial institution and the fact that the Company has a junior position in regards to the remaining collateral associated with that loan, as well as the liquidity and net realizable value of the remaining assets underlying the collateral. The ultimate value that may be recovered by the Company is dependant on numerous factors including market conditions relative to the value of and ability to sell the Company's

common stock, and the financial status of its former Chairman and Chief Executive Officer. At December 31, 2003, the Company performed a test for impairment of its loan receivable by analyzing the value of the collateral, and determined that the loan receivable was not impaired. While the loan receivable was not impaired as of December 31, 2003, the termination of the Company's Chairman and Chief Executive Officer by the Board of Directors in February 2003, together with the fluctuations in the quoted market value of the Company's common stock, which comprises the remaining collateral, are indicators of impairment. Based on the Company's assessment as of and through February 2004, the Company estimates that the value of the collateral approximates the amount of the Company's recorded loan. If actual market conditions are less favorable or other factors arise that are significantly different than those anticipated by management, a write-down of this asset might be required.

YEARS ENDED DECEMBER 31, 2003 AND 2002

Revenue

Total revenue increased 2.3%, or $531,000, to $23,296,000 in 2003 from $22,765,000 in 2002. The increase in revenue was the result of an increase in product revenue of 7.2% or $911,000, to $13,608,000 in 2003 from $12,697,000 in 2002, partially offset by a 3.8% or $380,000 decrease in service revenue to $9,688,000 in 2003 as compared to service revenue of $10,068,000 in 2002.

Product Revenue. The increase in product revenue in 2003 compared to 2002 occurred in the Diagnostics segment and was due primarily to increased sales in year 2003 associated with newly released AccuRun products and custom (OEM) panels, which included one large custom order from an international distributor. The increase in product revenues was partially offset by a lower level of contract manufacturing work at the Laboratory Instrumentation segment. In 2003 the Company had limited revenue from sales of our PCT products. Sales of the Company's PCT products continues to be slower than expected due primarily to longer sales cycles than anticipated. Factors associated with this sales cycle include the initial selling price of the PCT Barocycler and the limited amount of research data presently available demonstrating its capabilities and potential. Additional refinements in PCT instrumentation include the development of a less expensive and smaller, bench top version of the Barocycler which was just introduced in 2004.

Service Revenue. The decrease in service revenue was primarily related to a decline of $1,006,000 of contract research activities and a decrease of $114,000 of PCT related grant revenues in 2003 compared to 2002, in which there was strong activity in two service contracts related to HIV vaccine development and Hepatitis C work at the Biotech segment. These decreases were partially offset by higher revenues in year 2003 associated with increased repository service work amounting to approximately $878,000 combined with an increased level of billable hours associated with government contract reimbursable work at the Biotech segment. In 2003, the Biotech segment signed a contract with the Fred Hutchinson Cancer Research Center to act as a central processing laboratory for the HIV Vaccine Trial Network. Revenue from this project is expected to exceed $1,000,000 annually. The Company expects to receive approximately $10 million of service related revenues in year 2004 associated with ongoing contract work at its Biotech segment.

Gross Profit

Overall gross profit decreased 0.8%, or $71,000 to $8,431,000 in 2003 from $8,502,000 in 2002. Product gross profit increased 3.0%, or $184,000, to $6,345,000 in 2003 from $6,161,000 in 2002; product gross margin decreased to 46.6% in 2003 from 48.5% in 2002. Service gross profit decreased $255,000 or 10.9% to $2,086,000 in 2003 from $2,341,000 in 2002; service gross margin decreased to 21.5% in 2003 from 23.2% in 2002.

Product Gross Margin. The decline in product gross margin was due to a lower level of instrument sales in year 2003 at the Laboratory Instrumentation segment over a relatively fixed cost structure, partially offset by an increased level of product sales at the Diagnostics segment.

Service Gross Margin. The decrease in service gross margin was primarily due to less profitable research contracts at the Biotech segment, whereas year 2002 service revenues included increased activity associated with two service contracts related to HIV vaccine development and Hepatitis C work at the Biotech segment.

Research and Development

Research and development expenditures declined 30.4%, or $795,000, to $1,816,000 in 2003 from $2,611,000 in 2002. The decreased level of expenditures was associated primarily with a reduced level of activity on PCT related projects following the commercial introduction of PCT products in late September 2002. The Company expects that it will incur significant research and development expenses in connection with the further development of additional PCT products. In 2002, there was an increase in development work in AccuChart Plus, a quality control data management software program for analyzing, tracking and archiving daily run control data for monitoring test kit performance.

Selling and Marketing

Selling and marketing expenses amounted to $3,283,000 in 2003 relatively unchanged from $3,286,000 in 2002. The Company continued to incur marketing and promotion related costs in both 2003 and 2002 associated with the commercial launch the PCT Barocycler in September 2002.

General and Administrative

General and administrative costs increased 5.8%, or $237,000, to $4,346,000 in 2003 from $4,109,000 in 2002. In 2003, there were legal, audit and director fees incurred by the Special Oversight Committee of the Company's Board of Directors, formed in February 2003, in conjunction with the termination of the Company's Chairman and Chief Executive Officer, for the purpose of overseeing the management of the affairs of the Company during the transition period. The Company also incurred increased legal fees associated with the March 2003 adoption of a Shareholder Purchase Rights Plan. In addition, the Company incurred approximately $245,000 of costs in year 2003 associated with investment banking activities evaluating both strategic and financing opportunities for the Company. These costs were partially offset by reduced compensation costs incurred in 2003 due to the elimination of the salary that would have been paid to the Company's former Chairman and Chief Executive Officer who was terminated in February 2003, and lower employee health care costs.

Operating Loss from Continuing Operations

Operating loss from continuing operations amounted to $1,014,000 in 2003 compared to an operating loss from continuing operations of $1,504,000 in 2002. The operating loss in year 2003 included approximately $213,000 of costs incurred by the Special Oversight Committee of the Company's Board of Directors (net of reduced compensation costs) combined with approximately $245,000 of costs associated with investment banking activities as discussed in further detail above in the caption entitled "*General and Administrative.*" The Diagnostics segment's operating income increased to $1,704,000 in 2003 from $1,478,000 in 2002, due to an increase in product sales associated with newly released Accurun® products and custom (OEM) panels. The Biotech segment's operating loss decreased to $274,000 in 2003 from $319,000 in 2002, primarily due to additional revenues generated by increased repository services combined with an increased level of billable hours associated with government contract reimbursable work partially offset by higher wages, supplies and facilities costs. The operating loss of the PCT segment decreased to $1,552,000 in 2003 from $2,156,000 in 2002

primarily due to reduced patents, trade show and research and development costs, partially offset by a lower level of PCT related grant revenues. The PCT segment, which includes both private and public (National Institutes of Health) funding of segment research, continues to experience lower than expected product sales since commercial launch in September 2002 associated with a longer than expected selling cycle. The Laboratory Instrumentation segment's operating loss increased to $892,000 in 2003 from $507,000 in 2002. This segment recorded an 18.8% decline in revenue due to a lower level of contract manufacturing work coupled with increased facility related costs.

Interest Expense

Interest expense, incurred primarily on the Company's outstanding mortgage on the Company's headquarters located in West Bridgewater, Massachusetts, increased $43,000 in 2003 as compared to 2002. The increase was a result of a mortgage covenant waiver fee as the Company failed to meet its debt service coverage and other covenants for the year ended December 31, 2002. The Company also failed to meet this debt service coverage covenant for the year ended December 31, 2003, however the financial institution has notified the Company of its intent to waive this default.

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. Accordingly, the Company has not recognized an income tax benefit associated with the loss from operations in the years 2003, 2002 and 2001.

Loss from Continuing Operations

Loss from continuing operations amounted to $1,289,000 for the year ended December 31, 2003 as compared to a loss of $1,713,000 for the year ended December 31, 2002 as a result of the items discussed above.

Discontinued Operations

In the third quarter of 2002, the Company adjusted its estimate of remaining accrued liabilities to exit the clinical laboratory testing business based upon new developments. The liability was reduced to $855,000 as of September 30, 2002. The major component of the remaining accrual as of September 30, 2002 was estimated lease exit and facility related costs ($532,000) with the remainder for health care claims, other regulatory audit adjustments, and for other miscellaneous costs associated with exiting this business segment. This resulted in recording an after tax gain of $225,000 in the third quarter of 2002. See also Note 13 of Notes to Consolidated Financial Statements hereunder, included in Part II, Item 8 of this Form 10K.

Net Loss

The Company had a net loss of $1,289,000 in 2003 as compared to a net loss of $1,488,000 in 2002.

YEARS ENDED DECEMBER 31, 2002 AND 2001

Revenue

Total revenue from continuing operations increased 4.3%, or $939,000, to $22,765,000 in year 2002 from $21,826,000 in year 2001. The increase in revenue was the result of a 15.3% increase in service revenue or $1,334,000, to $10,068,000 in 2002 from $8,733,000 in 2001, partially offset by a small decrease in product revenue of 3.0%, or $396,000, to $12,697,000 in 2002 from $13,093,000 in 2001.

Product Revenue. The decrease of $396,000 in product revenue was due primarily to decreases of product sales at the Biotech segment associated with reduced purchases of lyme disease test kits by one large end user which subsequently ceased using this product and a decrease of $254,000 of product sales at the Laboratory Instrumentation segment (the latter segment experienced strong sales to existing customers in the first half of 2001).

Service Revenue. The $1,334,000 increase in service revenue was primarily related to an increase of approximately $612,000 in revenues related to its Hepatitis C work at the Biotech segment, and increased grant revenue of approximately $277,000 at the Company's PCT segment.

Gross Profit

Overall gross profit decreased 2.3%, or $203,000, to $8,502,000 in 2002 from $8,705,000 in 2001. Product gross profit decreased 8.8%, or $594,000, to $6,161,000 in 2002 from $6,755,000 in 2001; product gross margin declined to 48.5% in 2002 from 51.6% in 2001. Services gross profit increased 20.0% or $391,000 to $2,341,000 in 2002 from $1,950,000 in 2001, while service gross margin increased to 23.2% in 2002 from 22.3% in 2001.

Product Gross Margin. A decrease in both product gross profit and margin was associated with increased sales of higher margin catalog products in 2001 at the Diagnostics segment and higher raw material costs in 2002, a decrease in high margin product sales at the Biotech segment in 2002, and lower revenues from instrument sales in 2002 over a relatively fixed cost structure (which includes increased costs associated with a facility lease renewal effective in February 2002 coupled with a facility sublease that expired in January 2002) at the Laboratory Instrumentation segment.

Service Gross Margin. The increase in both service gross profit and margin was primarily due to increased activity associated with two service contracts related to HIV vaccine development and Hepatitis C work at the Biotech segment, partially offset increased wage expense and higher facility operating costs at the Biotech segment in 2002.

Research and Development

Research and development expenditures increased 13.3%, or $308,000, to $2,611,000 in 2002 from $2,303,000 in 2001. The increased level of expenditures was associated with ongoing PCT related projects including optimization protocols for various tissue types. In addition, there was an increase in development work on AccuChart Plus®, a quality control data management software program for analyzing, tracking and archiving daily run control data for monitoring test kit performance. Since the Company's acquisition of BioSeq Inc. in 1998, the Company has invested 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, as it seeks to develop new applications for PCT.

Selling and Marketing

Selling and marketing expenses increased by 12.7%, or $370,000, to $3,286,000 in 2002 from $2,916,000 in 2001. The Company incurred significant marketing and promotion related costs in 2002 primarily associated with its introduction of the PCT Barocycler at the Pittsburgh Conference industry trade show and related ongoing sales, marketing and promotion efforts associated with the September 2002 commercial launch of the PCT Barocycler , and expects these PCT related activities to continue in 2003.

General and Administrative

General and administrative costs increased 3.3%, or $132,000, to $4,109,000 in 2002 from $3,977,000 in 2001, due to higher wage and facility lease and utility costs incurred in 2002 partially

offset by a one time $54,000 credit associated with a telecommunications claim and the cessation, commencing January 2002, of amortization of goodwill associated with the Laboratory Instrumentation segment, compared to 2001, in which the Company benefited from the reversal of an $80,000 legal expense accrual associated with the June 2001 legal settlement reached with Paradigm Group, LLC. In the second quarter of 2001, the Company increased its provision for doubtful accounts by $82,000 based on a significant deterioration in the financial condition of a customer in its Diagnostics segment.

Operating Income (Loss) from Continuing Operations

Operating (loss) from continuing operations amounted to $(1,504,000) in 2002 compared to an operating (loss) of $(491,000) in 2001. The Diagnostics segment's operating income decreased to $1,478,000 in 2002 from $1,674,000 in 2001 due to a decline in product gross margin. The Biotech segment's operating (loss) increased to $(319,000) in 2002 from $(212,000) in 2001; a 14.3% increase in service revenues coupled with an increase in service gross margin was more than offset by increased sales and marketing expenses and increased general and administrative expenses. The operating loss of the PCT segment increased to $(2,156,000) in 2002 from $(1,493,000) in 2001 due to increased research and development costs associated with the final phases of product development and advanced prototype manufacture and increased sales, promotion and marketing costs associated with the commercial launch, in late September of 2002, of the PCT Barocycler .

The Company continues evaluate the market for the PCT Barocycler , as the sales cycle appears to be longer in duration than originally envisioned. While the Company believes strongly in the benefits of PCT's novel technology, the market potential of the existing PCT Barocycler appears uncertain. The manufacture of PCT products at the laboratory instrument segment of the business was part of the Company's plan to return BBI Source Scientific, Inc. to profitability in year 2003. The Company intends to evaluate other applications and products utilizing PCT, including expansion of the PCT product line, and to reexamine the core contract manufacturing business of BBI Source Scientific, Inc. If the Company is unable to execute its business plans related to PCT, we may be required to write down the value of our intangible long-lived assets and goodwill in future periods.

Interest Expense

Interest expense decreased to $248,000 in 2002 from $438,000 in 2001. The Company redeemed the remaining $2,040,000 (face value) of outstanding 3% Senior Subordinated Convertible Debentures ("Debentures"), which were originally issued in August 2000, plus accrued interest and a premium of $190,000 (which was charged to interest expense) in early 2001. Interest expense in 2001 also included interest on the Company's line of credit, which was terminated by the Company in February 2001. Both years' include interest expense associated with the Company's outstanding mortgage.

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; accordingly, the Company has not recognized an income tax benefit associated with the loss from continuing operations in 2002 and 2001, as these tax assets have been fully reserved for. The Company incurred state income and franchise tax expense of approximately $3,000 and $16,000 in 2002 and 2001, respectively.

Loss from Continuing Operations

Loss from continuing operations amounted to $1,713,000 for the year ended December 31, 2002 as compared to a loss of $887,000 for the year ended December 31, 2001 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. The Company retained certain other assets and liabilities of BBICL, primarily property, plant and equipment, together with the facility lease subsequent to the closing date; see also Note 13 of Notes to Consolidated Financial Statements hereunder, included in Part II, Item 8 of this Form 10K. The Company wrote down all of the retained assets not otherwise redistributed to other business units to their estimated net realizable value.

The Company accrued $710,000 as of December 31, 2002 for its estimate of remaining liabilities to exit the clinical laboratory testing business. The major component of this remaining accrual is estimated lease exit and facility related costs ($504,000) with the remainder for health care claims, other regulatory audit adjustments, and for other miscellaneous costs associated with exiting this business segment. The Company adjusted its estimated remaining liability in the third quarter and recorded an after tax gain of $225,000.

Revenues from discontinued operations, net of intercompany eliminations, were $973,000, in the period January 1, 2001 to February 20, 2001. Operating (losses) from discontinued operations was $0 for the year ended December 31, 2002 and were $0 and $(136,000) for the years ended December 31, 2002 and 2001, respectively. The Company recorded a gain of $4,334,000, net of taxes of $969,000, in 2001. Income (loss) from discontinued operations was $225,000 for the year ended December 31, 2002 as discussed above, and $4,334,000 for the year ended December 31, 2001. The Company utilized prior period net operating loss carryforwards, previously reserved for by the Company in 2000, to partially offset the tax effect of this gain. Additionally, the Company took a tax benefit of $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 the first quarter of 2001.

In accordance with a transition services agreement, the Company operated the clinical laboratory business on behalf of the buyer during the period February 20, 2001 through December 2001 although most operations ceased activity by the end of June 2001. All of the revenues generated by, and substantially all costs associated with operating the business subsequent to the closing date of the transaction were 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**.**

Net Income (Loss)

The Company had a net (loss) of ($1,488,000) in 2002 as compared to net income of $3,448,000 in 2001. The 2002 net (loss) included an after-tax gain of $225,000 from discontinued operations, whereas in 2001, the Company recorded an after-tax gain of $4,334,000 associated with discontinued operations.

LIQUIDITY AND FINANCIAL CONDITION

As of December 31, 2003, the Company had approximately $7.7 million in working capital. The Company had cash of $967,185 at December 31, 2003 compared to cash of $975,649 at December 31, 2002. The Company experienced operating losses from continuing operations of $1,014,000 and $1,504,000 for the years ended December 2003 and 2002, respectively. It is anticipated there may be additional working capital requirements in year 2004 associated with ongoing PCT Barocycler sales and marketing activities, together with additional research and development activities in order to expand the PCT product line; the existing PCT product line has experienced lower than expected sales since commercial launch in September 2002 associated with a longer than expected selling cycle. Management has met its recent historical cash flow needs by managing its working capital, which includes steps to minimize and/or defer capital expenditures, and utilizing proceeds from the February 2001 sale of one of its business segments. It plans to manage its future liquidity needs

through cost reductions, additional selling initiatives, and utilization of a line of credit as discussed further hereunder The Company also expects to receive approximately $10 million of service related revenues in year 2004 associated with ongoing contract work at its Biotech segment.

The Company provided $454,000 of net cash from operations in the year ended December 31, 2003, as compared to net cash (used) in operations of ($200,000) for the year ended December 31, 2002. In year 2003, the Company incurred a lower operating loss; in addition, there were increased cash receipts on accounts receivable associated with the sale of the Company's products and services, coupled with lower cash outlays associated with a reduced level of inventory as compared to year 2002. The operational use of cash during 2002 was primarily the result of a larger operating loss incurred coupled with the cash outlays for the buildup of PCT raw materials inventory, partially offset by an increase in trade accounts payable and an increased level of cash collections on outstanding accounts receivable.

Cash used in investing activities for the year ended December 31, 2003 was $110,000 compared to $625,000 during year 2002. The decline in cash used for investing in 2003 was due to managements' decision to reduce and/or defer capital expenditures, whereas in year 2002, capital expenditures included the purchase of a DNA Sequencer at the Company's Biotech segment and the construction of several preproduction PCT Barocyclers™ as demonstration units.

Cash used in financing activities for the year ended December 31, 2003 was $64,000 compared to cash used of $392,000 during 2002. In early 2002, the Company pledged $1,000,000 via a deposit in an interest bearing escrow account at a financial institution; this was partially offset by repayment to the Company of a loan to Richard T. Schumacher as discussed further below.

In February 2004, the Company entered into a three year, $2,500,000 line of credit agreement with a private lender. The line of credit bears interest at the base rate plus 3%, carries commercially standard unused line and collateral management fees (payable monthly), and is collateralized by trade accounts receivable and inventory of the Company. Borrowings under the line are limited to commercially standard terms and percentages of accounts receivable at present. The line of credit contains covenants regarding maintenance of minimum debt service coverage ratios, and provides certain restrictions on the payments of dividends and incurring additional debt.

Based on current forecasts and the February 2004 establishment of a line of credit as discussed above, management believes the Company has sufficient liquidity to finance operations for the next twelve months. Management's forecasts involve assumptions that could prove to be incorrect. If the Company continues to incur operating losses or incurs negative cash flows from operations, it may need to raise additional funds. There can be no assurance that these funds will be available when required on terms acceptable to the Company, if at all. If adequate funds are not available when needed, the Company may be required to further reduce certain of its costs and delay, scale back, or eliminate certain of its activities, any of which could have a material adverse long term effect on its business, financial condition and results of operations. In order to meet the Company's longer term (i.e., in excess of twelve months) liquidity requirements, the Company is continuing to evaluate various sources of additional financing, including but not limited to, sale of business segments, strategic alliances and private placements of debt or equity securities, which could result in dilution to the Company's stockholders. In this regard, on October 25, 2002, the Company retained an investment banking firm to advise the Company in the evaluation of strategic opportunities aimed at increasing shareholder value and liquidity by increasing the capital needed for growth; their engagement continues at this time.

Contractual Obligations

The following is a summary of the Company's future contractual obligations as of December 31, 2003:

	Payments Due by Period				
Contractual Obligations	**Total**	**Less than 1 year**	**1-3 years**	**4-5 years**	**More than 5 years**
Mortgage payments*	$ 3,654,000	$ 287,000	$ 575,000	$ 575,000	$ 2,217,000
Operating Lease Obligations	56,000	21,000	35,000		
Note Payable	16,000	5,000	11,000		
Real Estate Facility Leases **	3,607,000	1,208,000	1,858,000	541,000	
Minimum future royalty payments***					
Obligations relating to Discontinued Operations****	408,000	193,000	115,000	20,000	80,000
Total Contractual Obligations***	**$ 7,741,000**	**$ 1,714,000**	**$ 2,594,000**	**$ 1,136,000**	**$ 2,297,000**

*

Future monthly payments on this mortgage include principal and interest, based on a 20-year amortization schedule with a balloon payment representing the remaining balance due in full on March 10, 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 information presented in the table above is presented using an assumed annual mortgage interest rate of 9.75% for all periods presented.

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The Company leases certain office space, repository, research and manufacturing facilities under operating leases with various terms through October 2007. The real estate leases for facilities located in Maryland include renewal options at either market or increasing levels of rent. The Company leases 27,000 square feet of space in Garden Grove, California where its BBI Source business unit manufactures laboratory instruments. The lease for this facility expires January 31, 2005 and there is currently no extension or renewal option. In March 2004, the Company entered into an eleven year lease agreement with an existing landlord for approximately 65,160 sq ft of new repository space located in Frederick, MD; this lease is scheduled to take effect in two stages, August 1, 2004 and August 1, 2005. Assuming occupancy of the new facility by the Company on August 1, 2004, the landlord has agreed to terminate in full the Company's remaining obligations pursuant to an existing facility lease in Frederick, MD which was scheduled to terminate in November 2006. Incremental minimum lease payments pursuant to the new lease (which are net of savings associated with the concurrent termination of the existing lease) would amount to $55,900 in year 2004, $885,000 in years 2005-2006, $1,755,000 in years 2007-2008, and $6,563,000 thereafter; these amounts are not included in the table above as this lease is subject to cancellation at the sole option of the Company on or before April 30, 2004 without penalty.

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The Company acquired in 1998 all the remaining outstanding common stock of BioSeq, Inc., a development stage company involved with PCT. In accordance with the provisions of a technology transfer agreement assumed in the transaction, the Company is obligated to pay a 5% royalty on net sales (until March 2016) of future sales by any entity of the Company utilizing PCT, with required minimum royalty payments having ended in 2003. The Company announced the availability of its PCT products for commercial sale in the latter part of year 2002.

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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. The Company's estimate of remaining short and long term accrued liabilities to exit the clinical laboratory testing business is $408,000 as of December 31, 2003. See also Note 13 of Notes

to Consolidated Financial Statements hereunder, included in Part II, Item 8 of this Form 10K; future reductions in amounts due pursuant to the Lease Termination Agreement are not reflected in the above table.

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In February 2004, the Company entered into a three year, $2,500,000 line of credit agreement with a private lender; any amounts due pursuant to this agreement are not included in the table.

Related Party Transaction

As of December 31, 2001, the Company had entered into a one year loan of $525,000 to Richard T. Schumacher, the Company's former Chairman and Chief Executive Officer and a current Director of the Company, renewable at the Company's option, and collateralized by 90,000 of Mr. Schumacher's shares of the Company's common stock. This loan constituted an increase from the $350,000 that had been loaned as of September 30, 2001. Interest on the loan was payable at the annual rate of 7%, of which $8,216 was remitted to the Company in the spring of 2003; in February 2004, the Company's Board of Directors determined this payment constituted the full amount owed and that the Company and Mr. Schumacher no longer have any further dispute over this obligation. As of December 31, 2001, the loan was shown on the balance sheet as a decrease to stockholders equity. In January 2002, the principal of these loans was repaid in full with a portion of the proceeds of the loans described in the following sentence. The Company's loans were replaced by the Company's pledge of a $1,000,000 interest bearing deposit at a financial institution to secure the Company's limited guaranty of loans in the aggregate amount of $2,418,000 from the financial institution to an entity controlled by Mr. Schumacher. The loans are personally guaranteed by Mr. Schumacher. The Company's pledge is secured by a junior subordinated interest in the collateral provided by Mr. Schumacher to the financial institution. The remaining collateral as of December 31, 2003 includes substantially all of his common stock holdings in the Company. The Company's original loan and subsequent pledge of $1,000,000 were made to assist Mr. Schumacher 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 the Company 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 options and concluded that the original loan to Mr. Schumacher and the subsequent pledge were the best option and in the best interests of the Company's stockholders in the belief that it would, among other things, avoid selling pressure on the Company's common stock and relieve the financial pressures on Mr. Schumacher that could otherwise divert his attention from the Company. In January 2003, the $1,000,000 account was used to satisfy the Company's limited guaranty obligation. The Company has now satisfied its obligation under the limited guaranty and pledge with the financial institution. The Company continues to maintain its junior interest in collateral pledged by Mr. Schumacher to the financial institution. The remaining collateral includes certain of Mr. Schumacher's common stockholdings in the Company. The Company reflected the $1,000,000 pledge as restricted cash on its balance sheet until the cash was used to satisfy the Company's limited guaranty in January 2003 and since then has reflected a $1,000,000 loan receivable on its balance sheet in stockholder's equity.

On February 14, 2003, the Company announced that its Board of Directors terminated Mr. Schumacher as Chairman and Chief Executive Officer, effective immediately. Mr. Schumacher remains a Director of the Company. Kevin W. Quinlan, President and Chief Operating Officer, continued to lead day-to-day operations. A special committee of the Board of Directors was appointed to oversee the management of the affairs of the Company until such time as a new Chief Executive Officer is employed.

On July 9, 2003, the Company announced that Mr. Schumacher agreed to accept an engagement with the Company as an Executive Project Consultant to advise the Company with respect to the strategic direction of the Company's PCT and BBI Source Scientific activities and the Company's ownership interest in Panacos Pharmaceuticals, Inc. BBI Source Scientific, Inc. is the Company's California-based instrument subsidiary, which developed and manufactures the PCT Barocycler instrument. As part of this engagement, Mr. Schumacher has continued to reevaluate the ongoing business prospects for both the Company's Laboratory Instrumentation segment and PCT activities. On February 9, 2004, the Company announced it had extended until December 31, 2004 the Executive Consultant Agreement it has with Mr. Schumacher. Under the terms of the Consulting Agreement, Mr. Schumacher is serving in an advisory role directing the Company's PCT and BBI Source Scientific activities, the Company's interest in Panacos Pharmaceuticals, Inc. and such other duties as the President or the Board of Directors of the Company assigns to him. In connection with his Consulting Agreement, Mr. Schumacher is being paid an annualized salary of $250,000. In addition to his salary, Mr. Schumacher may receive, in the discretion of the Company's Board of Directors, a bonus in an amount to be determined by the Board of Directors in recognition of the successful completion of his duties and responsibilities under the agreement, and he is also eligible to participate in the Company's health and medical insurance, disability insurance, group life insurance and group travel insurance, and 401(k) retirement plans.

Recent Accounting Standards

In April 2003, the FASB issued SFAS No. 149, "Amendment of Statement 133 on Derivative Instruments and Hedging Activities." This Statement amends and clarifies financial accounting and reporting for derivative instruments, including certain derivative instruments embedded in other contracts (collectively referred to as derivatives) and for hedging activities under FASB Statement No. 133, "Accounting for Derivative Instruments and Hedging Activities." This Standard is effective for contracts entered into or modified after June 30, 2003. The application of SFAS No. 149 has not had a material effect on the Company's consolidated financial statements.

In May 2003, the FASB issued SFAS No. 150, "Accounting for Certain Financial Instruments with Characteristics of both Liabilities and Equity." This Statement establishes standards for how an issuer classifies and measures certain financial instruments with characteristics of both liabilities and equity. This Standard is effective for financial instruments entered into or modified after May 31, 2003. The application of SFAS No. 150 has not had a material effect on the Company's consolidated financial statements.

In January 2003, the FASB issued FIN No. 46, "Consolidation of Variable Interest Entities, an Interpretation of ARB 51." The primary objectives of FIN No. 46 are to provide guidance on the identification of entities for which control is achieved through means other than through voting rights ("variable interest entities" or "VIEs") and how to determine when and which business enterprise should consolidate the VIE. This new model for consolidation applies to an entity for which either: (a) the equity investors (if any) do not have a controlling financial interest; or (b) the equity investment at risk is insufficient to finance that entity's activities without receiving additional subordinated financial support from other parties. In addition, FIN No. 46 requires that both the primary beneficiary and all other enterprises with a significant variable interest in a VIE make additional disclosures. The Company is required to apply FIN No. 46 to all new variable interest entities created or acquired after January 31, 2003. For variable interest entities created or acquired prior to February 1, 2003, the Company is required to apply FIN No. 46 on July 1, 2003. The application of FIN 46 has not had a material effect on the Company's consolidated financial statements.

Forward-Looking Information

This Annual Report on Form 10-K contains forward-looking statements within the meaning of Section 27A of the Securities Act of 1933 and Section 21E of the Securities Exchange Act of 1934. These statements include, but are not limited to statements regarding:

- the timing of new product introductions;
- the Company's goal to expand its product lines;
- market acceptance and the commercial success of the Company's PCT products;
- the Company's inventory;
- business strategies;
- approvals and clearances from government agencies for the Company's products;
- dependence on significant customers and contracts;
- increased research and development expenses relating to PCT;
- expectations of international sales;
- the recoverability of the loan receivable from the former Chairman and Chief Executive Officer;
- availability of debt and equity financing;
- general economic conditions; and
- the Company's financial performance and business operations.

In some cases, forward-looking statements are identified by terms such as "may," "will," "should," "could," "would," "expects," "plans," "anticipates," "believes," "estimates," "projects," "predicts," "potential" and similar expressions intended to identify forward-looking statements. These statements are only predictions and involve known and unknown risks, uncertainties, and other factors that may cause the Company's actual results, levels of activity, performance, or achievements to be materially different from any future results, levels of activity, performance, or achievements expressed or implied by such forward-looking statements. Also, these forward-looking statements represent the Company's estimates and assumptions only as of the date of this report. Except as otherwise required by law, the Company expressly disclaims any obligation or undertaking to release publicly any updates or revisions to any forward-looking statement contained in this report to reflect any change in the Company's expectations or any change in events, conditions or circumstances on which any of the Company's forward-looking statements are based. Factors that could cause or contribute to differences in the Company's future financial results include those discussed in the risk factors set forth in Item 7 of this report as well as those discussed elsewhere in this report. The Company qualifies all of our forward-looking statements by these cautionary statements.

RISK FACTORS

This report contains forward-looking statements that involve risks and uncertainties, such as statements of our objectives, expectations and intentions. The cautionary statements made in this report should be read as applicable to all forward-looking statements wherever they appear in this report. Our actual results could differ materially from those discussed herein. Factors that could cause or contribute to such differences include those discussed below, as well as those discussed elsewhere in this report.

WE RELY ON PURCHASE ORDERS AND CONTRACTS FROM A SMALL NUMBER OF CUSTOMERS FOR A LARGE PORTION OF OUR REVENUES; THE LOSS OF BUSINESS FROM THESE CUSTOMERS COULD MATERIALLY REDUCE OUR REVENUES AND HARM OUR BUSINESS.

Purchase orders account for the majority of our orders; none of our customers have contractually committed to make future product purchases from us. In 2003, our three largest commercial customers, Kyowa, American Red Cross and Quest, together accounted for approximately 9.7% of our revenues. In addition, the various agencies of the National Institutes of Health, including the National Institutes of Allergies and Infectious Disease, the National Cancer Institute and the National Heart Lung and Blood Institute, in the aggregate, accounted for approximately 25% of our revenues in 2003. Each agency within the National Institutes of Health, however, makes independent purchasing decisions. The loss of any major customer, including any agency within the National Institutes of Health, the failure of any agency of the National Institutes of Health to fully fund any contract or renew any contract with us, or a material reduction in any major customer's purchases would materially reduce our revenues and our operating results.

IF WE ARE UNABLE TO INCREASE OUR SALES OF QUALITY CONTROL PRODUCTS TO END-USERS OF INFECTIOUS DISEASE TEST KITS, THEN OUR FUTURE REVENUES COULD BE IMPACTED.

Currently, we sell most of our quality control products for infectious disease test kits to test kit manufacturers and regulators, which is a relatively small market. However, we also sell our quality control products to end-users of infectious disease test kits, including hospital laboratories, blood donor testing centers, public health laboratories and commercial laboratories. This end-user market is a larger market which has not yet become accustomed to using quality control products to monitor test results, but which we believe is a growing market. Currently, we expect an increase in both the frequency of use and the number of products used by our current end-user customers. However, these end-users of infectious disease test kits may not increase their use of our products. Further, large manufacturers and distributors of quality control products that have historically sold to the non-infectious disease market and that have greater financial, manufacturing and marketing resources than we have could begin selling their products to the end-users of infectious disease test kits. This would increase competition for an adequate supply of the rare specimens of plasma and serum necessary for certain of our quality control and run control products. If the end-user market for quality control products for infectious disease testing does not develop further, or if we are unable to increase sales of our products to this market, our future revenues could be substantially less than we have projected.

IF OUR BBI BIOSEQ, INC. AND BBI SOURCE SCIENTIFIC, INC. SUBSIDIARIES CONTINUE TO HAVE SUBSTANTIAL OPERATING LOSSES, THEN WE MAY NOT BE ABLE TO REALIZE THE BOOK VALUE OF THEIR ASSETS.

Our BBI BioSeq subsidiary has incurred significant operating losses, since our acquisition of that company in September 1998. This subsidiary may not be successful in marketing and further developing its technology, and its technology may never achieve commercial viability. Accordingly, our BBI BioSeq subsidiary may never become profitable and it may be necessary to write off some or all of the current net book value of its intangible assets related to its patents.

As a result of our July 1997 acquisition of Source Scientific, Inc., we recorded approximately $2,200,000 of goodwill. Since this acquisition, our BBI Source Scientific subsidiary has also incurred significant cumulative operating losses That subsidiary may continue to have operating losses and may never become profitable. If operating losses continue, it may be necessary to write off some or all of the remaining goodwill associated with BBI Source Scientific.

IF WE ARE UNABLE TO OBTAIN BOTH THE NECESSARY REGULATORY APPROVALS AND SUBSTANTIAL FUNDS FOR OUR BBI BIOSEQ SUBSIDIARY'S PRODUCTS, OR IF DEMAND FOR NEW PRODUCTS AND SERVICES FAILS TO MATERIALIZE, OUR FUTURE REVENUES AND INCOME WILL BE LESS THAN WE HAVE PROJECTED.

Our BBI BioSeq subsidiary, in conjunction with our other subsidiaries has developed products that involved significant development, preclinical and clinical testing, regulatory approvals and investment of substantial funds prior to their commercialization. Our BBI BioSeq subsidiary and BBI Source Scientific subsidiary have developed a pressure cycling technology process into a working laboratory instrument now available for commercial sale. We first introduced our Barocycler instrument and related disposable PULSE tubes based upon pressure cycling technology for commercial sale in September 2002. Demand for these commercial applications of pressure cycling technology may not materialize as expected. As a result, we may not be successful in selling the Barocycler instrument and disposable PULSE tubes in sufficient numbers to be commercially viable.

In addition, we may not be successful in further developing pressure cycling technology into other commercially viable products and services, or such activities may take longer than currently expected; and if successful in such development activities, demand for such products and services may not develop as we anticipate.

While we have eleven issued U.S. patents and four foreign patents as of December 31, 2003 relating to pressure cycling technology, certain pressure cycling technology applications may not fall within the claims of those issued patents. Further, individuals and groups utilizing pressure cycling technology may not be required to license such technology from us. Further, our future revenues and income could be less than we have projected.

BECAUSE OF THE LENGTHY SALES CYCLES OF OUR PCT PRODUCTS, WE MAY INCUR SIGNIFICANT EXPENSES BEFORE WE GENERATE ANY REVENUES RELATED TO THOSE PRODUCTS.

Our customers have required several months to test and evaluate our PCT related products. This increases the possibility that a customer may decide to cancel or change plans, which could reduce or eliminate our sales to that customer. As a result of this lengthy sales cycle, we have incurred and may continue to incur significant research and development expenses, and selling, general and administrative expenses, before we generate the related revenues for these products, and we may never generate the anticipated revenues if a customer cancels or changes its plans. Factors associated with this sales cycle include the initial selling price of the PCT Barocycler and the limited amount of research data presently available demonstrating its capabilities and potential. Additional refinements in PCT instrumentation include the development of a less expensive and smaller, bench top version of the Barocycler which was just introduced in 2004; however, there can be no assurance that this bench top model will be successful.

IF THE FDA REQUIRES CLEARANCE OR APPROVAL FOR OUR PRODUCTS THAT ARE DESIGNATED ONLY FOR RESEARCH AND NOT FOR DIAGNOSTIC PROCEDURES OR OUR PRODUCTS THAT WE BELIEVE ARE EXEMPT FROM FDA CLEARANCE AND INITIATES ENFORCEMENT ACTION FOR OUR FAILURE TO DO SO, WE WILL LIKELY EXPEND SIGNIFICANT RESOURCES TO RESOLVE THE MATTER WHICH COULD HARM OUR BUSINESS.

In the United States, the Food, Drug, and Cosmetic Act prohibits the marketing of most IN VITRO diagnostic products until the Food and Drug Administration either clears or approves the products through processes that are time-consuming, expensive and uncertain. Some IN VITRO diagnostic products may be exempt from FDA clearance or approval if they have undergone validation

studies. As of December 31, 2003, 44 of our Accurun ® | products currently on the market have met the FDA's regulatory requirements.

During 2003, our Accurun®. External Run Controls products accounted for approximately 13.43% of our revenue. It is possible that the FDA may not agree that some of these products are entitled to an exemption and may adopt a different interpretation of the Food, Drug, and Cosmetic Act or other laws it administers. We believe that products which are used only for research and not in diagnostic procedures are not subject to FDA clearance or approval. We currently label some of our products "for research use only" because they are not intended for use in diagnostic procedures, and have not been cleared or approved by the FDA. It is possible, however, that some purchasers of these products may use them for diagnostic purposes rather than for research, despite our labeling. Under any of these circumstances, the FDA could allege that some or all of these products should have been cleared or approved, or otherwise validated prior to marketing, and could initiate enforcement action against us. If the FDA initiates enforcement action against us, we will likely expend a large amount of time, money, resources and management attention to resolve the matter. In addition, if we cannot obtain or are delayed in obtaining FDA clearances or approvals for our products, we may encounter delays or be unable to ever sell those products.

IF WE ARE UNABLE TO OBTAIN A STEADY AND ADEQUATE SUPPLY OF RARE SPECIMENS OF PLASMA AND SERUM, THEN WE MAY BE UNABLE TO PRODUCE OUR QUALITY CONTROL PANEL PRODUCTS AND OUR ACCURUN®. EXTERNAL RUN CONTROLS PRODUCTS WHICH WOULD HARM OUR BUSINESS.

We manufacture our diagnostic products, including our quality control panel products and Accurun® | External Run Controls products, from human plasma and serum which we obtain from nonprofit and commercial blood centers in the United States and from similar sources throughout the world. Our BBI Diagnostics business unit, which manufactures and sells these diagnostic products, accounts for approximately 52% of our revenues. Our quality control panel products and Accurun®. External Run Controls products contain rare plasma specimens that we collect from individuals who have been infected with particular diseases. The specimens are rare because we can collect them only during the brief period of time when the markers for a particular disease in an infected individual are converting from negative to positive. It is difficult to identify such infected individuals and to collect specimens from them during the brief period of time when the markers for a particular disease are converting from negative to positive. As a result, quantities of these specimens are limited. As we sell our quality control panel products and Accurun® External Run Controls products, we must find replacement specimens that are equally rare. We may also face competition to obtain these specimens which could further limit our ability to obtain the specimens and to produce our quality control panel products and Accurun® External Run Controls products. A limit in our ability to produce our products would reduce our future revenues and operating results.

IF WE ARE NOT ABLE TO REACT QUICKLY TO TECHNOLOGICAL CHANGE, WE MAY NOT BE ABLE TO COMPETE EFFECTIVELY.

The infectious disease test kit industry is characterized by rapid and significant technological change, and changes in customer requirements. As a result, our ability to continue to compete effectively in this industry depends upon our ability to enhance our existing products and to develop or acquire, and introduce in a timely manner, new products that take advantage of technological advances and respond to customer requirements. We may not be successful in developing and marketing such new products or enhancements to our existing products on a timely basis, if at all, and such products may not adequately address the changing needs of the marketplace. Furthermore, rapid technological development may result in our products or services becoming obsolete or noncompetitive before we recover our investment in research, development and commercialization.

WE MAY BE SUBJECT TO CLAIMS OF INFRINGEMENT OF THIRD-PARTY INTELLECTUAL PROPERTY RIGHTS, OR DEMANDS THAT WE LICENSE THIRD-PARTY TECHNOLOGY, WHICH COULD RESULT IN SIGNIFICANT EXPENSE AND PREVENT US FROM SELLING ONE OR MORE OF OUR PRODUCTS.

We have in the past been, and may in the future be, notified that we may be infringing intellectual property rights possessed by other third parties. In February 2004, we received a letter from Institut Pasteur (Paris, France) alleging that several of our quality control products may infringe on patents held jointly by Institut Pasteur and the NIH. Specifically, Institut Pasteur alleged that our ACCURUN products and our Performance Panels infringed on US patent No. 5,135,864 and that our Seroconversion Panels infringed on US patent No. 4,708,818. We are in the process of investigating and gathering additional information to respond to these claims. While we cannot estimate the amount of a loss, if any, associated with the resolution of these allegations, we dispute all of these allegations and intends to vigorously pursue all defenses available to the Company.

We cannot guarantee that other infringement claims by third parties or other claims for indemnification resulting from infringement claims will not be asserted in the future or that such assertions, if proven to be true, will not materially and adversely affect our business, financial condition and results of operations. We cannot predict the extent to which we might be required to seek licenses, pay royalties or alter our products so that they no longer infringe the rights of others. We also cannot guarantee that the terms of any licenses we may be required to seek or royalties we may be required to pay will be reasonable. Similarly, changing our products or processes to avoid infringing the rights of others may be costly or impractical and could detract from the value of our products. If a judgment of infringement were obtained against us, we could be required to pay substantial damages and a court could issue an order preventing us from selling one or more of our products. Further the cost and diversion of management attention brought about by such litigation could be substantial, even if we were to prevail. Any of these events could result in significant expense to us and may materially harm our business and our prospects.

WE MAY NOT BE ABLE TO FULLY COLLECT THE PRINCIPAL AND INTEREST DUE ON A $1,000,000 RECEIVABLE FROM OUR FORMER CHAIRMAN AND CHIEF EXECUTIVE OFFICER WHICH COULD HARM OUR BUSINESS AND FINANCIAL CONDITION.

As of January 2003, we recorded a $1,000,000 receivable from our former Chairman and Chief Executive Officer, Richard T. Schumacher. We continue to maintain a junior security interest in collateral pledged by Mr. Schumacher to a financial institution. The remaining collateral as of December 31, 2003 includes certain of Mr. Schumacher's shares of our common stock. The collateral and personal assets of Mr. Schumacher may not be sufficient to permit us to fully recover the principal, interest and other costs associated with this receivable. If the value of the collateral decreases, we may have to write down or write off the receivable. Therefore, we cannot be certain that we will collect the full amount of the receivable. Our failure to collect all or a portion of this receivable could harm our business and financial condition.

A FEW STOCKHOLDERS CONTROL A SIGNIFICANT PERCENTAGE OF VOTING POWER AND MAY EXERCISE THEIR VOTING POWER IN A MANNER ADVERSE TO OTHER STOCKHOLDERS' INTERESTS.

Our former Chairman and Chief Executive Officer, Mr. Richard T. Schumacher, and our other existing officers and directors collectively have voting control over approximately 15% of the outstanding shares of our common stock as of December 31, 2003. In addition, approximately 22.60% of the outstanding shares of our common stock as of December 31, 2003 were controlled by Mr. Richard Kiphart, an unaffiliated investor. Accordingly, these stockholders, should they choose to act in concert, are in a position to exercise a significant degree of control and to significantly influence

stockholder votes on the election of directors, increasing the authorized capital stock, and authorizing mergers and sales of assets. These stockholders may act in a manner that is adverse to your personal interests.

PROVISIONS IN OUR CHARTER AND BY-LAWS AND OUR SHAREHOLDER RIGHTS PLAN MAY DISCOURAGE OR FRUSTRATE STOCKHOLDERS' ATTEMPTS TO REMOVE OR REPLACE OUR CURRENT MANAGEMENT.

Our amended and restated articles of organization and restated bylaws contain provisions that may make more difficult or discourage changes in our management that our stockholders may consider to be favorable. These provisions include:

a classified board of directors;

advance notice for stockholder nominations to the board of directors;

limitations on the ability of shareholders to remove directors; and

a provision that allows a majority of the directors to fill vacancies on the board of directors.

These provisions could prevent or frustrate stockholders' attempts to make changes in our management that our stockholders consider to be beneficial.

On February 27, 2003, our Board of Directors adopted a Shareholder Purchase Rights Plan. This Plan may have the effect of discouraging or preventing a change in control.

All of these provisions could limit the price that our stockholders might receive in the future for shares of our common stock.

THE EXERCISE OF ALL OUTSTANDING OPTIONS AND THE CONVERSION OF ALL OUTSTANDING WARRANTS COULD HAVE AN ADVERSE EFFECT ON THE PRICE OF OUR COMMON STOCK.

We have 1,245,825 options outstanding as of December 31, 2003 which are exercisable at various prices. In addition, we have outstanding warrants, with various strike prices, which are exercisable for a total of 135,556 shares of our common stock as of December 31, 2003. The options and warrants exercisable as of December 31, 2003 represent approximately 20.2% of our issued and outstanding common stock based on the number of shares issued and outstanding as of December 31, 2003 on a fully diluted basis. The exercise of our outstanding options and warrants could place downward pressure on the price of our common stock.

WE ARE INCURRING SIGNIFICANT LOSSES AND CANNOT ASSURE THAT WE WILL BECOME PROFITABLE.

We incurred net losses in five out of the last six years. For the year ended December 31, 2003, we incurred a net loss of $1,289,000. For the year ended December 31, 2001 we had net income of $3,447,000, but the results for that year included $4,334,000 from discontinued operations. We cannot assure that we will become profitable or that we can maintain profitability if we attain it.

It is anticipated that we may need additional future working capital requirements in connection with PCT Barocycler sales and marketing activities as this segment of the business continues to experience lower than expected product sales since commercial launch in September 2002 associated with a longer than expected selling cycle. Management has met its recent historical cash flow needs by managing its working capital and utilizing proceeds from the February 2001 sale of one of its business segments. We plan to manage its future liquidity needs through cost reductions and additional selling initiatives. If revenues are lower than anticipated or expenses are higher than anticipated or if we continue to incur operating losses, we may require additional capital sooner than expected and there can be no assurance that we will be able to obtain additional financing or capital on acceptable terms or that we will be successful in eliminating or scaling back certain of our activities. We may also need additional capital to grow both the Diagnostics and Biotech segments of the business. If adequate funds are not available when needed, the Company may be required to further reduce its fixed costs and delay, scale back, or eliminate certain of its activities, any of which could have a material adverse long term effect on its business, financial condition and results of operations. We are considering various sources of additional financing, including but not limited to, sale of business segments, strategic alliances and private placements of debt or equity securities. .

PART III

ITEM 10. DIRECTORS AND EXECUTIVE OFFICERS OF THE REGISTRANT.

Information regarding the Company's executive officers appears in Part I, Item 1-Business under the heading "Executive Officers of the Registrant" at page 18 of this report. Set forth below is certain information with respect to the Company's Directors as of February 2004.

Name	Age	Position
R. Wayne Fritzsche (1)(2)	54	Chairman of the Board
Calvin A. Saravis (1)(2)(3)	74	Director
J. Donald Payne (1)	48	Director
P. Thomas Vogel (1) (2)	64	Director
Kevin W. Quinlan	54	President and Chief Operating Officer, Treasurer and Director
Richard T. Schumacher	53	Director and Executive Project Consultant

(1) Member of the Audit Committee.

(2) Member of the Compensation Committee.

(3) Member of the Oversight Committee.

Mr. R. Wayne Fritzsche has served as Chairman of the Board of Directors since October 2, 2003, subsequent to being elected as a Class I Director of the Company on October 2, 2003. Mr. Fritzsche has served as a member of the Company's Scientific Advisory Board since 1999. Mr. Fritzsche is the founder of Fritzsche & Associates, Inc., a consulting firm which provides strategic, financial, and scientific consulting to medical companies in the life sciences/healthcare arena, and has served as President since 1991. Since 2003, Mr. Fritzsche has also served as interim President of Chemokine

Pharmaceutical Company, Inc. (formerly PGBP Pharmaceuticals), a small molecule discovery company. Since 2001, Mr. Fritzsche has served as a board member of Opexa Pharmaceuticals, a multiple sclerosis/cell immunology therapy company, and Vascular Sciences, Inc., an extracorporeal/macular degeneration company. He was also a board member of Intelligent Medical Imaging, an automated microscopic imaging company, from 1994 to 1997, Clarion Pharmaceuticals, a drug development company using novel esters, from 1994 to 1996, Nobex Pharmaceuticals, a drug delivery firm, from 1996 to 2001, Cardio Command, Inc., a transesophageal cardiac monitoring and pacing firm, from 1999 to 2001, and Hesed BioMed, an antisense oligonucleotide and catalytic antibody company from 2000 to 2002. Mr. Fritzsche holds a BA from Rowan University, and an MBA from the University of San Diego.

Dr. Calvin A. Saravis has served as a Director of the Company since 1986. Dr. Saravis also serves as Chairman of the Company's Scientific Advisory Board. Since 1984, he has been an Associate Professor of Surgery (Biochemistry) at Harvard Medical School (presently emeritus) and an Associate Research Professor of Pathology at Boston University School of Medicine (presently emeritus). From 1971 to 1997, Dr. Saravis was a Senior Research Associate at the Mallory Institute of Pathology and from 1979 to 1997, he was a Senior Research Associate at the Cancer Research Institute-New England Deaconess Hospital. Dr. Saravis received his Ph.D. in immunology and serology from Rutgers University.

Mr. J. Donald Payne was appointed as a Director of the Company effective December 30, 2003 to fill the Class II Board vacancy created by the resignation of Mr. William A. Wilson as a Director of the Company. Mr. Wilson, a Board member since June 2001 and Chairman of the Board from February 2003 to October 2003, resigned on October 3, 2003 to pursue other activities. Mr. Payne will serve the remainder of Mr. Wilson's Board term, which is set to expire at the 2004 Annual Meeting of Stockholders, and has been appointed to serve as Chairman of the Audit Committee of the Board of Directors. Since September 2001, Mr. Payne has been President and Director of Nanospectra Biosciences, Inc., an early-stage, privately-held medical device company developing products for cancer, ophthalmology, and bio-defense diagnostics. From September 1998 to May 2001, Mr. Payne served as Senior VP and CFO of Sensus Drug Development Corporation, a bio-pharmaceutical company sold to Pharmacia in 2001. Prior to Sensus, from March 1997 to September 1998, Mr. Payne served as VP and CFO of LifeCell Corporation, a publicly held bio-engineering company. From May 1992 to February 1997, Mr. Payne was VP Finance and CFO of Aprogenex, a biotech company engaged in the development, manufacturing, and marketing of medical device products using a proprietary DNA probe technology. Mr. Payne also worked for 10 years at UMC Petroleum Corporation and its predecessor entities, where he was CFO of its private and public entities. Prior to UMC, Mr. Payne worked for Arthur Andersen in audits of public and private companies. Mr. Payne graduated summa cum laude from Texas A&M University in May 1976 with a Bachelor's Degree in Business Administration. Mr. Payne also graduated summa cum laude from the Jesse H. Jones Graduate School of Administration at Rice University in May 1992 with a Master's Degree in Business Administration (MBA). He is a Certified Public Accountant in Texas, and a member of the AICPA and Financial Executives Institute.

Mr. P. Thomas Vogel was appointed to the Company's Board of Directors effective January 9, 2004. In addition, Mr. Vogel was appointed to serve on the Board of Director's Audit and Compensation Committees. Mr. Vogel will fill the new Class II vacancy created by the unanimous decision by the Company's Board of Directors to expand its size from five to six members. The term for Class II members is set to expire at the 2004 Annual Meeting of Stockholders. Since April 2002, Mr. Vogel has served as the President and CEO of AdipoGenix, Inc, an early-stage drug discovery company focusing on obesity and metabolic diseases, with a unique approach to directly targeting the fat cell itself. From 2000 to January 2002, Mr. Vogel served as President and CEO of Arradial, Inc., an early stage biopharmaceutical company. From 1996 to 2000, Mr. Vogel was CEO and Director of

Mosaic Technologies, Inc., an early-stage molecular biology company. In 1995, Mr. Vogel founded the Charlestown Group, a venture capital firm with a mission of investing in early-stage companies in medical and information technologies. Mr. Vogel worked with the Charlestown Group until 2000. From 1992 to 1995, Mr. Vogel was President of Fisher Scientific Company, a $1billion laboratory supply distribution business. Mr. Vogel served as President of PB Diagnostics from 1991 to 1992, as President of Instrumentation Laboratory from 1990 to 1991, and as President of Serono Diagnostics from 1988 to 1990. Mr. Vogel was in the venture capital arena from 1982 to 1987. Prior to that, from 1974 to 1982, Mr. Vogel was at the Diagnostics Division of Abbott Laboratories, Inc., where he served as Divisional Vice President and General Manager of Diagnostic Products. Mr. Vogel began his professional career at Texas Instruments, Inc., where he held a number of key positions from 1964 to 1973, including plant management in Germany, Italy and Singapore. Mr. Vogel graduated from the Georgia Institute of Technology with a Bachelor's Degree in Electrical Engineering and from The Wharton Business School with a Master's Degree in Business Administration.

Mr. Kevin W. 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 (now PricewaterhouseCoopers LLP) from 1975 to 1981. Mr. Quinlan is a Certified Public Accountant and received a M.S. in accounting from Northeastern University and a B.S. in resource economics from the University of New Hampshire.

Mr. Richard T. Schumacher, the Founder of the Company, has served as a Director since 1978, and since July 9, 2003, he has served as an Executive Project Consultant to the Company pursuant to a consulting agreement with the Company, as described in Item 13 entitled "Certain Relationships and Related Transactions" below. He was Chief Executive Officer and Chairman of the Board from 1992 to February 2003, and served as President from 1986 to August 1999. Mr. Schumacher served as the Director of Infectious Disease Services for Clinical Sciences 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.

Section 16(a) Beneficial Ownership Reporting Compliance

Section 16(a) of the Securities Exchange Act of 1934, as amended, requires the Company's officers and directors, and persons who own more than 10% of the Company's Common Stock, to file reports of ownership and changes in ownership on Forms 3, 4 and 5 with the Securities and Exchange Commission and Nasdaq. Officers, directors and greater than 10% stockholders are required by SEC regulations to furnish the Company with copies of all Forms 3, 4 and 5 they file.

Based solely on the Company's review of the copies of such filings it has received and written representations from certain reporting persons, the Company believes that all of its officers, directors and greater than 10% stockholders complied with all Section 16(a) filing requirements applicable to them during the Company's fiscal year ended December 31, 2003.

Code of Ethics

Pursuant to Section 406 of the Sarbanes-Oxley Act of 2002, we have adopted a Code of Ethics for Senior Financial Officers that applies to our principal executive officer and our principal financial officer, principal accounting officer and controller, and other persons performing similar functions. The company will provide a copy of its code of ethics to any person without charge upon request. If we

make any substantive amendments to this Code of Ethics or grant any waiver, including any implicit waiver, from a provision of this Code of Ethics to our principal executive officer, principal financial officer, principal accounting officer, controller or other persons performing similar functions, we will disclose the nature of such amendment or waiver, the name of the person to whom the waiver was granted and the date of waiver in a report on Form 8-K.

Audit Committee

We have an Audit Committee, which consists of Mr. R. Wayne Fritzsche, Dr. Calvin A. Saravis, Mr. J. Donald Payne and Mr. P. Thomas Vogel. The Board of Directors has reviewed the qualifications of each member of the Audit Committee and has determined that each member of the Audit Committee is "independent" under the current listing standards of the Nasdaq National Market applicable to Audit Committee members. Our Board of Directors has also determined that Mr. J. Donald Payne qualifies as an Audit Committee Financial Expert, as defined in Item 401(h) of Regulation S-K and Section 407 of the Sarbanes-Oxley Act of 2002, and is independent in accordance with applicable Nasdaq listing standards. Other information regarding the Audit Committee of our Board of Directors is incorporated by reference to the Proxy Statement under the caption "*Report of the Audit Committee of the Board of Directors*."

PART IV.

ITEM 15. EXHIBITS, FINANCIAL STATEMENT SCHEDULES AND REPORTS ON FORM 8-K.

[PLEASE NOTE THAT THE FOLLOWING PAGE REFERENCES REFER TO THE PAGES CONTAINED IN THE COMPANY'S FILING ON FORM 10-K AS FILED WITH THE SEC ON MARCH 29, 2004]

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:

EXHIBIT INDEX

Exhibit No.		Reference
3.1	Amended and Restated Articles of Organization of the Company	A**
3.2	Amended and Restated Bylaws of the Company	A**
3.3	Amendment to Amended and Restated Bylaws of the Company	C**
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**
4.14	Rights Agreement dated as of February 27, 2003 between Boston Biomedica, Inc., and Computershare Trust Company, Inc.	P**
10.1	Lease Agreement, dated July 28, 1995, for New Britain, Connecticut Facility between MB Associates and the Company	A**
10.2	1987 Non-Qualified Stock Option Plan*	A**
10.3	Employee Stock Option Plan*	A**
10.4	1999 Non-Qualified Stock Option Plan*	I**
10.5	1999 Employee Stock Purchase Plan*	I**
10.6	Underwriters Warrants, each dated November 4, 1996, between the Company and each of Oscar Gruss & Son Incorporated and Kaufman Bros., L.P.	B**
10.7	Loan Agreement dated March 31, 2000	C**
10.8	First Amendment to lease dated as of December 12, 2001 by and between Cabot Industrial Properties, L. P. and BBI Source Scientific, Inc.	D**
10.9	Lease Agreement, dated May 16, 1997, for Gaithersburg, Maryland facility between B.F. Saul Real Estate Investment Trust and the Company	E**
10.10	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**
10.11	Contract, dated July 1, 1998, between the National Institutes of Health and the Company (NO1-A1-85341)	G**
10.12	Contract, dated July 1, 1998, between the National Heart Lung and Blood Institute and the Company (NO1-HB-87144)	G**
10.13	Agreement with Paradigm Group for the purchase of warrants dated August 18, 1999	H**
10.14	Agreement with MDBio for the purchase of common stock and common stock warrants, dated September 30, 1999	J**
10.15	Lease Agreement dated September 30, 1999, for Frederick, Maryland facility, between MIE Properties, Inc., and the Company.	J**

10.16	Repository Contract with National Institute of Allergy and Infectious Disease, Division of AIDS (NO1-A1-95381), dated August 16, 1999.	J**
10.17	Securities Purchase Agreement dated as of August 25, 2000, by and among Boston Biomedica, Inc., and GCA Strategic Investment Fund Limited.	K**
10.18	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**
10.19	Mortgage and Security Agreement dated March 31, 2000	L**
10.20	Asset Purchase Agreement dated February 20, 2001, by and between BBI Clinical Laboratories, Inc., Boston Biomedica, Inc., and Specialty Laboratories, Inc.	M**
10.21	Promissory Note dated July 10, 2001, as amended on October 4, 2001, by and among Boston Biomedica, Inc. and Richard T. Schumacher.	N**
10.22	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.	O**
10.23	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.	O**
10.24	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.	O**
10.25	Pledge Agreement effective as of January 15, 2002, by and between Boston Biomedica, Inc. and Commerce Bank and Trust Company.	O**
10.26	Limited Guaranty dated as of January 15, 2002, by and between Boston Biomedica, Inc. and Commerce Bank and Trust Company.	O**
10.27	Description of Compensation for Certain Directors*	D**
10.28	Consultant Agreement between Boston Biomedica, Inc. and Richard T. Schumacher	Q*
10.29	Agreement between Boston Biomedica, Inc. and Richard T. Schumacher	Q*
10.30	Revolving Credit and Security Agreement dated as of February 5, 2004	R*
10.31	Consultant Agreement between Boston Biomedica, Inc. and Richard T. Schumacher entered into as of December 31, 2003	R*
10.32	Contract effective 06/01/2001, between the National Cancer Institute and the Company (NO2-CP-11001)	R*
21.1	Subsidiaries of the registrant	R*
23.1	Consent of PricewaterhouseCoopers LLP, independent accountants	R*
23.2	Consent of Weinberg & Company, P.A., independent accountants	R*

31.1	Principal Executive Officer Certification Pursuant to Item 601(b)(31) of Regulation S-K, as adopted pursuant to Section 302 of the Sarbanes-Oxley Act of 2002	Filed herewith
31.2	Principal Financial and Accounting Officer Certification Pursuant to Item 601(b)(31) of Regulation S-K, as adopted pursuant to Section 302 of the Sarbanes-Oxley Act of 2002	Filed herewith
32.1	Principal Executive Officer Certification Pursuant to Item 601(b)(32) of Regulation S-K, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002	Filed herewith
32.2	Principal Financial and Accounting Officer Certification Pursuant to Item 601(b)(32) of Regulation S-K, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002	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, 2002.

D

Incorporated by reference to the registrant's Quarterly Report on Form 10-Q for the fiscal quarter ended March 31, 2002.

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 June 30, 2000.

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.

O

Incorporated by reference to the registrant's Annual Report on Form 10-K for the fiscal year ended December 31, 2001.

P

Incorporated by reference to Exhibit 4 of the registrant's Current Report on Form 8-K filed March 12, 2003.

Q

Incorporated by reference to the registrant's Quarterly Report on Form 10-Q for the fiscal quarter ended September 30, 2003.

R

Incorporated by reference to the registrant's Annual Report on Form 10-K for the fiscal year ended December 31, 2003.

*

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 Company filed a Form 8-K dated October 2, 2003 announcing that Mr. R. Wayne Fritzsche and Dr. Calvin A. Saravis were elected as directors of the Company at the Company's Special Meeting in Lieu of Annual Meeting of Stockholders held on October 2, 2003. The Company also announced that William A. Wilson resigned from the Board of Directors on October 3, 2003 to pursue other activities.

The Company filed a Form 8-K dated November 5, 2003 announcing that the Audit Committee of the Board of Directors of the Company engaged Weinberg & Company P.A. ("Weinberg & Company") to act as the Company's independent accountants for the remainder of fiscal 2003, effective immediately.

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: June 25, 2004

Boston Biomedica, Inc.

By: /s/ KEVIN W. QUINLAN

Kevin W. Quinlan
President and Chief Operating Officer
and Treasurer

EXHIBIT INDEX

Exhibit No.		Reference
3.1	Amended and Restated Articles of Organization of the Company	A**
3.2	Amended and Restated Bylaws of the Company	A**
3.3	Amendment to Amended and Restated Bylaws of the Company	C**
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**
4.14	Rights Agreement dated as of February 27, 2003 between Boston Biomedica, Inc., and Computershare Trust Company, Inc.	P**
10.1	Lease Agreement, dated July 28, 1995, for New Britain, Connecticut Facility between MB Associates and the Company	A**
10.2	1987 Non-Qualified Stock Option Plan*	A**
10.3	Employee Stock Option Plan*	A**
10.4	1999 Non-Qualified Stock Option Plan*	I**
10.5	1999 Employee Stock Purchase Plan*	I**
10.6	Underwriters Warrants, each dated November 4, 1996, between the Company and each of Oscar Gruss & Son Incorporated and Kaufman Bros., L.P.	B**
10.7	Loan Agreement dated March 31, 2000	C**
10.8	First Amendment to lease dated as of December 12, 2001 by and between Cabot Industrial	D**

Exhibit No.	Reference
Properties, L. P. and BBI Source Scientific, Inc.	

10.9	Lease Agreement, dated May 16, 1997, for Gaithersburg, Maryland facility between B.F. Saul Real Estate Investment Trust and the Company	E**
10.10	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**
10.11	Contract, dated July 1, 1998, between the National Institutes of Health and the Company (NO1-A1-85341)	G**
10.12	Contract, dated July 1, 1998, between the National Heart Lung and Blood Institute and the Company (NO1-HB-87144)	G**
10.13	Agreement with Paradigm Group for the purchase of warrants dated August 18, 1999	H**
10.14	Agreement with MDBio for the purchase of common stock and common stock warrants, dated September 30, 1999	J**
10.15	Lease Agreement dated September 30, 1999, for Frederick, Maryland facility, between MIE Properties, Inc., and the Company.	J**
10.16	Repository Contract with National Institute of Allergy and Infectious Disease, Division of AIDS (NO1-A1-95381), dated August 16, 1999.	J**
10.17	Securities Purchase Agreement dated as of August 25, 2000, by and among Boston Biomedica, Inc., and GCA Strategic Investment Fund Limited.	K**
10.18	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**
10.19	Mortgage and Security Agreement dated March 31, 2000	L**
10.20	Asset Purchase Agreement dated February 20, 2001, by and between BBI Clinical Laboratories, Inc., Boston Biomedica, Inc., and Specialty Laboratories, Inc.	M**
10.21	Promissory Note dated July 10, 2001, as amended on October 4, 2001, by and among Boston Biomedica, Inc. and Richard T. Schumacher.	N**
10.22	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.	O**
10.23	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.	O**
10.24	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.	O**
10.25	Pledge Agreement effective as of January 15, 2002, by and between Boston Biomedica, Inc. and Commerce Bank and Trust Company.	O**
10.26	Limited Guaranty dated as of January 15, 2002, by and between Boston Biomedica, Inc. and Commerce Bank and Trust Company.	O**
10.27	Description of Compensation for Certain Directors*	D**

10.28	Consultant Agreement between Boston Biomedica, Inc. and Richard T. Schumacher	Q*
10.29	Agreement between Boston Biomedica, Inc. and Richard T. Schumacher	Q*
10.30	Revolving Credit and Security Agreement dated as of February 5, 2004	R*
10.31	Consultant Agreement between Boston Biomedica, Inc. and Richard T. Schumacher entered into as of December 31, 2003	R*
10.32	Contract effective 06/01/2001, between the National Cancer Institute and the Company (NO2-CP-11001)	R*
21.1	Subsidiaries of the registrant	R*
23.1	Consent of PricewaterhouseCoopers LLP, independent accountants	R*
23.2	Consent of Weinberg & Company, P.A., independent accountants	R*
31.1	Principal Executive Officer Certification Pursuant to Item 601(b)(31) of Regulation S-K, as adopted pursuant to Section 302 of the Sarbanes-Oxley Act of 2002	Filed herewith
31.2	Principal Financial and Accounting Officer Certification Pursuant to Item 601(b)(31) of Regulation S-K, as adopted pursuant to Section 302 of the Sarbanes-Oxley Act of 2002	Filed herewith
32.1	Principal Executive Officer Certification Pursuant to Item 601(b)(32) of Regulation S-K, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002	Filed herewith
32.2	Principal Financial and Accounting Officer Certification Pursuant to Item 601(b)(32) of Regulation S-K, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002	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, 2002.

D
Incorporated by reference to the registrant's Quarterly Report on Form 10-Q for the fiscal quarter ended March 31, 2002.

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 June 30, 2000.

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.

O

Incorporated by reference to the registrant's Annual Report on Form 10-K for the fiscal year ended December 31, 2001.

P

Incorporated by reference to Exhibit 4 of the registrant's Current Report on Form 8-K filed March 12, 2003.

Q

Incorporated by reference to the registrant's Quarterly Report on Form 10-Q for the fiscal quarter ended September 30, 2003.

R

Incorporated by reference to the registrant's Annual Report on Form 10-K for the fiscal year ended December 31, 2003.

*

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.

QuickLinks